FULL/LONG TITLE OF THE STUDY	A single centre, feasibility study using Dynamic Lycra Garments to address pain and instability associated with Hip Dysplasia
SHORT STUDY TITLE / ACRONYM	HIP Lycra study
PROTOCOL VERSION NUMBER AND DATE	Version 1.0, 25/08/2025
IRAS Number:	342748
Study Sponsor:	Royal National Orthopaedic Hospital (RNOH) NHS Trust
Sponsor Reference Number	342748
Funder Reference Number:	In house funding
This protocol has regard for the HRA guidance and order of content	

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature: Date:

..../...../.....

Name (please print):

Ira Jakupovic

Position: Head of Research and Innovation Centre (RIC)

Chief Investigator:

Signature: Date:

..../...../.....

Name: (please print):

Jim Ashworth-Beaumont,

Contents

KEY STUDY CONTACTS	
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Joint-sponsor(s)/co-sponsor(s)	n/a
Funder(s)	n/a
Key Protocol Contributors	Details as above
Committees	n/a

STUDY SUMMARY	
Study Title	A single centre, feasibility study using Dynamic Lycra Garments to address pain and instability associated with Hip Dysplasia
Internal ref. no. (or short title)	Dynamic Lycra Garments for hip dysplasia
Study Design	Feasibility/pilot study. Prospective, non-blinded, non-controlled. Single Centre.
Study Participants	Consenting patients receiving standard care + dynamic lycra garment intervention
Planned Size of Sample (if applicable)	8-12
Follow up duration (if applicable)	12 weeks
Planned Study Period	1 year October 2025 – 1 October 2026
Research Question/Aim(s)	The research question underpinning the project is as follows, “Can the use of dynamic compression shorts during daily

	activities improve short term treatment outcomes in hip dysplasia patients?". This feasibility study will assess prevalence of hip dysplasia and hypermobility, refine the research protocol and measures, identify any complications of garment use, establish compliance and feedback on aspects of experience; gathering early evidence of effect and establish potential for future interventional study. The intention of this study is primarily to establish the practicality of studying these effect of the garments over the period of a study, gather the opinions of patients and thereby allow us to assess the justification for further quantitative study, rather than the adjunctive effect of the shorts themselves. The findings will inform the development of a study design which can more fully establish the generalisable degree to which this intervention can deliver effective relief from pain and disability for patients with hypermobility and hip dysplasia.

FUNDING AND SUPPORT IN KIND	
FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	A feasibility study to be undertaken with in house funding at this stage.

ROLE OF STUDY SPONSOR AND FUNDER

The study sponsor retains management of the study design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results and controls the final decision regarding any of these aspects of the study.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

This is a feasibility study.

