PhysiOtherapist-led exercise versus Waiting-list control for patiEnts awaiting Rotator cuff repair surgery: a pilot randomised controlled trial with nested qualitative study	
Acronym: POWER	
Version and Date of Protocol:	v1.0_08 Jun 2021
Sponsor:	University Hospitals of Derby and Burton NHS Foundation Trust (UHDB)
Chief Investigator:	Chris Littlewood
Local Study Reference:	UHDB/2021/016
IRAS Number:	295809
ISRCTN/ ClinicalTrials.gov number:	NCT04974242
Funder(s):	National Institute for Health Research Post-Doctoral Fellowship Scheme Email: academy@nihr.ac.uk Tel: 0113 3466280
This protocol has regard for the HRA guidance	

Confidentiality Statement

This document contains confidential information that must not be disclosed to anyone other than the Sponsor, the Investigator Team, host NHS Trust, regulatory authorities, and members of the Research Ethics Committee.

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 Derby CTSU'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.

Protocol v1.0_08 Jun 2021authorisation signatures:

Chief Investigator:

Signature:  Date: 08 / Jun / 2021

……..

Name (please print): Chris Littlewood

……..

KEY STUDY CONTACTS

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STUDY SUMMARY

Study Title:	PhysiOtherapist-led exercise versus Waiting-list control for patiEnts awaiting Rotator cuff repair surgery: a pilot randomised controlled trial (POWER)
Local Study Reference:	UHDB/2021/016
Study Design:	Two-arm, parallel group, pilot randomised controlled trial (RCT) with integrated qualitative study
Study Participants:	Adults diagnosed with tears of the rotator cuff and awaiting elective surgical repair
Planner Number of Sites:	4 sites
Planned Sample Size:	76
Treatment Duration:	12 weeks
Follow Up Duration:	6 months
Planned Start Date:	1 September 2021
Planned Recruitment End Date:	28 February 2022
Planned Study End Date:	31 August 2022
Research Question/ Aims:	In adult patients diagnosed with tears of the rotator cuff and awaiting elective surgical repair, is it feasible to conduct a future, fully powered, multi-site RCT to test the hypothesis that physiotherapist-led exercise is superior to waiting-list control in terms of clinical and cost-effectiveness?

FUNDING AND SUPPORT IN KIND

Funder(s)	**Financial and Non-Financial Support Given**
National Institute for Health Research Post-Doctoral Fellowship Scheme Email: academy@nihr.ac.uk Tel: 0113 3466280	Research grant: £533,072

ROLES & RESPONSIBILITIES

Sponsor

The Sponsor, UHDB, take on overall responsibility for appropriate arrangements being in place to set up, run and report the research project. The sponsor is not providing funds for this study but has taken on responsibility for ensuring finances are in place to support the research.

Funder

The study is funded by the National Institute for Health Research, Post-doctoral fellowship programme.

Study Management Committees

Trial Management Group

The trial management group will meet regularly to oversee the day-to-day management of the trial, including all aspects of the conduct of the trial. Any problems with study conduct and participating centers will be raised and addressed during TMG meetings.

Trial Steering Committee

The trial steering committee will oversee and supervise the progress of the trial and ensure that it is being conducted according to the protocol and the applicable regulations. The TSC is an independent body that includes majority members who are not involved with the running of the trial.

Protocol Contributors

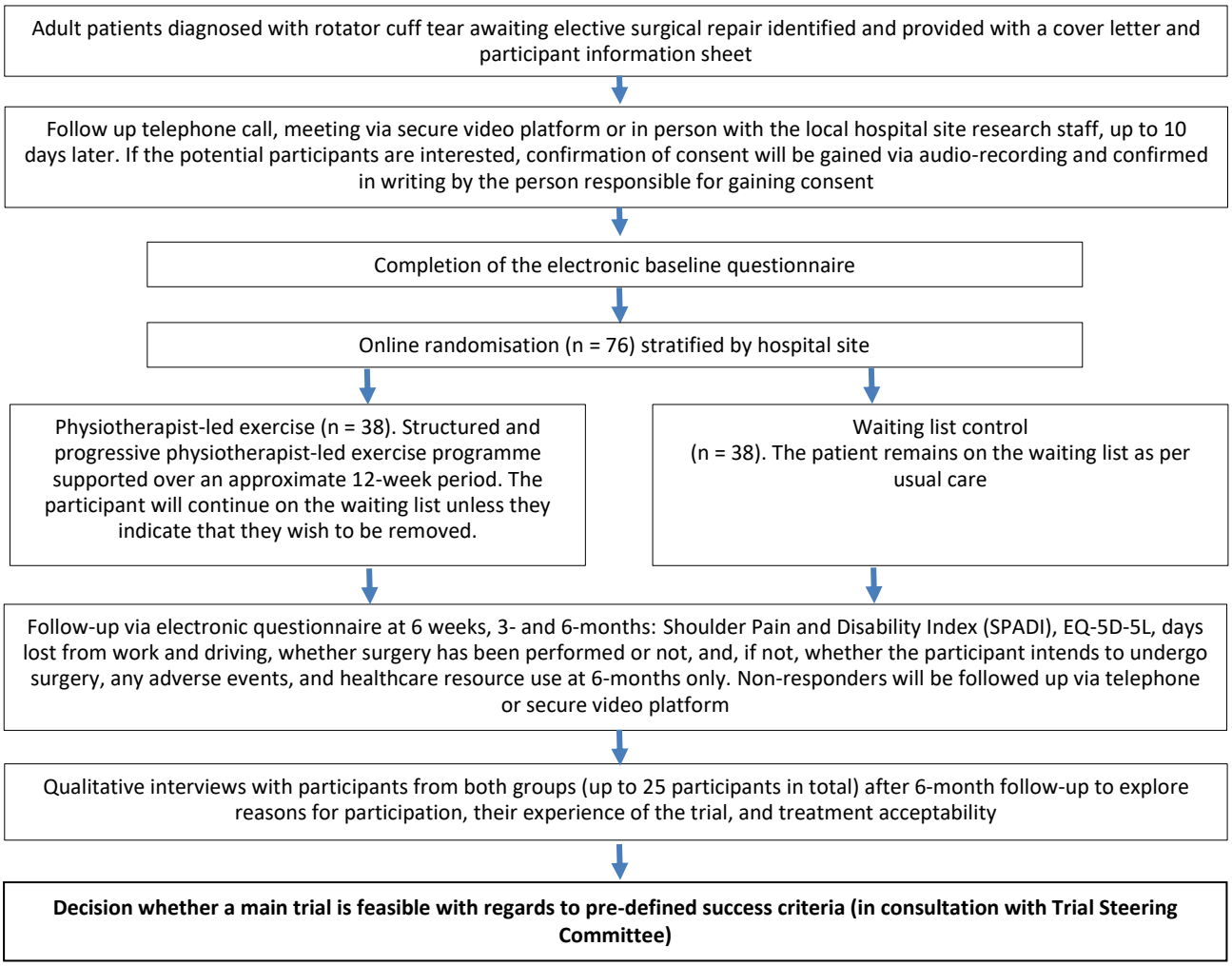
A number of protocol contributors have been involved in the development of this protocol, these include; the Chief Investigator (CL), Statistician (JB), Data Manager and Trial Manager, fellowship mentors (NF, JW). Protocol contributors are responsible for inputting into the design of the study, ensuring that it is designed transparently and efficiently.

