ClinicalTrials.gov Cover Page

Official Study Title: What are the isokinetic strength and self-reported functional outcomes (ATRS) at 12 months after non-surgical management of Achilles tendon rupture using the SMART protocol?

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Sponsor: Liverpool University Hospitals NHS Foundation Trust

Responsible Party: Jeff Morton – Chief Investigator

Liverpool University Hospitals
NHS Foundation Trust

Study Acronym: Achilles Tendon Rupture: Patient Outcomes at 12 months

Full Study title: “What are the isokinetic strength and self-reported functional outcomes (ATRS) at 12 months after non-surgical management of Achilles tendon rupture using the SMART protocol?”

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FUNDERS Number: NA

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 Liverpool University Hospitals NHS Foundation Trust** 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 Liverpool University Hospitals NHS Foundation Trust

Signature:

..... Date: ...../...../.....

Name (please print):

.....

Position: .....

Chief Investigator:

Signature: Date: ...../...../.....

Name: (please print): Jeff Morton

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Committees	n/a

STUDY SUMMARY

Study Title	What are the isokinetic strength outcomes and self-reported functional outcomes (ATRS) at 12 months following non-surgical management of Achilles tendon rupture using the SMART protocol?

Internal ref. no. (or short title)	Achilles Tendon Rupture patient outcomes at 12 months
Study Design	Cross-sectional observational
Study Participants	A convenience sample of Achilles tendon rupture patients, managed in the orthopaedic department of Liverpool University Hospital NHS Foundation Trust will be recruited. Participants will be invited to attend Aintree University Hospital or Broadgreen Hospital and asked to complete the ATRS outcome measure to gain insight into the self-perceived functional recovery from their Achilles tendon rupture injury after 12 months. Following a standardised warm up, they will complete isokinetic dynamometry testing where the outcomes of peak torque, work performed and Limb Symmetry Index will be recorded.
Planned Size of Sample (if applicable)	115
Follow up duration (if applicable)	Not applicable
Planned Study Period	2 years and 6 months
Research Question/Aim(s)	1. To determine the recovery of plantarflexor strength for NHS patients at 12 months after sustaining an Achilles tendon rupture injury, having been managed using the Swansea Morriston Achilles Rupture Treatment protocol. 2. To determine the self-reported functional outcomes of NHS patients at 12 months after sustaining an Achilles tendon rupture injury, having been managed using the Swansea Morriston Achilles Rupture Treatment protocol. 3. To investigate the relationship between ATRS scores and isokinetic strength scores for patients who have sustained an Achilles tendon rupture, managed with the SMART protocol after 12 months.

GLOSSARY OF ABBREVIATIONS

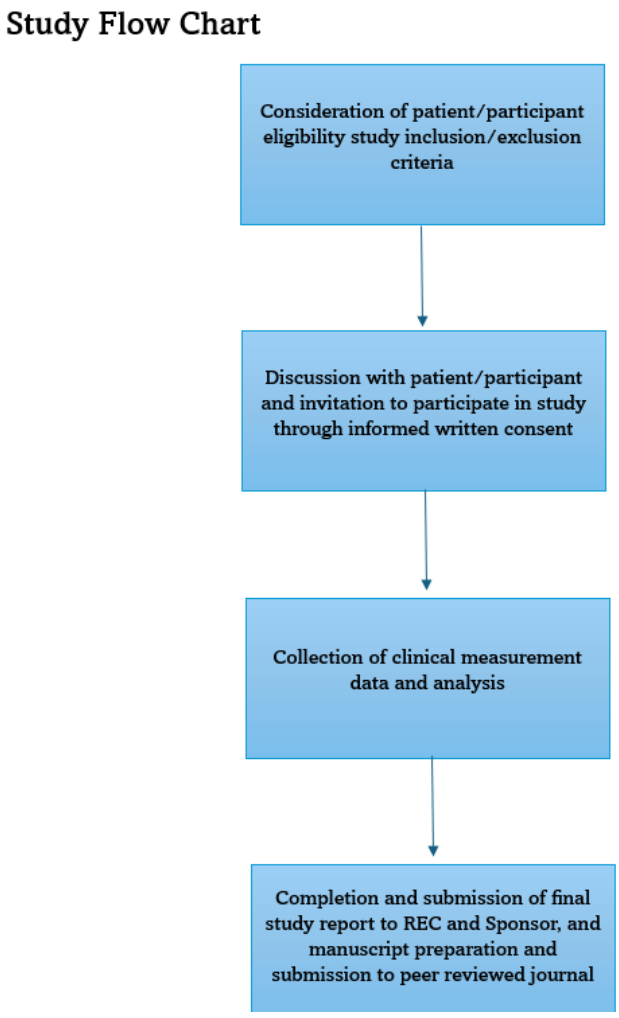
AE	Adverse event
ATR	Achilles tendon rupture
CI	Chief Investigator
CRF	Case Report Form
HRA	Health Research Authority