PROTOCOL CONTRIBUTORS

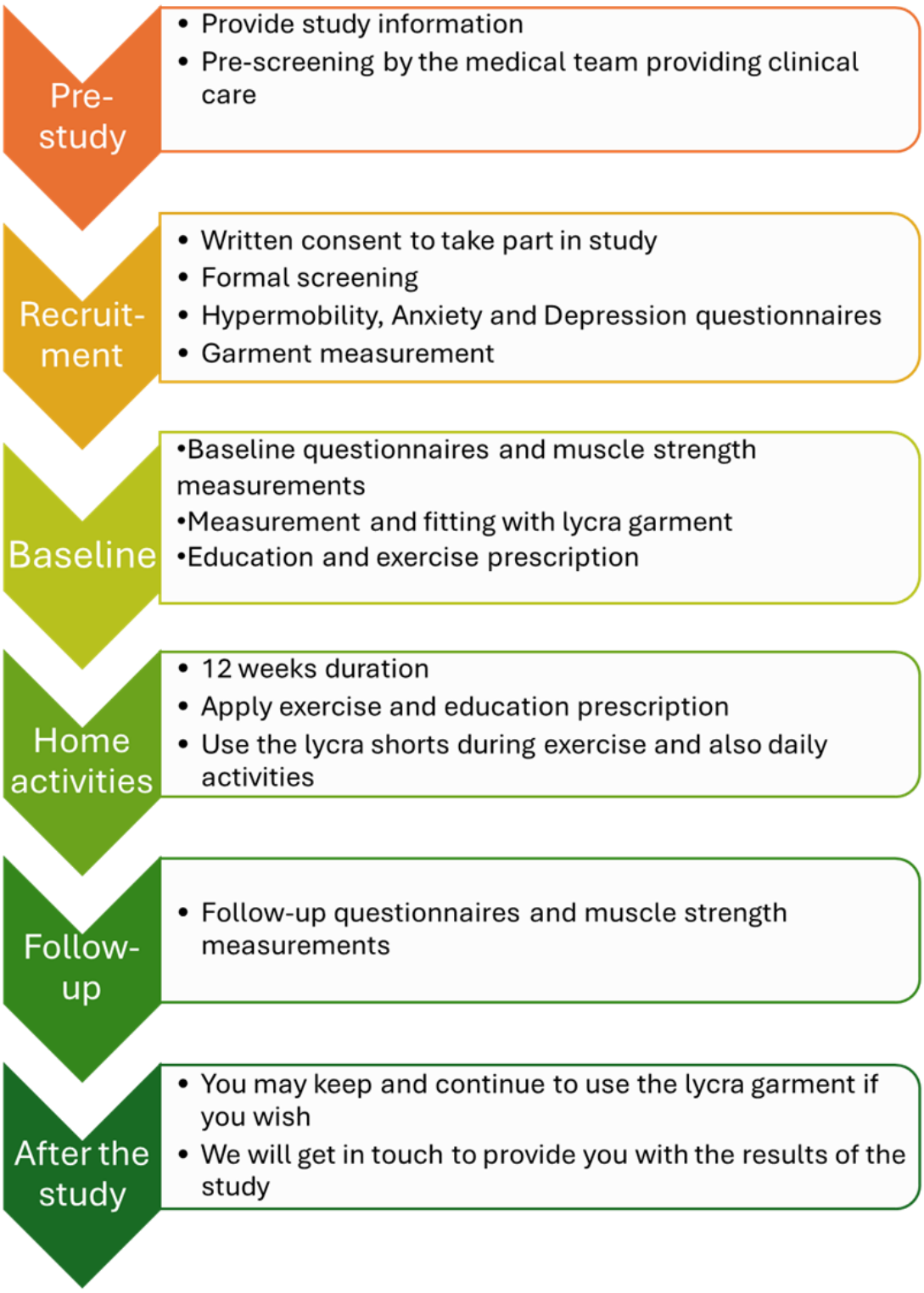
The research team (CI, PI) assume responsibility for the study design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results.
The sponsor controls the final decision regarding any of these aspects of the study.
A goal of this study is to gain informed feedback and opinion from members of the patient group of interest.

KEY WORDS:

Hip Dysplasia
Hypermobility
Ehlers Danlos Syndrome
Dynamic lycra garments
Orthotics
Physiotherapy

STUDY FLOW CHART

Fig 1: Patient information flowchart outlining the hip lycra garment study procedures. Participants may withdraw consent and exit the study at any point, without giving a reason.



ABBREVIATIONS	
AE	Adverse Event
AR	Adverse Reaction
CI	Chief Investigator
CRF	Case Report Form
DDH	Developmental Dysplasia of the Hip
DLS	Dynamic Lycra Shorts
GCP	Good Clinical Practice
GP	General Practitioner
HRA	Health Research Authority
ICF	Informed Consent Form
ISF	Investigator Site File
NHS	National Health Service
NIHR	National Institute for Health Research
PI	Principal Investigator
REC	Research Ethics Committee
RNOH	Royal National Orthopaedic Hospital NHS Trust
SAE	Serious Adverse Event

STUDY PROTOCOL

A singe centre, feasibility study using Dynamic Lycra Garments to address pain and instability associated with Hip Dysplasia.