Contents

LIST OF ABBREVIATIONS

AE	Adverse Event
CI	Chief Investigator
CRF	Case Report Form
DMEC	Data Monitoring and Ethics Committee
GCP	Good Clinical Practice
ICF	Informed Consent Form
ISF	Investigator Site File
ISRCTN	International Standard Randomised Controlled Trials
NHS R&D	National Health Service Research & Development
PI	Principal Investigator
PIC	Participant Identification Centre
PIS	Participant Information Sheet
QA	Quality Assurance
QC	Quality Control
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
SDV	Source Data Verification
SOP	Standard Operating Procedure
TMG	Trial Management Group
TSC	Trial Steering Committee
TMF	Trial Master File

STUDY FLOW CHART



1. BACKGROUND

Shoulder pain presents a significant personal, social and economic burden and impacts on work, ability to undertake leisure and household tasks and causes disturbed sleep (1). Tears of the rotator cuff are regarded as a significant cause of shoulder pain and rates of surgery to repair the torn rotator cuff have risen approximately 200% over recent years, from 1995 to 2011, across Europe and the USA (2–5). In the UK NHS, 8838 surgical repairs of the rotator cuff were undertaken in 2018/2019 (6). Depending on complexity, the cost of surgical repair ranges from £3676 to £6419 (7) meaning that direct NHS treatment costs alone range from £32.5 to £56.7 million annually.

Once a decision to undergo rotator cuff repair surgery has been made, most patients are placed on the elective surgery waiting list, and it can take weeks or months to receive the surgery. While the rates of surgery to repair the torn rotator cuff have risen over previous years, during the Covid-19 pandemic, elective orthopaedic surgery has been affected dramatically, with many operations, including those to repair the rotator cuff, postponed with ongoing uncertainty about when 'normal' elective surgery might continue. This means that waiting times have increased significantly, causing a backlog of patients on waiting lists and creating a tremendous burden for patients and the NHS. It is also likely that the current waiting lists are not reflective of the full burden as some clinicians have opted not to place patients on the elective surgery waiting list at this time of great uncertainty.

Two previous studies have evaluated the impact of physiotherapy on the need for surgery. One prospective cohort study in the USA, reported that 75% of patients with non-traumatic tears of the rotator cuff did not subsequently require surgery (8). A randomised controlled trial (RCT), in Sweden, evaluating the impact of physiotherapist-led exercise (9) on the need for subacromial decompression surgery for patients diagnosed with subacromial impingement syndrome, not rotator cuff tear, reported that 80% of participants did not subsequently require surgery. Cautiously extrapolating these data, if a programme of physiotherapist-led exercise (cost ranging from £115 to £204 per patient), delivered virtually while patients were on the surgical waiting list, resulted in 20% of patients not requiring rotator cuff repair surgery, for an outlay of £1 million to £1.8 million (8 838 x £115 to £204), there would be considerable NHS treatment cost savings per year of £6.5 to £11.3 million. If benefits to the individual patient and societal costs are added to this calculation, including work costs, this figure would rise considerably. Also, as the number of patients awaiting rotator cuff repair surgery continues to increase, this cost saving will increase further.

2. RATIONALE

While waiting for surgery, many patients continue to experience significant pain and disability, including difficulties with activities of daily living and self-care, difficulty sleeping (a particular problem for patients with shoulder pain), and some will continue to be unable to work and experience significant de-conditioning. Given current uncertainty about when elective surgery will re-start in many services, and how the backlog of patients might be managed, waiting times will simply increase. If treatment could be delivered to patients while on the waiting list with potential to reduce pain and disability, and also potentially reduce the need for surgery, there would be clear and significant patient benefit and also benefit to the NHS in terms of reducing the number of surgeries, meaning those patients with the greatest need for surgery will be able to get access to it more quickly.

In this context, the POWER trial will address an important current NHS issue, is Covid-proof in design, and has potential for significant impact beyond the current pandemic.

3. OBJECTIVES AND OUTCOME MEASURES/ ENDPOINTS

3.1. Objectives

Research question: In adult patients diagnosed with tears of the rotator cuff and awaiting elective surgical repair, is it feasible to conduct a future, fully powered, multi-site RCT to test the hypothesis that physiotherapist-led exercise is superior to waiting-list control in terms of clinical and cost-effectiveness?

Objectives

1) Estimate the numbers of eligible patients and rate of recruitment (Screened, Eligible, Approached, Randomised (SEAR)).
2) Describe the reasons for not wanting to participate based on SEAR data.
3) Report treatment fidelity with regards to the number of participants who receive physiotherapy, the number of appointments attended and self-report exercise adherence (intervention group only)
4) Report the completion rate of outcome measures.
5) Describe the number and nature of adverse events six-months following randomisation.
6) Report the number and proportion of participants who report an intention to proceed to surgery or who have received surgery within six-months post randomisation.
7) Barriers and facilitators to recruitment, retention and treatment acceptability (qualitative data).

3.2. Outcome

The primary outcome is to determine if the study is feasible based on the criteria in Section 10.

