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Study Title:	Can a brief behavioural assessment improve exercise adherence in older people with musculoskeletal conditions? A feasibility randomised controlled trial
Short Title	Adherence for Exercise Rehabilitation in Older people (AERO) trial

Ethics Ref: 18/SC/0416

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Funder:	Physiotherapy Research Unit, Nuffield Orthopaedic Centre
Chief Investigator Signature:	

Jonathan Room Date 28th June 2018

The investigators declare no conflicts of interest to declare

Confidentiality Statement

This document contains confidential information that must not be disclosed to anyone other than the Sponsor, the Investigator Team, HRA, host organisation, and members of the Research Ethics Committee, unless authorised to do so.

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1. SYNOPSIS

Study Title	Can a brief behavioural assessment improve exercise adherence in older people with musculoskeletal conditions? A feasibility randomised controlled trial	
Internal ref. no. / short title	Adherence for Exercise Rehabilitation in Older people (AERO) trial	
Study Design	Feasibility Randomised Controlled Trial	
Study Participants	People over 65 years of age with a musculoskeletal condition	
Planned Sample Size	40-50	
Planned Study Period	1 year	
	Objectives	**Outcome Measures**
Primary	To assess the feasibility of the study design to determine if a large scale RCT is possible.	Recruitment numbers, dropout rate, fidelity and acceptability
Secondary	To assess participants exercise adherence, and behavioural regulation regarding exercise	• Self-reported adherence Scale and exercise diary • Tilburg Frailty Indicator (TFI) • Physical Activity Scale for the Elderly (PASE) • EQ 5D 5L • Self-Efficacy for Exercise Scale • Exercise regulation Questionnaire (BREQ-3) • Global rating of change (GROC) • VAS score, self-rated capacity to exercise, confidence to exercise and motivation to exercise
Tertiary	Acceptability of the intervention	Qualitative interviews

2. ABBREVIATIONS

CI	Chief Investigator
COPD	Chronic Obstructive Pulmonary Disease
CRF	Case Report Form
GCP	Good Clinical Practice
HRA	Health Research Authority

ICF	Informed Consent Form
NHS	National Health Service
NRES	National Research Ethics Service
PASE	Physical Activity Scale for the Elderly
PI	Principal Investigator
PIL	Participant/ Patient Information Leaflet
R&D	NHS Trust R&D Department
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
SOP	Standard Operating Procedure
TFI	Tilburg Frailty Indicator

3. BACKGROUND AND RATIONALE

Prescribed exercise is a common treatment modality used by physiotherapists(1); surveys of practice confirm its use across a range of conditions(2–6) . Exercise has been documented as an effective treatment option for numerous conditions, including musculoskeletal complaints such as knee and hip osteoarthritis (7,8), back Pain (9,10), neck pain (11,12), work-related arm, neck or shoulder complaints(13), rotator cuff impingement (14), subacromial impingement syndrome (15), ankle sprains(16), hamstring injuries (17), and falls prevention(10). This is in addition to its use in conditions such as diabetes (18), heart disease (10,19), chronic obstructive pulmonary disease (COPD) (10) and chronic fatigue syndrome (10). In a number of chronic conditions its effectiveness may be comparable to drug interventions (20).

In a seminal paper on exercise adherence Slujis et al (21) found that 22% of patients were non-adherent with 41% being partially adherent. Similar figures have been demonstrated subsequently (22). Exercise adherence can affect treatment outcomes, such as pain, physical function and physical performance (23,24). Given that adherence may limit the effectiveness of prescribed exercise, it is an important consideration for those who prescribe exercise.