ICMJE	The International Committee of Medical Journal Editors
LUHFT	Liverpool University Hospitals Foundation Trust
NHS	National Health Service
NRES	National Research Ethics Service
PI	Principal Investigator
PIS	Participant/ Patient Information Sheet
REC	Research Ethics Committee
SAE	Serious Adverse Event
SMART	Swansea Morriston Achilles Rupture Treatment
UHLG	University Hospitals of Liverpool Group

KEYWORDS

Achilles tendon rupture, Physiotherapy, orthopaedics, trauma, rehabilitation

STUDY FLOW CHART



1. INTRODUCTION

1.1 BACKGROUND

The Achilles tendon is the strongest and largest tendon in the human body, playing a critical role in plantarflexion and facilitating activities such as walking, running, and jumping. However, it is also the most frequently ruptured tendon (9). The injury and associated disability have a significant impact on patient quality of life and healthcare services (5). Achilles tendon ruptures are increasingly common, particularly among middle-aged recreational athletes, with an incidence estimated at 18 per 100,000 person-years (1,3).

Historically, operative repair was considered the gold standard due to concerns regarding re-rupture risk and return to function; however, recent high-quality evidence suggests that non-surgical management may yield comparable outcomes when functional rehabilitation protocols are applied appropriately (3–5).

The Swansea Morriston Achilles Rupture Treatment (SMART) protocol represents a structured, progressive approach to non-operative rehabilitation. It emphasizes early mobilisation, protected weight-bearing, and a gradual return to sport or high-level function through targeted strength and neuromuscular training (3). While short-term outcomes of non-surgical protocols have demonstrated promising results, there remains limited high-quality data on long-term isokinetic strength and patient-reported functional outcomes beyond six months (7).

1.2 RATIONALE FOR CURRENT STUDY

This study aims to evaluate isokinetic plantarflexor strength and self-reported functional outcomes at 12 months following non-surgical management of Achilles tendon ruptures using the SMART rehabilitation protocol. By assessing both objective and subjective recovery metrics, we aim to contribute to the growing evidence base for evidence-informed, conservative Achilles tendon rehabilitation.

Isokinetic strength testing offers a validated objective method to assess plantarflexor function and limb symmetry (2). When combined with validated patient-reported outcome measures such as the Achilles Tendon Total Rupture Score (ATRS) (6), this dual assessment may provide a comprehensive picture of recovery after 12 months. Understanding these long-term outcomes is essential to guide rehabilitation progression, inform return-to-sport decisions, and support patient-centred care in non-operatively managed populations.

Research question:

What are the isokinetic strength outcomes and self-reported functional outcomes (ATRS) at 12 months following non-surgical management of Achilles tendon rupture using the SMART protocol?

Hypothesis:

1. Patients with Achilles tendon ruptures managed non-surgically using the SMART protocol will demonstrate incomplete recovery of plantarflexor strength. This hypothesis will be tested by measuring plantarflexor strength using isokinetic dynamometry. Comparison will be made by testing the non-injured limb of the participating subjects.