4. STUDY DESIGN

Pragmatic multi-centre, external pilot RCT with feasibility objectives using a parallel group design with 1:1 allocation ratio and integrated qualitative study.

5. STUDY SETTING

Orthopaedic and affiliated physiotherapy services at four NHS hospitals. Delivery of the intervention will be flexible including via secure video platform, for example NHS Attend Anywhere which is a secure web-based platform for patients with pre-arranged video consultation appointments, via telephone, or face-to-face, according to patient preference and safety. Remote delivery of a physiotherapy intervention for shoulder disorders has previously been reported as feasible and acceptable (10) and non-inferior to face-to-face provision (11).

6. ELIGIBILITY CRITERIA

6.1. Inclusion Criteria

- Adult patients on the elective orthopaedic waiting list for surgical repair of the rotator cuff.

6.2. Exclusion Criteria

- Unable to provide informed consent.

7. STUDY PROCEDURES

7.1. Recruitment

7.1.1. Patient Identification

Potential participants will be identified from the elective surgical waiting lists by the local Principal Investigator (clinical) and local research staff at the hospital sites.

7.1.2. Screening

No further screening measures will be implemented.

7.2. Consent

Once a potential participant is identified, a participant information sheet with cover letter (POWER RCT Participant Information Sheet) and consent form (POWER RCT Consent Form), will be provided. This will be followed up by a telephone call, meeting via secure video platform (according to local hospital site availability), or in person supported by a recruitment script (POWER Recruitment Script) from the local hospital research staff at the hospital sites, up to 10 days later. The study will be discussed and there will be an opportunity to ask questions. If the potential participant expresses an interest, confirmation of consent, in this non-CTIMP low-risk study, will be audio-recorded by the local hospital research staff asking the participant to confirm their name before reading each item of the consent form and asking them whether they consent or not. On completion of the consent discussion, the local research staff will sign and date the consent form, confirming that informed consent has been gained and a recording saved securely at the local hospital site, to confirm this. Once saved, the audio-recording would be immediately deleted from the recording device. A letter will also be sent to the participants' GP confirming their involvement, if consent to do so is provided (POWER GP Letter).

Informed consent will be obtained prior to the participant undergoing procedures that are specifically for the purposes of this study. The Principal Investigator (PI) retains overall responsibility for the informed consent of participants at their site and must ensure that any person delegated responsibility to participate in the informed consent process is duly authorised, trained and competent according to the REC approved protocol and applicable guidelines and regulations.

7.3. Randomisation

Upon confirmation of informed consent and completion of baseline assessment, individual participants will be randomly allocated via an online randomisation system set up by Derby Clinical Trials Support Unit to ensure allocation concealment. Randomisation will be 1:1 and stratified by hospital site.

7.4. Blinding

No measures to blind participants, clinicians, research team or oversight committees will be implemented.

7.5. Study Interventions

Intervention: Structured and progressive physiotherapist-led exercise programme, delivered flexibly via secure video platform, for example NHS Attend Anywhere which is a secure web-based platform for patients with pre-arranged video consultation appointments, via telephone, or face-to-face, according to patient preference and safety. Reflective of current guidance for exercise programmes for people with rotator cuff disorders, an individualised programme developed in relation to the participant's specific goals will be prescribed by the physiotherapist and supported over approximately six contact sessions across a 12-week period. The exercise programme is based on the principle of self-dosing and is based on establishing the current functional capacity of the patient in relation to the most challenging shoulder movements. The development process and resultant programme of physiotherapist-led exercise has been reported (12) and is supported by a study-specific exercise booklet (POWER exercise booklet) is provided to the patient, electronically or in paper form according to patient preference. Further detail is provided in Appendix 1.

The exercise approach described here enables adaptation to the individual participant who, in the context of this POWER trial, are likely to present with quite different levels of exercise capacity at the outset. Following an initial consultation and exercise prescription, the patient will maintain responsibility for undertaking the exercise but will discuss with the physiotherapist, at individually negotiated and agreed time points over approximately six sessions across a 12-week time period, for follow-up self-management support and advice regarding exercise progression (13,14). Participants undertaking the physiotherapist-led exercise programme will continue on the waiting list for rotator cuff surgery unless they indicate that they wish to be removed. In this event, the surgical team will be notified by the local PI.

Control: To continue on the waiting list for rotator cuff repair surgery, as per usual care.

7.6. Study Assessments

To meet the study objectives, the following assessments at baseline and follow-up will be undertaken. The assessments will be via electronic questionnaires; baseline data will be inputted by local hospital research staff directly, and links to the follow-up questionnaires will be sent to the participants by text or email. Non-responders will be followed-up by local hospital research staff by telephone or secure video platform to enable minimal data collection.

Baseline assessments

Measure	Description
Patient descriptors	
Demographics	Gender, date of birth, height, weight
Duration of shoulder pain	Patient self-report in months: 1 question
Smoking status	Patient self-report: 1 question (current tobacco smoker/ past tobacco smoker / current e-cigarette vaper / past e-cigarette vaper/ never smoked or vaped)
Diabetes	Patient self-report: Yes/ No
Employment	Patient self-report: Current employment status: 1 question
Previous physiotherapy for current shoulder problem	Patient self-report: Yes/ No
Preference for treatment intervention	Patient self-report: 1 question with 3 options
Clinical status	
Shoulder Pain and Disability	Patient self-report: Shoulder Pain and Disability Index (SPADI) 13 items, 11 discrete responses per item
Health related quality of life	Patient self-report: EuroQol: EQ-5D-5L
Diagnosis	
Size & location of rotator cuff tear (if available)	Medical records: Size according to imaging (Ultrasound scan (USS) or MRI): 1 question with 5 options (small <1cm, medium ≥1 but <3cm, large ≥3 but <5cm, massive ≥5cm, not known). Location according to imaging (USS or MRI): 1 question with 5 options – more than one can apply (supraspinatus, infraspinatus, subscapularis, teres minor, not known)

The SPADI is a patient self-report measure of shoulder pain and disability that has been validated for use over the telephone (15). The EQ-5D-5L is a generic measure of health related quality of life that provides a single index value for health status that can be used for the purpose of clinical and health economic evaluation (16).