Adherence to prescribed exercise is an importance consideration for older people. Exercise adherence in the older population is affected by health status (25), and it is known that older people are more likely to have long term conditions or multiple long term conditions (26), for which prescribed exercise is a treatment option (10). Engagement in exercise is known to be poor in the older population following discharge from hospital (27), or discharge from physiotherapy (28). This is an important consideration, as treatment outcomes in older people are linked to compliance with interventions (29). A number of different factors have been reported to affect exercise adherence in older people, these include low self-efficacy, low motivation, depression, lack of interest, fear of falling, health status, physical ability, low expectations, socioeconomic status and exercise programme characteristics (25,27,28). It is of

importance to understand the role of personal factors and programme characteristics. However, it is also critical to establish if there is anything the clinician can do to enhance exercise adherence in older people.

The aim of exercise adherence interventions is to increase the likelihood that people will follow prescribed exercise, in this way they fulfil the definition by NICE (30) of a behaviour change intervention, '…sets of techniques, used together, which aim to change the health behaviours of individuals, communities or whole populations'. Many previous behavioural interventions have been designed utilizing what Martin Eccles calls the ISLAGIATT principle, 'it seemed like a good idea at the time' (31). A recent systematic review of exercise adherence interventions for older populations concluded that there was a need for the development of theoretically derived interventions in the area of exercise adherence for older people (32).This lack of theoretical underpinning could potentially limit the effectiveness of interventions. Therefore this project will review exercise adherence in older people piloting a brief behavioural assessment and targeted adherence approaches against usual care.

4. OBJECTIVES AND OUTCOME MEASURES

Objectives	Outcome Measures	Time points
Primary Objective To determine if a large scale RCT is feasible	Recruitment numbers, dropout rate, fidelity and acceptability	End of study
Secondary Objectives To assess participants exercise adherence, and behavioural regulation regarding exercise	Self-reported adherence Scale and exercise diary Questionnaires – Tilburg Frailty Indicator (TFI) Physical Activity Scale for the Elderly (PASE) EQ 5D 5L Self-Efficacy for Exercise Scale Exercise regulation Questionnaire (BREQ-3) Global rating of change (GROC) VAS – self rated score of capacity to exercise, confidence to exercise and motivation to exercise	6 week follow up and 12 week follow up

Tertiary Objectives To determine if the intervention is acceptable to participants	Qualitative interviews with sub-sample of participants	Post 12 week follow up prior to end of study

5. STUDY DESIGN

This study will be a two arm feasibility randomised controlled trial. Participants will be randomised between usual care or the intervention arm which will consist of a brief behavioural assessment and recommended adherence strategies based on the outcome of the assessment. A sub sample of the population will undergo a qualitative study to assess acceptability of the intervention.

6. PARTICIPANT IDENTIFICATION

6.1. Study Participants

For the main study participants will be 65 years or older who are attending physiotherapy for a musculoskeletal problem. For the qualitative sub-study and sub sample of the same population will be used in addition to physiotherapy staff that carried out the intervention.

6.2. Inclusion Criteria

- Participant is willing and able to give informed consent for participation in the study.
- Male or Female, aged 65 years or above.
- Referred to physiotherapy with a musculoskeletal problem
- Able to converse in and read English

6.3. Exclusion Criteria

The participant may not enter the study if ANY of the following apply:

- Any comorbidity that precludes exercising such as unstable angina, or acute illness
- Dementia or cognitive impairment precluding the ability to follow an exercise programme
- Patients referred to physiotherapy for post-surgery rehabilitation

7. STUDY PROCEDURES

This study will be a two arm feasibility randomised controlled trial. Participants will be randomised between usual care or the intervention arm which will consist of a brief behavioural assessment and recommended adherence strategies based on the outcome of the assessment.