2. Patients with Achilles tendon ruptures managed non-surgically using the SMART protocol will report suboptimal functional outcomes at 12 months post-injury. This hypothesis will be tested by using the Achilles Tendon Total Rupture Score (ATRS) outcome measure.

Secondary hypothesis:

There will be a positive correlation between isokinetic plantarflexor strength and ATRS scores at 12 months post-injury.

1.3 Scientific Review

This protocol underwent independent scientific peer review by Professor Lyndon Mason (Consultant Foot & Ankle Surgeon), who evaluated the study design, methodology, and scientific validity. No concerns were raised regarding the protocol content.

2. STUDY OBJECTIVES

Primary:

To evaluate plantarflexor muscle strength recovery in patients 12 months after non-surgical management of Achilles tendon ruptures using the SMART rehabilitation protocol, as measured by isokinetic dynamometry.

To assess self-reported functional outcomes at 12 months post-injury using the Achilles Tendon Total Rupture Score (ATRS).

Secondary:

To explore the relationship between isokinetic strength measures and self-reported functional outcomes (i.e., correlation between LSI and ATRS).

3. STUDY DESIGN

This is a double-center, cross-sectional observational study conducted at Aintree University Hospital and

Broadgreen Hospital, targeting patients 12-15-month post-injury. To address the research question, we will invite patients for an optional one-off testing session 12-15 months following their Achilles tendon rupture injury. We will collect and analyse measures of plantarflexor muscle strength using isokinetic dynamometry and get patients to complete the ATRS outcome measure to gain insight into their functional recovery. Patients identified as eligible according to the protocol inclusion and exclusion criteria will be invited to participate in the study through informed written consent so that their clinical measurements can be used as research data for analysis.

Isokinetic plantarflexor strength testing will be conducted using the Humac®/Norm dynamometer at 12-15 months post-injury in line with usual care. All assessments will be performed by trained clinicians to ensure consistency across testing sessions. Participants will be instructed to refrain from vigorous lower limb activity for at least 24 hours prior to testing.

A standardised warm-up will be completed, consisting of five minutes gentle cycling on a static exercise bike at a self-selected pace which will aim to increase heart rate and breathing rate whilst still being able to maintain a conversation.

Following this, participants will be semi-reclined in the dynamometer chair with the knee flexed to 90°, as measured manually with a goniometer. The protocol for testing will be completed in accordance to the manufacturers advice. In brief, the ankle joint will be aligned with the axis of rotation of the dynamometer, typically corresponding to the lateral malleolus. Participants will be asked to wear flat soled shoes to minimise movement of the heel during the test. The foot will then be securely strapped to the footplate to minimize accessory movements, and the trunk, pelvis, and thigh will be stabilized using padded straps. Plantigrade of the ankle will be used to determine the 'neutral' position, with ranges of testing extending from 15° dorsiflexion through to 40° plantarflexion.

Testing will consist of five maximal-effort concentric plantarflexion contractions at an angular velocity of 90°/s, five maximal-effort concentric plantarflexion contractions at an angular velocity of 30°/s, preceded by 7 sub-maximal familiarisation repetitions. The uninvolved limb will be tested initially, followed by the involved limb. This set up and process has been previously investigated and demonstrated to be reliable for measures of peak torque (PT) and to a lesser degree, but still demonstrating moderate reliability, peak torque values relative to body weight (PT:BW) (Al Uzri et al, 2017)

Outcome measures collected from the dynamometer will include peak plantarflexion torque (Nm), peak plantarflexion torque normalised to bodyweight (Nm/kg). A PT Limb Symmetry Index (LSI) will be calculated as (injured limb peak torque / uninjured limb peak torque) × 100 as an internal control measure to judge recovery of plantarflexor strength. PT:BW values will also be analysed as an external control measure in order to allow for comparison to other published findings in the literature. Testing will be discontinued if participants report pain or discomfort during the assessment. If coefficient variation exceeds 10%, the patient will be invited to perform the test again after a 15-minute rest period.