1. BACKGROUND

Muscle-tendon-related pain exists in about half of patients with hip dysplasia (DDH), the condition where the hip socket doesn't fully cover the ball portion of the upper thighbone, affecting patients' self-reported hip disability and muscle strength negatively (Jacobsen JS et al 2018). DDH has long been known to be a risk factor for pain and degenerative changes in the hip joint (Wilkin et al 2017). A strong association between hypermobility and DDH in adults has been shown (Santore et al 2020).

Joint proprioceptive deficit is documented in a variety of musculoskeletal conditions including osteoarthritis, ligament and meniscal injuries, and individuals with increased joint hypermobility, such as those with Ehlers-Danlos Syndrome (EDS). A meta-analysis finding concluded that lower limb joint proprioception is reduced in those with benign joint hypermobility syndrome (BJHS) compared to non-BJHS cohort (Smith et al 2013).

Conservative treatment methodologies are important in addressing hip pain (Ladurner 2021). Lycra garments are deployed in rehabilitation and high-performance populations, the therapeutic effects of which are thought to arise from neurophysiological modulation of muscle tone, prolonged stretch to shortened muscles; mechanical dampening down of excessive, inefficient movement; supporting unstable areas of the body; and enhancing sensory feedback (Snowdon et al 2018).

Postural correction has been shown to reduce hip pain in adult with acetabular dysplasia (Lewis et al 2015) while lycra orthoses have reduced pain and improved stability in the shoulder (Matthews et al 2015) and in the hip (Higo et al 2023). A range of primary and secondary outcome measures were deployed to show that, in a 4 week duration randomised control trial (RCT) of compression garments on EDS patient shoulder stability there was high satisfaction with improvement in focal pain, stability and function along with objectively measured high-speed power development, albeit with no significant carry over effect (Chaléat-Valayer et al, 2002).

In summary it is possible that, in patients living with both DDH and joint hypermoblity dynamic lycra shorts (DLS) could be beneficial in reducing pain associated with posture and physical activity. The existing evidence to justify use in this population currently lacks both quality and strength.

2. RATIONALE

It is envisaged that the long-term aim of clinical trials programme by the research team will be to establish a generalizable evidence base for/against the use of lycra compression shorts to improve treatment outcomes in these populations. However, the scope of the current proposed feasibility study is limited to testing of the pathway and research protocol, participant adherence and feedback and gather early evidence of effect size, power calculation and to guide decision making as to whether this intervention is appropriate for further study and underpin funding applications (commercial/academic partners).

3. THEORETICAL FRAMEWORK

The intervention, dynamic lycra shorts, are a made-to-order CE marked item which are marketed towards treating the symptoms of joint hypermobility amongst many other pathologies. No generalisable peer-reviewed evidence currently exists to support their treatment effectiveness in the current population of interest, as an adjunct to current approach which is based around exercise and education. Furthermore, qualitative aspects of use of these highly compressive lycra garments, such as impact on

self-care or comfort, that could negatively impact on sustained use have not been explored in the peer-reviewed literature. Before embarking upon a randomised trial it is important to confirm;
the incidence of presentation of the target population, hypermobile DDH patients who are suitable for study inclusion.

- the fraction of whom are likely to consent and then choose to remain within the study protocol until the planned conclusion.
- extent of compliance with the intervention.
- identify aspects of the protocol that, through researcher and participant experience, may require modification.
- gain informed participant feedback as to the potential benefits of further research on this and similar topics.
- the incidence of anxiety and/or depression in the target population, which is thought to be common and could be an important variable in determining the outcome of treatment.