Trial assessments

Assessment	Description
Feasibility of recruiting patients	Numbers of patients **s**creened, number **e**ligible, number **a**pproached, number **r**andomised (SEAR)
Barriers to recruitment	Reasons for not wanting to participate based on SEAR data
Follow-up rates	Follow-up response rates to questionnaires at 6-weeks, three- and six-months post-randomisation (including SPADI and EQ-5D-5L)
Treatment fidelity	Number of physiotherapy appointments attended and self-report exercise adherence (intervention group only)
Barriers and facilitators to recruitment, retention and treatment acceptability	Qualitative data (individual interviews at 6-months)

Follow-up assessments

Measure	Description	6 weeks	6 weeks MDC	3 months	3 months MDC	6 months	6 months MDC
Clinical status							
Shoulder Pain and Disability	Via questionnaire: SPADI 13 items, 11 discrete responses per item	✓	✓	✓	✓	✓	✓
Health related quality of life	Via questionnaire: EuroQol: EQ-5D-5L	✓		✓		✓	
Exercise adherence	Via questionnaire: To what extent do you agree with the following statement? 'I have been doing my exercises as often as prescribed.' (strongly agree/ agree/ not sure/ disagree/ strongly disagree)	✓		✓		✓	
Days lost from work (if applicable)	Via questionnaire	✓		✓		✓	
Days lost from driving (if applicable)	Via questionnaire	✓		✓		✓	

Has surgery been performed yet? If not, is their intention still to proceed to surgery?	Via questionnaire	✓	✓	✓	✓	✓	✓
Adverse events	Via questionnaire and clinician report	✓	✓	✓	✓	✓	✓
Health Care Utilisation							
Health Care Resource Use	Via questionnaire					✓	

7.7. Withdrawal Criteria

Participants are free to withdraw from the study at any time during participant follow-up. The local site PI, study CI and Derby CTSU will make every effort to ensure that the specific wishes of any participant who wishes to withdraw consent for further involvement in the trial are defined and documented. Participants who wish to withdraw from the treatments will have the option to still receive follow-up questionnaires, if they are willing.

7.8. Integrated qualitative study

7.8.1. Recruitment

Following the six-month follow-up point, a sample of patient participants will be purposively sampled from both treatment arms and interviewed to explore reasons for initial participation, their experience of the trial, and treatment acceptability, where relevant. Where possible sampling will purposively include a range of patient experience/views as regards having received surgery, still awaiting surgery, and deciding surgery is no longer needed.

Within the 6-month questionnaire, there will be an option to consent to contact for the purpose of discussing the qualitative study. If consent to contact is gained, a participant information sheet (POWER Qualitative Participant Information Sheet) and consent form (POWER Qualitative Consent Form), will be forwarded. The CI will subsequently contact the patient, via telephone, to discuss involvement in an individual qualitative interview. If the patient expresses interest, confirmation of consent will be recorded by the CI asking the participant to confirm their name before reading each item of the consent form and asking them whether they consent or not. On completion of the consent discussion, the CI will sign and date the consent form, confirming that informed consent has been gained and a recording saved on the secure electronic database developed by Derby CTSU to confirm this.

On confirmation of informed consent, a mutually convenient time to undertake the telephone interview will be agreed. Interviews will be audio-recorded with consent from the participant.

7.8.2. Qualitative Data Collection

The interviews will be based on a semi-structured topic guide (POWER interview topic guide) developed in relation to the pre-specified aims (approximately 30-minute interview). It is expected that up to 25 patients will be sufficient to attain rich data. Interviews will be conducted, recorded and subject to targeted transcription by the CI.

7.8.3. Qualitative Data Analysis

Data will be analysed thematically as outlined by Braun and Clarke (17). Inductive analysis of transcripts will be undertaken to ensure that the context of an individual participant's journey is preserved, while undertaking a broader thematic analysis to compare experiences across interviewees (17). Analysis will compare and contrast data across different subgroups of patients (those receiving the physio intervention versus those on the waiting list, those having undergone surgery versus those still awaiting surgery, those believing that surgery is no longer required) to identify commonalities and contrasts. Qualitative data findings will also be triangulated with findings from the SEAR data analysis (18) of numbers screened, eligible, approached and recruited to the study to explore reasons for initial participation, tensions around decisions to proceed to surgery if feeling better with the exercise programme, and concerns about the future if opting not to have surgery. Critical discussions amongst the research team and our PPI group, will then take place to verify, modify and refine the themes.

7.9. End of Study

The end of study will be defined as when all data has been received and queries resolved. The Clinical Trials Manager will notify the Sponsor, participating sites and REC within 90 days of the end of study. The clinical study report will be written within 12 months of the end of study.

8. SAFETY REPORTING

8.1. Definitions

Term	Definition
Adverse Event (AE)	Any untoward medical occurrence in a participant, including occurrences which are not necessarily caused by or related to study procedures.
Related AE	An untoward and unintended response in a participant to a study procedure. This means that a causal relationship between the study procedure and an AE is at least a reasonable possibility, i.e. the relationship cannot be ruled out.
Serious Adverse Event (SAE)	A serious adverse event is any untoward medical occurrence that: • results in death • is life-threatening • requires inpatient hospitalisation or prolongation of existing hospitalisation • results in persistent or significant disability/incapacity • consists of a congenital anomaly or birth defect Other 'important medical events' may also be considered serious if they jeopardise the participant or require an intervention to prevent one of the above consequences. NOTE: The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.
Related SAE	An adverse event that is both serious and, in the opinion of the reporting Investigator, believed with reasonable probability to be due to one of the study procedures.
Related & Unexpected SAE	A serious adverse event that; • is believed with reasonable probability to be due to one of the study procedures. • the nature and severity of which is not consistent with the information provided in the protocol i.e. it is not listed as an expected occurrence.

8.2. Operational Definitions for (S)AEs

For the purpose of this study, transient increases in shoulder pain associated with the programme of physiotherapist-led exercise are expected and will not be reported providing the participant is able to manage without the requirement for additional medication or consultation. Where participants report attendance at an appointment or consultation for pre-existing medical conditions or routine pre-operative or post-operative assessment or care, these will not be reported as adverse events.