Duration – 2 years and 6 months

Number of subjects: 115

3.1 STUDY OUTCOME MEASURES

The primary aim of this study is to assess the recovery of plantarflexor strength and self-reported functional outcomes in patients 12 months following non-surgical management of Achilles tendon rupture using the SMART protocol. To achieve this, both objective and subjective outcome measures will be collected during a single testing session.

Primary Outcome Measures

1. **Isokinetic Plantarflexor Strength**

    - **Peak Torque (Nm) -** The maximum rotational force produced by the plantarflexor muscles during an isokinetic contraction, measured in Newton-meters (Nm). This is a direct measure of muscle strength. In the context of Achilles tendon recovery, it reflects the ability of the calf muscles (gastrocnemius and soleus) to generate force through the tendon.

    - **Peak Torque normalised to bodyweight (Nm/kg) -** This metric adjusts for individual differences in body size, allowing for more accurate comparisons between participants. It is particularly useful in evaluating whether strength levels are appropriate relative to the individual's mass and functional demands.

    - **Limb Symmetry Index (LSI)** - This is a ratio comparing the performance of the injured limb to the uninjured limb, expressed as a percentage. A LSI ≥90% is considered indicative of satisfactory recovery (12).

2. **Achilles Tendon Total Rupture Score (ATRS)**

    - A validated, self-reported questionnaire assessing symptoms and functional limitations related to Achilles tendon rupture. The ATRS consists of 10 items scored from 0 to 10, with a maximum score of 100 indicating full recovery. (7)

Secondary Outcome Measures

- **Correlation between ATRS and Isokinetic Strength**

  The relationship between subjective functional recovery (ATRS) and objective strength metrics (peak torque and LSI) will be assessed using **Pearson's correlation coefficient**, assuming normal distribution of both variables. If normality assumptions are violated, **Spearman's rank correlation** will be used as a non-parametric alternative. Normality will be tested using the **Shapiro-Wilk test** prior to correlation

analysis.

Clinical Relevance

These outcome measures were selected to provide a comprehensive view of recovery. Isokinetic testing offers a reliable and reproducible method for quantifying muscle performance, while the ATRS captures the patient's perspective on their functional status. Together, these measures will help determine whether conservative management via the SMART protocol results in satisfactory recovery at 12 months post-injury.

4. PARTICIPANT ENTRY

4.1 PRE-REGISTRATION EVALUATIONS

Participants having sustained an Achilles tendon rupture will be identified using an existing database at Liverpool University Hospitals. Routinely, this injury is diagnosed clinically (6). This will take place at Aintree University Hospital and Broadgreen Hospital.

4.2 Participant identification

Participants will be identified by members of the research team. Participants meeting the inclusion criteria of the research protocol will be recruited by direct invitation. Potential participants will be initially screened via face-to-face interview to confirm eligibility. Once signed consent is obtained in writing, participants will proceed to be tested at Aintree University Hospital or Broadgreen Hospital. Potential participants will not be identified through Patient Identification Centres or recruited by publicity, posters, leaflets, adverts or websites. Muscle strength measures are taken routinely as part of the patient's rehabilitation program. The study seeks to obtain informed consent from the patients so that the clinical data collected can be used as research.

4.3 INCLUSION CRITERIA

Inclusion Criteria:
- Adults aged 18 and over
- Confirmed Achilles tendon rupture
- Non-surgical management via SMART protocol
- 12-15 months post-injury
- Ability to provide informed consent

4.4 EXCLUSION CRITERIA

Exclusion Criteria:
- Unable to provide consent
- Prior Achilles tendon surgery or re-rupture
- Neuromuscular disorders
- Non-adherence to protocol
- Previous contralateral history of achilles tendinopathy or rupture
- Participant unable to tolerate IKD testing

4.5 Participant Consent Process

Informed consent will be gained by members of the research team at the NHS sites. The participant must personally sign and date the latest approved version of the informed consent form before any study specific procedures are performed. Written and verbal versions of the participant information and informed consent will be presented to the participants detailing no less than:

- the exact nature of the study
- the implications and constraints of the protocol
- the potential side effects and any risks involved in taking part

Written informed consent will then be obtained by means of participant dated signature and dated signature of the person who presented and obtained the informed consent (RH and DS), who are suitably qualified and experienced and have been authorised to do so by the NHS trust (LUHFT). A copy of the signed Informed consent will be given to the participants. The original signed form will be retained at the study site.