4. RESEARCH QUESTION/AIM(S)

The research question underpinning the project is as follows, “Can the use of dynamic compression shorts during daily activities improve short term treatment outcomes in hip dysplasia patients?”.
In the context of this non-blinded, non-randomised cohort feasibility study the objective is to establish potential for further comparative interventional study. The primary outcome measure will be Functional status and health-related quality of life, as evaluated by the International Hip Outcome Tool 12 (iHOT 12).
Secondary outcomes applied are:

- Hip degree of motion strength testing- force
  - measured by hand dynamometer
- Goal Attainment Scaling (GAS) questionnaire
  - evaluating the extent to which patient's individual goals are achieved over the course of study intervention in the categories sport/recreation, occupation, social, lifestyle
- Hospital Anxiety & Depression Scale
  - Effect on mental health
- OPUS HQOL STATUS (2014)
- OPUS LOWER EXTREMITY FUNCTIONAL STATUS (2014)
- OPUS SATISFACTION (2014) Qs 1-9 fit and comfort of the Orthotic garment intervention.
  - These subscales are used for prosthetic and orthotic programs for quality assessment, to maintain awareness of improvement in activities, to evaluate changes in patient's functional status and quality of life, and to assess satisfaction with devices and services.

4.1 Objectives

This study is intended to establish the experience of patients within the limited duration of the study, of prescribed exercise wearing the shorts and also daily use of the shorts in self-selected sport, leisure and activities of daily living. An important aspect of the study is to establish the importance of underlying, secondary or negative factors that may contribute to the net treatment effect. Thus, we will gather valuable information about the feasibility of using this garment, not only as part of a limited term intervention for study or treatment but their effect on an individual's quality of life and practicality as an aid for longer term use.

4.2 Outcome

This feasibility study will refine the research protocol and measures, identify any complications of garment use, establish compliance and feedback on aspects of experience; gathering early evidence of effect and establish potential for future interventional study. The intention of this study is primarily to establish the practicality of studying the effects of the garments over the period of a study and assess the justification for further quantitative study, rather than the adjunctive effect of the shorts themselves. The findings will inform the development of a study design which can more fully establish the generalisable degree to which this intervention can deliver effective relief from pain and disability for patients with hypermobility and hip dysplasia.

5. STUDY DESIGN, METHODS OF DATA COLLECTION AND DATA ANALYSIS

This prospective, 2 x repeated measures, non-blinded, non-controlled study will invite a cohort of patients to take part in a study that combines usual care with adjunctive use of DLS for a limited period of 8-12 weeks, in accord with the Declaration of Helsinki.
The null hypothesis in relation to the primary outcome measure can be stated as follows: 'use of dynamic compression shorts during daily activities does not modify the degree of pain experienced by hip dysplasia patients.'
Protocol: Patient screened by the clinical care team, will be invited to participate by the medical team, based upon the inclusion and exclusion criteria specified. They will be provided with an information sheet (PIS). The medical team will pass the prospect's details to the research team who will subsequently make contact to invite to the initial, face to face baseline session. If the patient for any or no reason declines to continue at this or any point, they will continue on the standard treatment pathway.

Recruitment session: If the patient agrees to attend, they will attend at the research site. The researcher will affirm that the prospects have read and understood the PIS information. Written consent will be sought and witnessed. Hypermobility status will be evaluated. The shorts will be measured (a single circumferential tape measure at the level of the anterior superior iliac crests (ASIS)). The participant will complete a HADS 10 evaluation form. Following the session the participant's GP will be sent a study notification letter.

The shorts have an order-to-delivery time of 2 weeks. Following delivery of these to the research site, the following activities will take place in sessions/intervals as follows

1. **Baseline session.** i. strength testing, questionnaires and interview completion. ii. shorts fitting and education, standardised method. Orthosis and exercise education will then be provided.The outcome measures gathered at baseline and followup will include: iHOT-12 questionnaire Orthotics Prosthetics Users Survey (OPUS) satisfaction subscales Hand Dynamometer - muscle strength by hip degree of movement.
   Participants will be directed to wear the lycra shorts during all daily activity and physiotherapy exercise, where possible and diarise their experiences.

2. **Intervention window**. During the 12 weeks home trial period each participant will complete a formatted daily exercise and lycra garment intervention diary. Participants will be provided with a support contact telephone/email. All contact will be fully summarised in the participant activity timeline log.]