8.3. Recording and Reporting SAEs

AEs and SAEs will be recorded from the time of randomisation until completion of the 6-month questionnaire or when the permitted time for completion of this questionnaire has ended.
All (S)AEs occurring during the duration of the study will be self-reported by the participant or clinician (physiotherapist, surgeon, GP). All related and unexpected SAEs will be recorded by using the 'non-CTIMP safety report to REC form' from the HRA website. The completed form should be submitted to the Derby CTSU and REC within 15 days of the CI becoming aware of the event. Safety information will be reviewed during TMG and TSC meetings.

8.3.1. Assessment of AEs and SAEs

8.3.1.1 Severity

Severity of the AE will be judged accordingly;

- Mild: no interference with daily activities.
- Moderate: moderate interference with daily activities.
- Severe: considerable interference with daily activities (e.g. inability to work).

NOTE: to avoid confusion or misunderstanding the term "severe" is used to describe the intensity of the event, which may be of relatively minor medical significance, and is NOT the same as "serious" which is described in the safety definitions.

8.3.1.2 Causality

Clinical judgement should be used to determine the relationship between the study procedures and the occurrence of each AE;

- Not related: There is no evidence of a causal relationship between the event and study procedures.
- Related: There is evidence of a causal relationship between the event and study procedures i.e. a relationship to the study procedures cannot be completely ruled out.

Assessment of causality will be made by the principal investigator, in consultation with the CI where required.

8.3.1.3 Expectedness

The assessment of expectedness is only required if the event is deemed to be related to study procedures.

- Expected: Event previously identified and described in the protocol.
- Unexpected: Event not previously described in the protocol.

The expectedness assessment will be made by the principal investigator, in consultation with the CI where required.

8.4. Pregnancy reporting

Pregnancy reporting is not required.

8.5. Reporting Urgent Safety Measures

If any urgent safety measure is taken the research team will inform the Derby CTSU within 24 hours using the Derby CTSUs safety incident reporting form. The Derby CTSU will inform the REC and participating sites of the measures taken and the circumstances giving rise to those measures within 3 days on implementation of the urgent safety measure.

9. DATA HANDLING

The following section is a summary of data handling processes. A separate Data Management Plan (DMP) will be developed by the Derby CTSU and the CI and will include further detail on these processes.

9.1 System and compliance

An electronic software platform will be used for trial data capture. Data capture will be via a web-based, fully validated system, compliant with 21 CRF Part 11; Electronic records; Electronic signatures and EU Commission Directive 2005/28/EC with comprehensive audit trials. Derby CTSU will be responsible for database build and system validation. Data will be hosted externally according to General Data Protection Regulation guidance.

9.2 Source Data

Source data will consist of paper and electronic medical records depending on the data being collected. In some instances, the data is transcribed directly onto the eCRF and the eCRF will be considered source. The following table lists data collected in the study where the eCRF is not considered the source data:

Data	Source
Informed Consent	Paper consent form mailed to participant and audio recording
Size & location of rotator cuff tear	Medical records

Participating sites will keep records of all participating patients and all original recordings of informed consent discussions.

9.3 Workflow

The Derby CTSU Data Management team will maintain the EDC and the data will be hosted by the EDC supplier according to General Data Protection Regulation guidance. The trial database will be designed to capture the clinical data in accordance with the best principles of clinical data management and the relevant SOPs on *Research Electronic System Specification, Selection, Validation and Implementation, Case Report Form and Database Selection, Development & Release* and *Data Security & Access Control* developed by the Derby CTSU.

Access to the trial database will be restricted by role-based permission to authorised trial personnel. Users will be suitably trained on the system prior to being granted access. Individual user accounts will be password protected and will not be shared between members of the trial team.

Data will be entered into the eCRF by site staff and directly into the EDC system by participants for the purpose of collecting follow-up data. Post data entry, validation checks will be performed on the data to ensure accuracy and consistency according to the Data Validation Plan. All data queries generated as a result of these checks will be available for resolution by the site online. After data entry is complete, all data queries have been resolved, medical coding is complete and all forms have been signed by the PI, the database will be locked and released for statistical analysis.

Derby CTSU will be responsible for study control (from design to study close-out), database build and system validation. All clinical data will be collected, stored, processed and archived in accordance with the Data Management Plan for this trial and in line with the relevant SOPs on *Data Entry*, *Data Closeout Activities* and *Archiving* developed by the Derby CTSU and any relevant legislation.

9.4 Data Access and Security

All documents will be stored safely in confidential conditions. With the exception of regulatory authorities, only staff as listed on the Delegation Log and the trial monitor will have access to source documents. The CI and study statistician will have access to the secure, password protected, study database for the purpose of reporting to the TMG and TSC and at the end of follow up for final data cleaning/checking and end-of-study analysis.

On all clinical investigation-specific documents, other than the signed consent, the participant will be referred to by the clinical investigation participant number/code, not by name. Each participant will be assigned a study identity code number for use on study forms, other study documents and the electronic database. The investigator and trial team will ensure that the participant's identity is protected at every stage of their participation within the trial, according to the Caldecott principles. If

any patient information needs to be sent to a third party the trial team will adhere to maintaining pseudo-anonymous participant parameters in correspondence.

9.5 Archiving

At the end of the study, following completion of the end of study report, UHDB/ Derby CTSU will securely archive all centrally held study related documentation for a minimum of 10 years. At the end of the defined archive period arrangements for confidential destruction will be made. It is the responsibility of each PI to ensure that data and all essential documents relating to the study are retained securely for a minimum of 10 years after the end of study, and in accordance with national legislation. Derby CTSU will notify sites when study documentation held at sites may be archived, and then destroyed. All archived documents must continue to be available for inspection by appropriate authorities upon request.

10. STATISTICS AND DATA ANALYSIS

As this is a pilot RCT, the main analysis will focus on process outcomes, including consent rate, retention rate, and follow-up rates in line with the stated objectives. A detailed data analysis plan will be developed and reviewed by the TSC prior to any analysis being undertaken.