This assessment will be based on the COM-B behaviour change model. This model posits that for behaviour to take place, a person needs the capacity, opportunity and motivation. On the basis of this assessment one or more of the following interventions may be suggested to the patient, 'review of exercise programme', 'review of method of delivery', 'cues', 'reminders', 'discussion of barriers and problem solving', 'motivational interviewing', 'decision balance sheets', 'behavioural contract', 'goal setting review and monitoring telephone call. These interventions and all study procedure are described below. Participants will be followed up at 6 and 12 weeks. Feasibility of recruitment, retention and acceptability of the intervention will also be assessed. A subsection of participants will also take part in a qualitative interview, this will explore participants experience of the trial intervention, in addition to the participants experience of attempting to adhere to an exercise programme. Participants will have consented to be contacted with the potential of being invited to take part in an interview study on their initial consent form. Potential participants will be contacted after they have finished their 12 week follow up appointment, if interested they will be supplied with a separate PIS designed for this sub-study. If they are happy to take part a time will be arranged for the interview to take place. Participants will be asked to give written informed consent using a separate consent form for this sub-study. In addition to a sub-sample of the study participants, a sample of physiotherapy staff who delivered the intervention will also be invited to take part in an interview. Staff will be invited to participate after all participants have finished the intervention. If interested they will be supplied with a PIS designed specifically for staff for this sub-study. If they are happy to take part a time will be arranged for the interview. They will be asked to give written informed consent using a consent form designed for this sub-study.

7.1. Recruitment

Potential participants who are referred to physiotherapy will be sent an invitation letter, participant information sheet, reply slip and a free-post envelope with their appointment letter from the physiotherapy department. If participants are interested they will be requested in the invitation letter to contact the principal investigator via telephone, email or the reply slip which they can send back with the free-post envelope. Participants who respond will be given the opportunity to ask any questions that they feel relevant. They will also have at least 24 hours from receiving the information to decide if they wish to take part.

7.2. Screening and Eligibility Assessment

The maximum duration allowed between screening and recruitment will be three months. All referrals to the Nuffield Orthopaedic Centre, Physiotherapy Department will be screened by staff that routinely receive referrals and make appointments. Any referrals which are for people over 65 years old with a musculoskeletal condition will be sent an invitation letter as outlined above.

7.3. Informed Consent

If a potential participant agrees to take part, an appointment will be made to take informal consent prior to record baseline data. Where possible this will be made just prior to the participant's physiotherapy appointment to minimise any disruption to the participant.

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; what it will involve for the participant; the implications and constraints of the protocol; the known 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 to future care, without affecting their legal rights and with no obligation to give the reason for withdrawal

The participant will be allowed time to consider the information and the opportunity to ask questions about 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. The person obtaining consent will either be the Principal Investigator or another staff member of the Physiotherapy Research Unit, all of whom are GCP trained. A copy of the signed Informed Consent will be given to the participant and one copy to the medical notes. The original signed form will be retained at the study site.

Qualitative sub-study

Participants will have consented on their original consent form to be contacted with the potential of being invited to take part in an interview study. Potential participants will be contacted after they have finished their 12 week follow up appointment, if interested they will be supplied with a separate PIS designed for this sub-study. Participants will be given time to consider participation in this sub-study, up to 1 week, in addition to the opportunity to ask questions. If participants are happy to take part a time will be arranged for the interview to take place. Participants will be asked to give written informed consent using a separate consent form for this sub-study. This sub-study will also include physiotherapy staff who delivered the intervention. Staff will be invited to participate after all participants have finished the intervention. If interested they will be supplied with a PIS designed specifically for staff for this sub-study. They will be given to time to consider participating, up to one week, in addition to the opportunity to ask questions. If they are happy to take part a time will be arranged for the interview. They will be asked to give written informed consent using a consent form designed for this sub-study.

7.4. Randomisation, blinding and code-breaking

Participants will be randomised on the basis of the physiotherapist that they are seeing. All physiotherapists involved in delivering treatment will be randomised at the start of the study to either deliver usual care or the intervention. This will take place using opaque sealed envelopes. Therefore participant will receive usual care or the intervention depending upon whose treatment list they have been placed on. The assignment of any patient to a physiotherapist is undertaken by administration staff. The investigator or other research staff are not involved in this process, and will not be able to influence treatment allocation.