3. **Follow up session**: strength testing, follow up and repeat OPUS questionnaires and interview. Participant debrief either during this session or as a follow up communication.

4. At the **study conclusion** each participant will be asked to complete an interview and receive a debrief of their personal study data. They will be asked to reflect upon their qualitative experience and perceived personal and generalisable benefits of current and planned research into such conservative therapies.

Data will be collected using paper Case Report Forms (CRFs) designed by the research teams and stored in locked cabinets within the clinical facility.

The scores from the validated questionnaires, patient diaries and comments recorded at follow-up will be digitised and recorded on secure databases. As is appropriate in a small-scale study, quantitative results will be considered as descriptives such as mean, median, mode, percentage, frequency, skewness, and range. Qualitative data will be evaluated by analysing the content for systematic themes, patterns and features in participant experience.

All databases used during the study will be on password and firewall protected, NHS Trust proprietary systems and private cloud channels accessible only the research team.
Participant-specific study records will be anonymised by coding, with administrative decoding under the control of Principal Investigator (PI) only, in accordance with the NHS Code of Practice for Confidentiality.

Where hard copy records or questionnaires are generated during the study, these will be scanned electronically, and the hard copies will be destroyed. Research data will be stored on password protected Trust systems and accessible only by the research team.
Research data will be stored for 5 years following completion of the study. Personal data will be stored and accessed for the limited period of 12 months.

5.1 Definition of end of study

At conclusion of the Follow-up session at 12-week point. Last patient last visit.

6. STUDY SETTING

The initial approach to potential participants will be made by the Principal Investigator (PI) who is a senior member of the RNOH Hip Unit Therapies healthcare team. The PIS makes clear that the study activities will be carried out adjunctively, rather than as an alternative, to standard care.
As a single centre study, all participant contact will take place within Outpatient Physiotherapy Department at RNOH, where standard treatment will be provided in addition to the DLS intervention.

7. SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

Current treatment pathway, for hip dysplasia patients who are deemed appropriate for conservative treatment, is to be referred by the medical team to the Principal Investigator (PI) who triages all referrals. The PI is also the researcher responsible for executing the participant-facing research protocol. During the triage referrals the PI will identify and tag those prospective participants (prospects) who might be appropriate for inclusion. All patients attend a pre-treatment assessment appointment. During this

appointment, additional time will be allocated to discuss the study topic, pre-screen the prospects and issue the PIS if appropriate. Prospective participants will be given at least 24 hours to read the PIS and consider their participation in the study. Should the prospect signal their consent, they will be invited by the PI to a study baseline session where they will be given the opportunity to ask any questions. If they are happy to take part, informed, written consent will be gained.
This is a single cohort study.

7.2 Inclusion criteria

All patients passing through the RNOH Hip Unit, diagnosed with DDH suitable for conservative treatment with physiotherapy.

- Age 18 years or over.
- Both males and females.
- Able to attend the RNOH Stanmore site for in-person sessions.

7.3 Exclusion criteria

- Less than 18 years of age.
- Diagnosed other musculoskeletal pathology affecting hips or pelvis
- Prior surgical intervention to treat a lower limb disease/disorder
- Unable to attend the RNOH Stanmore site for in-person sessions.

7.4 Sampling

Consecutive, sample of convenience. Current treatment pathway, for hip dysplasia patients who are deemed appropriate for conservative treatment, is to be referred by the medical team to the Principal Investigator who triages all referrals. The PI is also the researcher responsible for executing the participant-facing research protocol. During the triage referrals the PI will identify and tag those prospective participants (prospects) who might be appropriate for inclusion.

7.5 Size of sample

8-12, commensurate with the available population and the pilot/feasibility study design.

7.6 Sampling technique

Sample of convenience. Current treatment pathway, for hip dysplasia patients who are deemed appropriate for conservative treatment, is to be referred by the medical team to the Principal Investigator who triages all referrals. The PI is also the researcher responsible for executing the participant-facing research protocol. During the triage of referrals, the PI will identify and tag those prospective participants (prospects) who might be appropriate for inclusion.