At the end of the study, we will review the findings and in discussion with the TSC make a recommendation about proceeding to a future fully powered RCT. The following success criteria will be used to inform decision-making:

Progression criteria	Red (Stop)	Amber (Amend)	Green (Go)
Recruitment rate [1]	<20	20 to <30	30 or more
Treatment fidelity [2]	<65	65 to <80	80 or more
Follow-up [3]	<65	65 to <80	80 or more

1. % of eligible patients
2. % of participants randomised to physiotherapist-led exercise to have received initial assessment and exercise prescription within the study period
3. % of SPADI questionnaires received at 6-months

10.1. Sample Size Calculation

To inform the development of a future, fully powered trial, and for the purpose of addressing the feasibility objectives, in keeping with recommendations for the sample size of an external pilot RCT, the target sample size is 76 (19).

10.2. Planned Recruitment Rate

Data from three sites that have expressed an interest in participating, suggest there are approximately 180 patients currently awaiting rotator cuff repair surgery at those sites. Assuming 30% of patients approached are randomised, we will need to approach 254 patients in total to achieve the target sample size of 76. Hence, initially working with four sites, the study information pack will be provided to patients on the elective orthopaedic waiting list for surgical repair of the rotator cuff. In addition to this initial mailing, recruitment will be sequential over six-months and include patients who are subsequently added to the waiting-list.

10.3. Statistical Analysis

10.3.1. Summary of Baseline Data and Flow of Patients

Descriptive statistics will be presented to summarize the distribution of baseline variables across each of the randomisation groups. Baseline variables, e.g. age, height, weight, will be reported using appropriate methods.

To meet objective one (estimate the numbers of eligible patients and rate of recruitment (Screened, Eligible, Approached, Randomised (SEAR)), a Consolidated Standards of Reporting Trials (CONSORT) flow diagram will be produced, showing the frequency of patients/ participants;

- Number of patients screened for eligibility at each site and overall.
- Number of patients found eligible as a proportion of those screened at each site and overall.
- Number of patients approached (study information provided) as a proportion of those eligible at each site and overall.
- Number of patients who consent to participate as a proportion of those approached at each site and overall.
- Number of participants randomised, include number allocated to each group

To meet objective two (describe the reasons for not wanting to participate based on SEAR data), the CONSORT diagram will include:

- Number of patients found eligible who were subsequently not approached and the reasons for this (e.g. surgery scheduled imminently, no time to approach, no contact details)
- Number of patients approached who subsequently did not want to participate and the reasons for this (e.g. surgery scheduled imminently, previous non-response to physiotherapy, not interested, not enough time, shoulder problem resolved).

To meet objective three (report treatment fidelity with regards to the number of physiotherapy appointments attended and self-report exercise adherence (intervention group only), the number and proportion of patients randomised to the programme of physiotherapist-led exercise who participated in one or more treatment sessions will be reported, as well as the mean number of treatment sessions attended and SD. Where participants in the intervention group received one or more treatment sessions, this will be reported via the CONSORT flow diagram as receiving the allocated intervention.

For the purpose of understanding self-report exercise adherence, participants will be asked to respond to the question; to what extent do you agree with the following statement? 'I have been doing my exercises as often as prescribed.' (strongly agree/ agree/ not sure/ disagree/ strongly disagree) and the number of responses in each category will be reported as a proportion of all responses at each follow-up time point.

To meet objective four (report the completion rate of outcome measures), the number and proportion of SPADI and EQ-5D-5L questionnaires completed at each follow-up time point, including via minimal data collection, will be reported.

To meet objective five (describe the number and nature of adverse events six-months following randomisation), the number and nature of adverse events which occur will be reported overall and by study arm.

10.3.2. Outcome Analysis

Between-group analysis of total SPADI score will be undertaken using ANCOVA for the purpose of generating associated confidence intervals to evaluate any signal of effectiveness of the intervention, to inform planning of a future trial (20). Analysis will be according to the Intention-to-Treat (ITT) principle and include any randomised participant, regardless of whether they received the study intervention. A secondary per protocol analysis will be conducted based on minimum fidelity criteria (one or more treatment sessions attended).

10.4. Subgroup Analyses

Not applicable.

10.5. Adjusted analyses

Not applicable.

10.6. Interim Analysis and Criteria for the Premature Termination of the Study

No pre-specified interim analyses are planned.

The Derby CTSU and/or Sponsor may suspend or prematurely terminate either the entire study, or the study at an individual site, for significant reasons that must be documented (e.g. an unacceptable risk to participants or serious repeated deviations from the protocol/ regulations). If this occurs the Derby CTSU/ Sponsor shall justify its decision in writing and will promptly inform any relevant parties (i.e. participants, investigators, participating sites, REC, regulatory bodies).

10.7. Analysis Groups

For the purpose of generating confidence intervals to facilitate evaluation of any signal of effectiveness, primary analysis will be according to the Intention To Treat (ITT) principle and include any randomised participant, regardless of whether they received the study intervention.

10.8. Procedure(s) to Account for Missing or Spurious Data

As this is a pilot RCT, no methods to account for missing data will be used but will be reported accordingly.

11. MONITORING, AUDIT & INSPECTION

Source documents and other documentation for this study will be made available to study monitors, the REC or regulatory authority inspectors. Authorised representatives of the Derby CTSU/ Sponsor may visit the participating sites to conduct audits/ inspections.

12. ETHICAL AND REGULATORY CONSIDERATIONS

12.1. Assessment and Management of Risk

For patients who would be recruited to this study, standard care is to remain on the waiting list for surgery. However, a programme of physiotherapist-led exercise is usually prescribed for patients with rotator cuff tears prior to consideration of surgery. Thus, physiotherapist-led exercise usually features in the standard treatment pathway, meaning that the risk compared to standard care is similar. The intervention, physiotherapist-led exercise, will be delivered by qualified physiotherapists who are trained in the specific exercise programme and who prescribe exercise as part of their usual clinical practice.

12.2. Peer review

This study has been peer reviewed as part of the NIHR application to re-purpose this funding. Further review has been undertaken by members of the TSC.

12.3. Public and Patient Involvement

One patient, currently awaiting surgery to repair the rotator cuff, has been consulted about this research. The patient was very supportive of the idea given that his own experience has been to improve while waiting for surgery and has now opted to further delay surgery given this improvement. The patient will continue to advise regarding study design and contribute to trial management as part of the TMG.

Further, the current TSC includes two patient members who have reviewed and are supportive of this study and will provide continued oversight for the duration of the study.