4.5 WITHDRAWAL CRITERIA

It will be clearly stated in the participant information sheet that the participant is free to withdraw from the study at any time for any reason without prejudice or impact on future care, and with no obligation to give the reason for withdrawal. The participant will be allowed as much time as required to consider the information, and the opportunity to question the Investigator, their GP, or other independent parties to decide whether they will participate in the study.

4.6 Study Intervention

This is a single-visit, cross-sectional observational study. Each participant will attend one research appointment at approximately 12 months (±3 month) following their Achilles tendon rupture.

Procedures Involved:

1. **Informed Consent**
    - Participants will be provided with a Participant Information Sheet (PIS) in advance and will sign a consent form before any study procedures begin.
2. **Completion of the Achilles Tendon Total Rupture Score (ATRS)**
    - A validated, self-reported questionnaire assessing symptoms and functional outcomes related to Achilles tendon rupture.
3. **Isokinetic Strength Testing**
    - Performed using a Human Norm isokinetic dynamometer to assess plantarflexion peak torque at 30°/s and 90°/s.
    - The test will be performed on both the injured and uninjured side for comparison.
    - Results will include peak torque (Nm), Peak Torque normalised to bodyweight (Nm/kg) and Limb Symmetry Index (LSI).

Duration and Number of Visits:

- **Number of visits:** One
- **Total duration:** Approximately 60–90 minutes per participant

Randomisation:

- **Not applicable**: This is an observational study with no intervention or group allocation.

Sample Collection, Transport, and Storage:

- **No biological samples will be collected**.
- There is no collection of blood, tissue, or other bodily fluids.
- As such, no transport or storage of samples is required.

Data Storage:

- Completed ATRS forms and strength test results will be anonymized and assigned a participant study ID.
- Paper forms will be stored in a locked filing cabinets in the physiotherapy department at Aintree University Hospital and Broadgreen Hospital.
- Digital data will be stored on a secure, password-protected NHS Trust server.

- Data will be retained in line with LUHFT research governance guidelines.

5. ADVERSE EVENTS

5.1 DEFINITIONS

No significant issues are expected from the study. The testing procedure involved is performed as part of routine care and it not associated with known risks. There are no anticipated additional adverse effects inclusive of pain, discomfort, distress, or intrusion brought by participation in this study. The research will be stopped if evidence was presented to show that isokinetic calf musculature strength testing should not be used in this cohort due to safety reasons.

5.2 REPORTING PROCEDURES

Although this is a low-risk, non-interventional observational study, all adverse events (AEs) that occur during the study visit will be documented and monitored to ensure participant safety. Any unexpected issues arising during isokinetic testing (e.g., pain, discomfort, dizziness) will be recorded in the study file and reviewed by the Chief Investigator.

If an adverse event is deemed to be: related to the study procedures (e.g., isokinetic testing), and unexpected (i.e., not anticipated based on routine clinical practice), then it will be reported to the Research Ethics Committee (REC) and Sponsor in accordance with Health Research Authority (HRA) guidelines.

All adverse events will be recorded in the Case Report Form (CRF) and reviewed by the Chief Investigator.

5.2.1 Non serious Adverse Events

Non-serious adverse events (e.g., transient muscle soreness, mild discomfort) will be recorded in the CRF and monitored by the research team. These events will be reviewed periodically to identify any patterns or concerns.

Participants will be advised to report any discomfort or issues experienced during or after testing. If necessary, the testing session will be discontinued, and appropriate clinical care will be provided.

5.2.2 Serious Adverse Events (SAEs)

Although unlikely in this study, any Serious Adverse Events (SAEs)—defined as events that result in death, are life-threatening, require hospitalisation, or result in significant disability—will be reported to the Sponsor and REC if they are:

- **Related** to the study procedures, and
- **Unexpected**.