7.7 Recruitment

During the triage referrals the PI will identify and tag those prospective participants (prospects) who might be appropriate for inclusion.
All patients attend a pre-treatment assessment appointment. During this appointment, additional time will be allotted to discuss the study topic, screen the prospects and issue the PIS if appropriate.
The initial approach to potential participants will be made by the Principal Investigator who is a member of the healthcare team. The PIS will make clear that the study activities will be carried out adjunctively,

rather than as an alternative, to standard care. Potential participants will be given at least 24 hours to read the PIS and consider their participation in the study.

Should the prospect signal their consent, they will be invited by the PI to a study baseline session where informed, written consent will be gained.

7.8 Participant identification

A member of the patient's existing clinical care team will be reviewing the referral details as part of standard triage protocol. During this referral triage process the PI will identify and tag those prospective participants (prospects) who might be appropriate for inclusion.
All patients attend a pre-treatment assessment appointment. During this appointment, additional time will be allotted to discuss the study topic, screen the prospects and issue the PIS if appropriate.
Participants will receive no payment for taking part in the study. However, participants will be able to retain the lycra shorts for continued use following conclusion of the study if the device proves to deliver personal benefit. Although this could be considered as a non-financial incentive to take part, the item will be provided as a prescribed item.

7.9 Consent

All patients attend a pre-treatment assessment appointment. During this appointment, additional time will be allotted to discuss the study topic, screen the prospects, issue the PIS if appropriate and answer any questions the prospect may have.
Should the prospect signal their consent, they will be invited by the PI to a study baseline session where informed, written consent will be gained prior to any study activities being undertaken.
The Principal Investigator will take written consent.

7.10 Consent provisions for collection and use of participant data and biological specimens

Participant-specific study records will be anonymised by coding, with administrative decoding under the control of Principal Investigator only, in accordance with the NHS Code of Practise for Confidentiality.
Information on which data will be collected and held by the research team will be outlined in the PIS, and participants will provide specific consent for access to their medical notes by the research team.
No biological specimens will be collected for this research study.

8. ETHICAL AND REGULATORY CONSIDERATIONS

Patient reported outcomes will be gathered using validated questionnaire tools. Physiological (muscle strength) measurements will be gathered using standardised methods, in the clinical environment, by the PI, a registered senior Physiotherapist.
The study design accords with the provisions of the Declaration of Helsinki 2024.

8.1 Assessment and management of risk

It is possible that safeguarding issues may arise during the study, such as a participant reporting suicidal ideation. As all participants will be current Trust patients, the PI is able to flag concerns to RNOH Adult Safeguarding department for further assessment.

8.2 Research Ethics Committee (REC) and other Regulatory review & reports

Before the start of the study, a favourable opinion will be sought from a REC for the study protocol, informed consent forms and other relevant documents (*e.g.* advertisements), and HRA approval. Substantial amendments that require review by NHS REC/HRA will not be implemented until that review is in place and other mechanisms are in place to implement at site. All correspondence with the REC/HRA will be retained.

It is the Chief Investigator's responsibility to produce the annual reports as required. An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended. The Chief Investigator will notify the REC of the end of the study. If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination. Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

8.3 Regulatory Review & Compliance

The trial will be conducted in accordance with the UK Policy Framework for Health and Social Care Research. Before any site can enrol patients into the study, the Chief Investigator/Principal Investigator or designee will ensure that the site is in receipt of appropriate REC/HRA approvals, they have issued confirmation of capacity and capability, and for multi-centre participating sites outside of RNOH, that they have been given Sponsor greenlight to start recruitment.