While developing the physiotherapist-led exercise programme, and associated materials including patient information sheets, patients were included in the development process and review of patient-facing material.

12.4. Research Ethics Committee (REC) & Regulatory Considerations

The study will be conducted in compliance with the approved protocol and the Declaration of Helsinki. The protocol and all related documentation (e.g. informed consent form, participant information sheet, questionnaires) have been reviewed and received approval by a Research Ethics Committee (REC). The investigator will not begin any participant activities until approval from the HRA and REC has been obtained and documented. All documentation and correspondence will be retained in the trial master file/investigator site file. Substantial amendments that require HRA and REC (where applicable) review will not be implemented until the HRA and REC grants a favourable opinion (with the exception of those necessary to reduce immediate risk to participants).

It is the responsibility of the Derby CTSU to ensure that an annual progress report (APR) is submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, annually until the study is declared ended. The Derby CTSU is also responsible for notifying the REC of the end of study (see Section 6.9) within 90 days. Within one year of the end of study, the Sponsor will submit a final report with the results, including any publications/abstracts to the REC.

Before any site can enroll a patient into the study confirmation of capacity must be sought from the site's research and development (R&D) department. In addition for any amendment that will potentially affect the site's permission, the research team must confirm with the site's R&D department that permission is ongoing (Section 11.10).

12.5. Protocol Compliance/ Non-Compliance

The CI is responsible for ensuring that the study is conducted in accordance with the procedures described in this protocol. Prospective, planned deviations and/or waivers to the protocol are not acceptable, however accidental protocol deviations (non-compliances) may happen and as such these will be recorded. Non-compliances will be recorded in the CRF and/or a non-compliance log kept in the ISF. All non-compliances will be reviewed and assessed by the PI (or appropriately delegated individual) to determine if they meet the criteria of a "serious breach" (Section 12.6). Non-compliances which are found to frequently recur are not acceptable, will require immediate action, and could potentially be classified as a serious breach.

12.6. Notification of Serious Breaches to GCP and/or the Protocol

A "serious breach" is a departure from the protocol, Sponsor procedures (i.e. SOPs), or regulatory requirements which is likely to effect to a significant degree –

(a) The safety or physical or mental integrity of the subjects of the study; or
(b) The scientific value of the study.

If the PI (or delegate) is unsure if a non-compliance meets these criteria, they should consult the Sponsor for further guidance.

If a serious breach is identified the investigator should notify the Derby CTSU immediately (i.e. within 1 working day) using the 'Non-CTIMP Notification of a Serious Breach' form. The report will be reviewed by the Derby CTSU and CI, and where appropriate, the Derby CTSU will notify the REC within 7 calendar days of being made aware of the breach.

12.7. Data Protection and Patient Confidentiality

The study will be conducted in accordance with the Data Protection Act 2018. We will ensure that participant's anonymity is maintained throughout the study and following completion of the study.

Participants will be identified on all study specific documents (except for the informed consent form and enrolment log) only by the participants study specific identifier (and initials if deemed necessary). This identifier will be recorded on documents, and the database. For the purpose of the electronic questionnaires, their IP address will also be stored in the database for functional reasons but will not be needed for analysis and therefore will never be extracted. The investigator site file will hold an enrolment log detailing the study specific identifier alongside the names of all participants enrolled in the study. All documents will be stored securely with access restricted to study staff and authorised personnel.

Verbal consent and subsequent qualitative interviews will be recorded by the CI and saved securely on the electronic database developed by Derby CTSU. Only the CI and invited members of the research team will have access to the saved recordings. On completion of the qualitative interviews, the CI will upload the recording and then immediately delete the recording from the audio recorder. Audio-recordings will be labelled with the participant identification number; identifiable patient details will not be used.

Audio-recordings will be subject to targeted transcription by the CI and edited to protect the anonymity of respondent. At the end of the study, audio-recordings will be kept for at least 10 years before they will be destroyed.

The CI will act as the custodian of the data generated in the study.

12.8. Financial and Other Competing Interests for the Chief Investigator, Principal Investigators at Each Site and Committee Members for the Overall Study Management

There are no conflicts of interest.

12.9. Indemnity

This study is sponsored by University Hospitals Derby and Burton NHS Foundation Trust who provide indemnity against negligent and non-negligent harm caused by the design and/or management of the study. For harm to participants arising from the conduct of the research indemnity is provided through the NHS schemes or professional indemnity of NHS staff.

12.10. Amendments

If changes to the study are required these will be discussed with the Sponsor, who is responsible for deciding if an amendment is required and if it should be deemed substantial or non-substantial. Substantial amendments will be submitted to the relevant regulatory bodies (REC, HRA) for review and approval. The amendments will only be implemented after approval and a favourable opinion has been obtained. Non-substantial amendments will be submitted to the HRA for their approval/ acknowledgment. Amendments will not be implemented until all relevant approvals are in place.

12.11. Access to Final Study Dataset

Request for the anonymised datasets generated during and/or analysed during the current study can be made by contacting the CI in the first instance. Only de-identified data are available for request in aggregated format or at the level of the individual participant.

13. DISSEMINATION POLICY

13.1. Dissemination Policy

The primary aim of this study is to establish the feasibility of conducting a future fully powered randomised controlled trial and hence dissemination plans, outputs and anticipated impact need to be considered in this context. The results report will be published in an open-access peer reviewed

publication with the highest possible impact factor. The findings will also be disseminated to patient and clinician groups and at relevant conferences, particularly the British Elbow & Shoulder Society Conference, as well as other outlets including social media and blog posts.