SAEs will be reported within 24 hours of the research team becoming aware of the event using the appropriate SAE reporting form. The Chief Investigator will assess causality and expectedness. All related and unexpected SAEs will be reported to the REC within 15 days.

Contact for SAE reporting:

- **Chief Investigator**: Jeff Morton
- **Email**: jeff.morton@liverpoolft.nhs.uk
- **Tel**: 0151 529 3335

Sponsor Contact:

- **Mrs Heather Rogers**
- **Email**: RGT@liverpoolft.nhs.uk
- **Tel**: 0151 706 2000

6. ASSESSMENT AND FOLLOW-UP

Assessment procedures have been detailed above and as all testing can be completed in a single visit, there is no indication for follow up.

7. STATISTICS AND DATA ANALYSIS

7.2.1 Size of sample

Based on a paired t-test comparing isokinetic plantarflexor strength between injured and uninjured limbs, a sample size calculation was completed with 80% statistical power and a significance level (alpha) of 0.05 was chosen. The analysis determined that 92 participants are required to detect a clinically meaningful difference in strength recovery. To account for potential dropouts or incomplete data, we plan to recruit a total of 115 participants (20% drop out).

7.2.2 Sampling technique

This study will employ a convenience sampling strategy. Participants will be identified from a pre-existing clinical database of patients who have sustained an Achilles tendon rupture and were managed non-surgically using the SMART protocol at Liverpool University Hospitals NHS Foundation Trust. Eligible individuals will be

invited to participate in a one-off assessment session 12-15 months post-injury.

Convenience sampling is appropriate for this observational study due to the specific inclusion criteria and the availability of a well-defined patient cohort. This approach allows for efficient recruitment of participants who meet the study requirements and have already undergone standardised rehabilitation. While convenience sampling may introduce selection bias, the use of objective outcome measures (isokinetic dynamometry) and validated patient-reported outcomes (ATRS) helps to mitigate this limitation and ensure data quality.

The rationale for this sampling strategy aligns with the study's methodological framework, which aims to describe normative recovery outcomes in a real-world NHS setting. The findings will inform clinical practice and future research by providing benchmark data for patients managed conservatively following Achilles tendon rupture.

8. REGULATORY ISSUES

8.1 ETHICS APPROVAL

The Chief Investigator has obtained approval from the Research Ethics Committee and Health Research Authority (HRA) approval. The study will be submitted to each proposed research site for Confirmation of Capacity and Capability. The study will be conducted in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions.

8.2 CONSENT

Informed consent will be gained by members of the research team at the relevant NHS site. The participant must personally sign and date the latest approved version of the informed consent form before any study specific procedures are performed. Written and verbal versions of the participant information and informed consent will be presented to the participants detailing no less than:

- the exact nature of the study
- the implications and constraints of the protocol
- the potential side effects and any risks involved in taking part

It will be clearly stated that the participant is free to withdraw from the study at any time for any reason without prejudice or impact on future care, and with no obligation to give the reason for withdrawal. The participant will be allowed as much time as required to consider the information, and the opportunity to question the Investigator, their GP, or other independent parties to decide whether they will participate in the study. Written informed consent will then be obtained by means of participant dated signature and dated signature of the person who presented and obtained the informed consent (RH & DS), who are suitably qualified and experienced

and have been authorized to do so by the lead NHS trust (Liverpool University Hospitals NHS Foundation Trust). A copy of the signed Informed Consent will be given to the participants. The original signed form will be retained at the study site.

8.3 CONFIDENTIALITY

The Chief Investigator will preserve the confidentiality of participants taking part in the study and will abide by the Data Protection Act (GDPR 2018).