8.4 Amendments

For any amendment to the study, the Chief Investigator or designee, in agreement with the sponsor will submit information to the appropriate body in order for them to issue approval for the amendment. It is the sponsor's responsibility to decide whether an amendment is substantial or non-substantial for the purposes of submission. If applicable, other specialist review bodies (e.g. Confidentiality Advisory Group (CAG)) need to be notified about substantial amendments in case the amendment affects their opinion of the study. The Chief Investigator or designee will work with sites (R&D departments at NHS sites as well as the study delivery team) so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

8.5 Peer review

This is a feasibility study, the study protocol and study documentation was internally reviewed by members of the Therapies research team, and by members of the RNOH Research & Innovation team.

8.6 Patient & Public Involvement

A stated purpose of this study is to garner participant experience and opinion as to the acceptability of the research, in individual terms of benefits *versus* any negative issues such as comfort or practicality in daily activities, as well as general benefits to patients.
Future study design will be informed by these findings. A summary of the study outcomes will be communicated to all study participants.

8.7 Protocol compliance

Protocol deviations, non-compliances, or breaches are departures from the approved protocol.

Accidental protocol deviations can happen at any time. They must be adequately documented on the relevant forms and reported to the Chief Investigator and Sponsor immediately.
Deviations from the protocol that are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach.
Sponsor will be notified of any potential breaches of governance within 24 hours of occurrence, to ensure appropriate Corrective and Preventative Actions (CAPAs) are generated and further management and reporting are addressed in a timely manner.

8.8 Data protection and patient confidentiality

All investigators and study site staff must comply with the requirements of the Data Protection Act 2018 (UK implementation of the EU General Data Protection Regulation (GDPR)) with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles.
The data will be generated within the RNOH clinical facility. The data will be analysed by the research team using Trust, protected computer systems. All databases used during the study will be on password and firewall protected, NHS Trust proprietary systems and private cloud channels accessible only the research team. No transfer of data to sponsors or external investigators will take place.
Personal data will be stored and accessed for the limited period of maximum 12 months after the study has ended. Research data will be stored for 5 years after study conclusion. Research data will be stored on password protected Trust systems and accessible only by the research team. Where hard copy records or questionnaires are generated during the study, these will be scanned electronically and the hard copies will be destroyed.
The study Sponsor is the custodian of study data and the PI will act as the data custodian until study completion.

8.9 Indemnity

Royal National Orthopaedic Hospital NHS Trust is party to NHS Litigation Authority (NHSLA) / NHS Resolution. As an NHS body it is liable for clinical negligence and other negligent harm to individuals covered by their duty of care. NHS Institutions employing researchers are liable for negligent harm caused by the design of studies they initiate.

8.10 Access to the final study dataset

Only the CI and PI will have access to the full study dataset. Site investigators will be able to access the full dataset if a formal request describing their plans is approved by the steering group.

9. DISSEMINATION POLICY

9.1 Dissemination policy

RNOH will own the data arising from the study. As current RNOH staff the investigators will retain the right to publish studies. On completion of the study, the data will be analysed and tabulated and a Final Study Report prepared. The study report will be made accessible on ClinicalTrials.gov.
No funding or supporting body needs to be acknowledged within the publications and whether they have reviewed and publication rights of the data from the study.
Participants will receive feedback of their individual results following the conclusion of the study. Following publication, all participants will receive a copy of the peer-reviewed article.

Participant may specifically request results from their PI and when would this information be provided after the results had been published. The study protocol, full study report, anonymised participant level dataset, and statistical code for generating the results will be made publicly available on request following publication in peer-reviewed journal(s).

9.2 Authorship eligibility guidelines and any intended use of professional writers

The immediate research team will be granted authorship on the final study report.

9.3 Archiving Arrangements

This is a single centre study and RNOH site will be responsible for their onsite level study archiving. The trial essential TMF along with any central trial database will be archived in accordance with the sponsor SOP for archiving arrangements.

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11 APPENDICES

Appendix 1 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made

This table should be used for amendments submitted after initial REC/HRA approvals. List details of all protocol amendments here whenever a new version of the protocol is produced.

Protocol amendments must be submitted to the Sponsor for approval prior to submission to the REC/HRA.