7.5. Baseline Assessments

Baseline assessment will, where possible, take place immediately prior to the participant's physiotherapy appointment, in order to reduce any burden on the participant. At baseline the following data will be collected:

- **Demographics**: Age, gender, condition referred for, marriage status, ethnicity
- **Tilburg Frailty Indicator (TFI)**(33): This is a self-report measure of frailty, it consists of two sections, detriments of frailty and component of frailty, the latter being divided into physical, psychological and social components.
- **Physical Activity Scale for the Elderly (PASE)** (34): This is a physical activity self-report questionnaire that takes around 5-10 minutes to complete.
- **EQ 5D 5L** (35,36): This self-report questionnaire is a measure of health-related quality of life.
- **Self-Efficacy for Exercise Scale** (37): This self-report scale measures self-efficacy expectations to continue to exercise in the face of barriers to exercise.
- **Exercise Regulations Questionnaire (BREQ-3)** (38,39): This self-report questionnaire measures motivation for exercise, it measures forms of intrinsic and extrinsic regulation of exercise behaviour.
- **VAS self-rated capacity to exercise, confidence to exercise and motivation to exercise:** Participants will be asked to rate their perceived capacity, confidence and motivation to exercise on a scale of 0-10, where 0 is no capacity/confidence/motivation' and 10 is maximum capacity/confidence/motivation

7.6. Subsequent Visits

A six week and a twelve week follow up will take place; these follow ups will be a research visit and not a standard clinical appointment. At both the 6 and 12 week follow up appointments the following data will be collected. This appointment can be conducted at either the participant's home, or within the physiotherapy department at the Nuffield Orthopaedic Centre.

- **Self-Reported Adherence**: This is a self-report scale ranging from 0-10, where patient will be asked to rate their adherence over the previous six weeks, ranging from 0 = 'no exercises performed' to 10 = 'all exercise performed as instructed', this scale has been used in previous exercise adherence studies(42,43)
- **Exercise Adherence Rating Scale (EARS):** This is a 6 item self-report questionnaire, that asks people to record the answer to 6 question on exercise adherence, on a 5 point Likert scale (40)
- **Exercise diary**: This diary will have been completed post physiotherapy, recording the number, sets and reps of exercises that the patient has been undertaken.
- **Global rating of Change:** This is the participants' perception of their change since their initial appointment; scores include 'very much worse' 'much worse', 'a little worse', 'about the same/no difference', 'a little better', 'much better', 'very much better'
- **Physical Activity Scale for the Elderly (PASE)** (36): This is a physical activity self-report questionnaire that takes around 5-10 minutes to complete.
- **EQ 5D 5L** (37,38): This self-report questionnaire is a measure of health-related quality of life.
- **Self-Efficacy for Exercise Scale** (39): This self-report scale measures self-efficacy expectations to continue to exercise in the face of barriers to exercise.
- **Exercise Regulations Questionnaire (BREQ-3)** (40,41): This self-report questionnaire measures motivation for exercise, it measures forms of intrinsic and extrinsic regulation of exercise behaviour.
- **VAS self-rated capacity to exercise, confidence to exercise and motivation to exercise:** Participants will be asked to rate their perceived capacity, confidence and motivation to exercise

on a scale of 0-10, where 0 is no capacity/confidence/motivation' and 10 is maximum capacity/confidence/motivation

Qualitative Interviews

A subsample of the study sample will be invited to take part in an interview to determine if the intervention is acceptable to participants. This will take place after the participants have completed their 12 week follow up.

7.7. Discontinuation/Withdrawal of Participants from Study

Each participant has the right to withdraw from the study intervention at any time. The attending investigator may also request the participant is withdrawn from receiving the study intervention. Where possible the participant will continue to be followed up. The PI (or delegated individual) will record any reason for withdrawal on the study CRF and the participant will be asked if the study team may use the data collected to the point of withdrawal and/or contact them for collection of patient reported follow up data.

7.8. Definition of End of Study

The end of the study will be the date of the last qualitative interview being conducted.