The custodians of data at the NHS research site will be the Mr. Raymond Healy and Mr. Daniel Scarffe. The confidentiality of personal data of patients participating within the study will be maintained in accordance with the NHS Code of Practice for Confidentiality. Personal data will be held within the patient's clinical notes, which are securely stored within the appropriate NHS department in manual files and on secured computer servers. Access to personal data is restricted to the medical team treating the patient and those authorized by Liverpool University Hospital NHS Trust. The data is not transferred outside of the NHS systems that would normally apply as part of the care that the patient receives. Personal data held within manual files will be stored in locked cabinets. Access to the rooms in which the data is stored is restricted to authorised NHS employees. Personal data held in electronic format will be maintained on secure NHS computer servers. Computers are password protected and access is restricted to authorised NHS employees. Data generated by the study will be stored on NHS computers which are password protected by secured servers. Access to the data on computers is restricted by password protection to those within the study team. Data will be pseudoanonymised by the research team by removal of the name, address, full post code or any other details that would lead to the identification of the patient. Research data will be stored on a password protected database.

Participant identifiable data will not be accessible to researchers outside of the direct clinical care team and those with specific authorisation from Liverpool University Hospitals NHS Foundation Trust. The name and any other identifying detail will NOT be included in any study data electronic file. No personal data will be disseminated in any format outside the direct care team and NHS data management systems. Pseudoanonymised data on hospital computers will be password protected. Archiving for study will be 5 years, as per Liverpool University Hospitals NHS Foundation Trust standard operating procedure.

8.4 INDEMNITY

The Liverpool University Hospitals NHS Foundation Trust will provide NHS Indemnity Cover as the sponsor of this study.

8.5 SPONSOR

The Liverpool University Hospitals NHS Foundation Trust will act as Sponsor for this study. It is recognised that as an employee of the Trust the Chief Investigator has been delegated specific duties, as detailed in the Sponsorship Approval letter and the CI agreement.

8.6 FUNDING

There is no external funding for this study.

8.7 AUDITS

The study may be subject to risk-based monitoring, inspection and audit by the Liverpool University Hospitals NHS Foundation Trust under their remit as sponsor and other regulatory bodies to ensure adherence to GCP and the NHS Research Governance Framework for Health and Social Care (2nd edition).

9. STUDY MANAGEMENT

The day-to-day management of the study will be coordinated by the Principal Investigators at Liverpool University Hospitals NHS Foundation Trust. All research data will be securely managed using REDCap (research Electronic Data Capture), a secure web-based application designed for data collection in clinical research. REDCap is hosted on NHS-approved servers and complies with data protection regulations including UK GDPR.

Access to the REDCap database will be restricted to authorised study personnel only. Each user will have individual login credentials, and audit trails will be maintained to track data entry and modifications. REDCap will be used to store pseudoanonymised participant data, including questionnaire responses and isokinetic strength testing results.

This system will ensure high data integrity, secure storage, and efficient management of study data throughout the research project.

The Trust Patient Experience and Engagement Team reviewed the study protocol and provided input into participant-facing materials

10. END OF STUDY

The study will be deemed complete when all data collection is completed and the analyses have been fully performed, and data has been locked which is anticipated to be after 2 years and 6 months from the start of the study. End of study declaration and final study report will be submitted to HRA/REC and sponsor notifying them of the conclusion of the study. All data will be held electronically.

All documents will be archived. Data will be archived for 5 years after the end of the study in line with the sponsor's standard operating procedure on archiving.

11. ARCHIVING

Data and all appropriate documentation will be stored for 5 years, as per Liverpool University Hospitals NHS Foundation Trust standard operating procedures.

12. PUBLICATION POLICY

The final study report will be co-authored by the Chief Investigator of the study Jeff Morton and all other members of the research team. Authorship of manuscripts produced to disseminate the outcomes of the study, including poster and oral presentations at appropriate conferences or as research articles in peer-reviewed journals will be determined according to The International Committee of Medical Journal Editors (ICMJE) recommendations that an author should meet all four of the following criteria to qualify for authorship of a manuscript:

1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work

2. Drafting the work or revising it critically for important intellectual content

3. Final approval of the version to be published

4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

13. REFERENCES

APA-Formatted Reference List:

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