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15. APPENDICES

15.1. Appendix 1 – The physiotherapist-led exercise programme

During the first meeting, the physiotherapist will ask the participant about treatment related goals linked to functional activities. For example, participants might have difficulty reaching to a shelf at home, lifting at work, or sports-related difficulties, including serving at tennis etc. Once these have been identified, the physiotherapist will break down the identified functional activities into component parts. For example, if the participant complains of difficulty reaching to a shelf, predominantly an activity of forward-flexion of the shoulder, initial assessment of exercise capacity will commence in relation to forward-flexion of the shoulder.
To highlight this, the assessment commences with testing of active-assisted forward flexion starting with the arm by the side and moving to 30^{o} (Figure 1). Given the lack of research evidence supporting an optimal number of repetitions and sets and considerable variation in clinical practice (21,22), a self-dosed approach will be taken where the participant is advised that the exercise should always be challenging to them. The participant could be challenged in relation to pain response, fatigue or perceived exertion, or a combination but this challenge should always be at a level that is acceptable to the individual participant. The level of acceptable response is likely to vary between participants but they will be re-assured that such challenge does not equate to damage and they should be guided by what is acceptable to them rather than with reference to generic guidance that might not be acceptable to them and hence would serve as a barrier to exercise adherence. So, for example, a participant might commence repeated active-assisted forward flexion with the arm by the side and moving to 30^{o}. The first 20 repetitions might be perceived as challenging but acceptable, but repetitions beyond this become unacceptable. Then, the participant records the type of exercise performed and the number of sets and repetitions in the POWER exercise booklet. This record sets the target for the participant to meet and exceed during their next exercise session. Such an approach facilitates progressive exercise. Participants will be advised to aim for a minimum of one exercise session per day, a minimum of five days per week, and up to three different exercise series will be prescribed, e.g. forward-flexion, abduction (reaching out to the side away from the body), and reaching behind back. Given the self-dosed nature of this programme, no upper limit will be prescribed providing the response remains within an individually acceptable limit. For example, participants would be asked to re-consider their approach to self-dosing if it was felt the number of exercises undertaken was contributing to pain that impaired sleep.

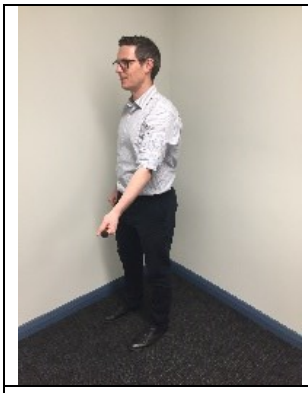

Figure 1 Active-assisted forward flexion starting with the arm by the side and moving to 30^{o}

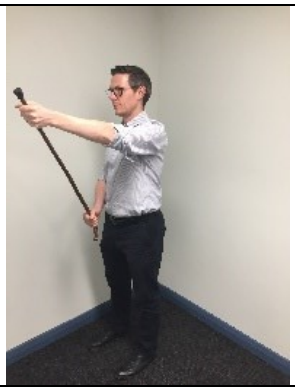

Figure 2 Active-assisted forward-flexion of the shoulder with the aim of reaching 90^{o}

If stage one exercises are perceived as not challenging, the participant will be able to move on to stage two exercises. Multiple exercise prescriptions and progressions are detailed in relation to various functional difficulties. These prescriptions and progressions are detailed in POWER exercise

booklet with photographs and descriptive text in sufficient detail to enable replication, informed by the TIDieR checklist (23). In this example, stage two exercise would be active-assisted forward-flexion of the shoulder with the aim of reaching 90^{o} (Figure 2). Following the same principles of progression, stage three would incorporate active-assisted flexion to 180^{o}. Although we expect that many participants will have exercise capacity greater than these initial stages, this assessment process is important in the context of exercise prescription because it teaches the participants how to progress but also regress their own exercise. This means that if the response to exercise becomes unacceptable when exercising away from the physiotherapist, the participant has the understanding of how to regress the exercise to maintain acceptable levels. Similarly, the patient also has understanding of how to progress the exercise, as they feel able. Such progression is an important component of effective exercise prescription (21)

Stages four, five and six, would include progression to active exercise; up to 30^{o} for stage four, up to 90^{o} for stage five (Figure 3), and then up to 180^{o} for stage six (Figure 4).

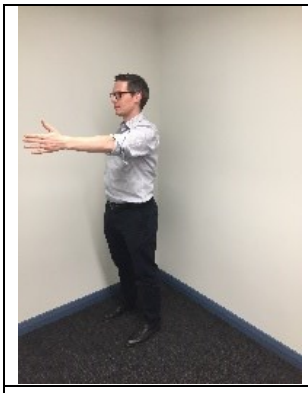

Figure 3 Active forward-flexion of the arm reaching to 90^{o}

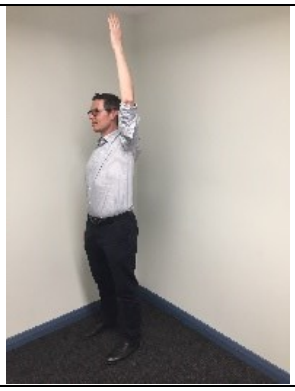

Figure 4 Active forward-flexion of the arm reaching to 180^{o}

Stages seven, eight and nine, would include progression to resisted exercise; up to 30^{o} for stage seven, up to 90^{o} for stage eight (Figure 5), and then up to 180^{o} for stage nine (Figure 6).

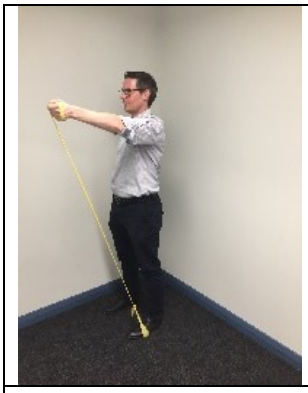

Figure 5 Resisted forward-flexion of the arm reaching to 90^{o}

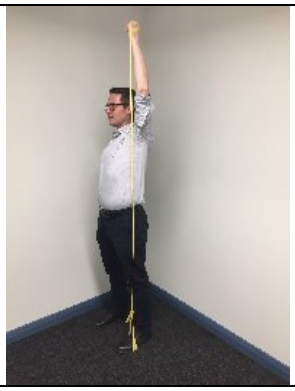

Figure 6 Resisted forward-flexion of the arm reaching to 180^{o}

The final stage of the physiotherapist-led exercise programme will include functional restoration with exercise prescribed by the physiotherapist in relation to the specific functional difficulty rather than isolated movements. In this example, the participant would be encouraged to undertake repeated reaching to the shelf, initially with assistance, then without and then against resistance provided through an elastic training band or hand-weight.

15.2. Appendix 1 - Amendment History

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

Detail all protocol amendments. Protocol amendments must be submitted to the Derby CTSU & Sponsor for approval prior to submission to the REC.