8. INTERVENTIONS

For those randomised to usual care, the physiotherapy session will continue as normal, the only change being that after physiotherapy participants will be asked to complete an exercise diary. For those randomised to the intervention, prior to their physiotherapy appointment they will be given a sheet with four short questions to answer. This will be done whilst sitting in the waiting room before the physiotherapy appointment. Following this the participant will be called in and assessed as normal. As part of the treatment they will be given an exercise programme as standard within physiotherapy. Following the exercise programme the participant will be asked to answer a further seven short questions; depending on the answers to both sets of questions, and following any discussion based on the answers as required, the physiotherapist will suggest one or more adherence approaches form a list of suggestions. These are; Review of exercise programme; Review of method of delivery; Cues or prompts; Discussion of barriers and problem solving; Motivational interviewing, Decision balance sheets; Behavioural contract; Goal setting review; Monitoring telephone call; Reminders. These are described below.

- Review of exercise programme: here the exercise programme the participant has been given can be reviewed with the physiotherapist. They will be able to demonstrate and pattern the exercise to the participant. It will be encouraged that the participant practices all sets and repetitions required with the physiotherapist.
- Review of method of delivery: this involves reviewing the way in which information about the participants' exercise is given to them, for example would the participant like their exercise

programme drawn out on paper, or perhaps they want to take a video on their phone. The participant will be asked how they would prefer to receive this information.

- Cues or prompts: here it will be suggested that participants could use a cue or prompt to help them to remember to undertake their exercise programme, for example a post-it note in a location they will be in when they need to think about exercise.
- Discussion of barriers and problem solving: here the therapist will discuss any potential barriers to undertaking exercise and attempt to suggest strategies that overcome those barriers; this could for example be a suggestion to do the exercise programme before sitting down at the end of the day, when it feels much hard to get up again and do it.
- Motivational Interviewing: this is a style of counselling that attempts to review and resolve participants' ambivalence. The motivation to change comes from the participant, rather than being imposed on them.
- Decision balance sheets: here participants can complete a decision balance sheet with regard to undertaking their exercises. These sheets allow a person to record the pros and cons of undertaking a behaviour, or 'what might happen if I do the behaviour' versus 'what might happen if I don't'.
- Behavioural contract: this involves the therapist and participant signing a contract regarding the behaviour (exercise programme) to be undertaken, e.g. I will exercise daily, 2-3 sets a day for 10 repetitions of the exercises prescribed. It can also include a section on when, where and how the participant is going to do their exercise programme.
- Goal setting review: this will involve reviewing the participants' goal(s) and making sure it is clear how the exercises included in their programme relate to the goal(s),
- Monitoring telephone call: if it is felt to be useful, participant can receive a telephone call to see how things are going, and to make any suggests that might help with regard to sticking with the exercise programme.
- Reminders: if helpful, participants can be asked to set reminders, e.g. reminder on phone, or alarm to remember to undertake their exercise programme.

To avoid contamination between the treatment groups, i.e. the chance that participants in the usual care group end up receiving elements of the intervention. The importance of non-contamination in the trial will be articulated to the physiotherapists delivering treatment. Additionally the physiotherapist delivering the intervention arm will be told not to discuss the intervention with colleagues in the department delivering the control arm.

All participants in both groups will be asked to complete an exercise diary recording the number of sets and repetitions that they completed. This will form the basis of the adherence outcome at 6 and 12 weeks after the initial treatment session. The number of exercises, sets and reps will be compared against the number of exercises, sets and reps prescribed in the treatment session. A percentage score of adherence will be calculated, total number of exercises, sets and reps undertaken divided by the total number of exercises, sets and reps prescribed multiplied by 100 (Ex-undertaken/Ex-Prescribed X 100), e.g. if a participant is given 2 exercises to perform with 3 sets of 10 repetitions daily for a week, the total number of prescribed exercises would be 420 for that week (3(sets) x 10 (reps) x 2 (different exercises) x 7 (number of days)); if the participant followed all their reps, sets and exercise for 6 days out of 7 and

then did not do anything for the 7th day, they would have completed 360 exercises. Therefore they would have an adherence percentage score of 85.71% (360/420 x 100).

The only exception to the above is there is a small chance that the participant will not be given an exercise programme. Should this occur then the participant will have to be withdrawn from the study as it is obviously not possible to adhere to an exercise programme that you have not been given, therefore no outcome measure would be possible. It is not envisaged that this is likely to be a significant problem as the number of patients receiving no exercise from physiotherapy are negligible, but should this happen with any kind of regularity this information will be of use in assessing the feasibility of this project.

Qualitative study

In addition to the trial outlined above a qualitative study will also take place with a subgroup of participants (approximately n=15) and clinicians who delivered the intervention (approximately n=5). They will undergo one-one interview. The aim of the interviews will be to obtain views about the intervention and how it was delivered in addition to exploring the experience of those trying to adhere to an exercise programme.

Training

The physiotherapists delivering the interventions will undergo training before the start of the study. This training will cover

- The premise of the COM-B model
- The model's definition of capability, opportunity, and motivation
- How to use the trial paperwork to make an assessment of these three components
- The adherence approaches that can be considered on the basis of the assessment

9. SAFETY REPORTING

9.1. Definition of Serious Adverse Events

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.

9.2. Reporting Procedures for Serious Adverse Events

A serious adverse event (SAE) occurring to a participant will be reported to the REC that gave a favourable opinion of the study where in the opinion of the Chief Investigator the event was 'related' (resulted from administration of any of the research procedures) and 'unexpected' in relation to those procedures. Reports of related and unexpected SAEs should be submitted within 15 working days of the Chief Investigator becoming aware of the event, using the HRA report of serious adverse event form (see HRA website).

10. STATISTICS AND ANALYSIS

10.1. Sample size

The sample size for the feasibility randomised controlled trial will be 40 to 50 participants, allowing for up to 25 participants per group. Whitehead et al (41) suggests that pilot trials recruit 20 participants per group, or 25 participants per group, for an 80% powered main trial or a 90% powered main trial respectively, assuming a small effect size of 0.1 to 0.3

10.2. Analysis plan

This is feasibility RCT, therefore the aims relate to the feasibility of several components of the trial and whether a large scale RCT i**s** possible. The following components will be analysed in relation to feasibility.

- Recruitment – The number of recruited participants in the recruitment window will be clear, but additional information will be analysed, such as the number of participants screened to allow for the recruitment target to be met. Also the reason for non-entry into the trial will be recorded, in order to provide realistic expectations of recruitment for a future larger scale RCT.
- Randomisation – Is randomisation acceptable to participants in this study? Does randomisation create comparable groups?
- Intervention acceptability – Is the intervention acceptable to participants? Do any participants attempt to cross groups? These issues will be explored in more depth as part of the qualitative study.
- Retention of participants – Drop outs and wherever possible the reason for drop out will be recorded.
- Fidelity - The principal investigator will conduct fidelity checks, this will involve observing treatment sessions to check adherence to the protocol.

10.3. Analysis of Outcome Measures

Participant characteristics will be summarised using descriptive statistics. Participants will be analysed on an intention to treat basis according to the group they were randomised to. The outcomes will be analysed by comparing differences in mean scores. As this is a feasibility trial the main aim of the analysis is to review the aspects of feasibility given in the preceding section, and not to find statistically significant results to demonstrate effectiveness of the intervention. In the future if a larger scale RCT is undertaken, the primary outcome measure is almost certainly going to be the percentage of exercise adhered to, taken from participants exercise diaries. This outcome will be compared (mean scores) across both groups.

Qualitative Interviews

The data from the interviews will be analysed using thematic analysis, using six steps proposed by Braun and Clarke(42) transcribing the data, generating initial codes, searching for themes, reviewing themes, defining and naming themes and producing the report. Data will be transcribed from the audio recordings, whilst initial ideas are recorded. Then data will then be coded, before codes are grouped into themes. To aid in the process of data analysis NVIVO 10 (or later version) software will be used. This computer programme is designed for the analysis of qualitative data. It allows the collection, sorting and analysing of data from qualitative methods such as interviews.

11. DATA MANAGEMENT

11.1. Access to Data

Direct access will be granted to authorised representatives from the Sponsor and host institution for monitoring and/or audit of the study to ensure compliance with regulations.

11.2. Data Recording and Record Keeping

All study data (pseudonymised by study number) will be entered on to Microsoft Excel 2010 or SPSS (SPSS version 22.0 or newer) computer software using password protected files on a password protected OUH FT Trust or Oxford Brookes University computer. This database will be accessible only to members of the study team. The participants will be identifiable by participant number in the database and the code list will not leave the Physiotherapy Research Office at the Nuffield Orthopaedic Centre.

The participants' name and any other identifiable details will not be included in any study data electronic files. The code list linking the study participant number to the name of the participant will be stored separately on an encrypted file on a password protected NHS computer at the Physiotherapy Research Office in the Nuffield Orthopaedic Centre. Qualitative transcripts will use pseudo initials and all identifiable information regarding people or place will be removed from transcripts. Forms containing personal data such as the consent form or reply slip will be stored in a lockable filing cabinet in the research office and accessible to only research members involved in the study. The Physiotherapy Research office is always locked if no staff are present.

The research members will ensure that the participants' anonymity is maintained. The study will comply with the Data Protection Act which requires data to be anonymised as soon as it is practical to do so.

At the end of the study the site file will be archived in the Physiotherapy Research Unit at the Nuffield Orthopaedic Centre. The office is accessible to only research members and is locked when empty. The study master file will be stored securely in the office premises for 5 years. The study database will be archived in an encrypted folder and stored securely on NHS servers.

12. QUALITY ASSURANCE PROCEDURES

The study may be monitored, or audited in accordance with the current approved protocol, GCP, relevant regulations and standard operating procedures.

13. ETHICAL AND REGULATORY CONSIDERATIONS

13.1. Declaration of Helsinki

The Investigator will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki.

13.2. Guidelines for Good Clinical Practice

The Investigator will ensure that this study is conducted in accordance with relevant regulations and with Good Clinical Practice.

13.3. Approvals

The protocol, informed consent form, participant information sheet and any proposed advertising material will be submitted to an appropriate Research Ethics Committee (REC), and HRA for written approval.

The Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

13.4. Reporting

The CI shall submit once a year throughout the study, or on request, an Annual Progress report to the REC Committee, HRA (where required) host organisation and Sponsor. In addition, an End of Study notification and final report will be submitted to the same parties.

13.5. Participant Confidentiality

The study staff will ensure that the participants' anonymity is maintained. The participants will be identified only by a participant ID number on all study documents and any electronic database, with the exception of the CRF, where participant initials may be added. All documents will be stored securely and

only accessible by study staff and authorised personnel. The study will comply with the Data Protection Act, which requires data to be anonymised as soon as it is practical to do so.

13.6. Expenses and Benefits

Reasonable travel expenses for any visits additional to normal care will be reimbursed on production of receipts, or a mileage allowance provided as appropriate.

13.7. Other Ethical Considerations

The study does not involve participants who are not able to consent for themselves.

14. FINANCE AND INSURANCE

14.1. Funding

The project is funded by the Physiotherapy Research Unit, Nuffield Orthopaedic Centre

14.2. Insurance

NHS bodies are legally liable for the negligent acts and omissions of their employees. If you are harmed whilst taking part in a clinical research study as a result of negligence on the part of a member of the study team this liability cover would apply.

Non-negligent harm is not covered by the NHS indemnity scheme. The Oxford University Hospitals NHS Foundation Trust, therefore, cannot agree in advance to pay compensation in these circumstances.

In exceptional circumstances an ex-gratia payment may be offered.

15. PUBLICATION POLICY

The Investigators will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged.

16. REFERENCES

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17. APPENDIX A: AMENDMENT HISTORY

Amendment No.	Protocol Version No.	Date issued	Author(s) of changes	Details of Changes made