Study Title: A Backwards Walking Programme following Hip and Knee Arthroplasty: A Feasibility Pilot Study

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Sponsor:	Oxford University Hospitals NHS Foundation Trust
Funder:	Physiotherapy Research Unit, Nuffield Orthopaedic Centre
Chief Investigator Signature:	

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. KEY CONTACTS

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Sponsor	Oxford University Hospitals NHS Foundation Trust
Funder(s)	Physiotherapy Research Unit, Nuffield Orthopaedic Centre
Statistician	N/A

2. LAY SUMMARY

Backwards walking has been shown to improve balance and walking in patients who have knee Osteoarthritis. We don't know if these benefits may also be seen after surgery with patients who have had a hip or knee replacement because of Osteoarthritis. This study will look to see if it is possible to conduct a bigger study into how effective backwards walking may be after joint replacement. Patients who come to the Nuffield Orthopaedic Centre in Oxford for a hip or knee replacement will be invited. They will be placed into one of two groups at random: a group where they have a course of physiotherapy plus a backwards walking programme or a group where they have a course of physiotherapy. The physiotherapy will last for 12 weeks and those who take part will take part in two study assessments. The first will be before any treatment and patients will complete five measures and also be issued with a simple tick box diary to complete over the 12 weeks. The second assessment will be after the treatment and will involve the same 5 measures and the diaries will be collected in. Participants at this assessment will also be asked if they would like to take part in an interview for the study. This is to see what the patients thought of the study. During the study the researcher will record things like how many patients say 'yes' to the study and how many participants drop out of the treatment to understand if a bigger study could take place.

3. SYNOPSIS

Study Title	A Backwards Walking Programme following Hip and Knee Arthroplasty: A Feasibility Pilot Study		
Internal ref. no. / short title	Backwards Walking in patients following Knee and Hip Replacement		
Study registration			
Sponsor	Oxford University Hospitals NHS Foundation Trust		
Funder	N/A		
Study Design	Mixed methods feasibility pilot study		
Study Participants	Men and women who have undergone hip or knee arthroplasty		
Sample Size	40 participants/ 20 per group		
Planned Study Period	12 months total length/ individual participant involvement 3 months		
Planned Recruitment period	01/03/2020 to 01/09/2020		
	Objectives	Outcome Measures	Time point(s)
Primary	To test the procedures and processes of the trial and to estimate parameters for the main trial sample size calculation	• Berg Balance Scale • Participant recruitment figures • Participant retention figures • Number of protocol violations • BW programme diary • Qualitative interviews	Baseline and 3 months
Secondary	To examine the consistency of the effects of the backwards walking programme on falls risk, balance, strength and gait speed following hip and knee joint arthroplasty	• Four Square Step Test • 2 minute walk test • 30 second stand test • Activities-specific Balance confidence scale • Falls diary	Baseline and 3 months
Intervention(s)	A 12 week backward walking programme alongside a standard course of physiotherapy		
Comparator	Standard course of physiotherapy		

4. ABBREVIATIONS

CI	Chief Investigator
CRF	Case Report Form
CTRG	Clinical Trials & Research Governance, University of Oxford
GCP	Good Clinical Practice
GP	General Practitioner
HRA	Health Research Authority
ICF	Informed Consent Form
NHS	National Health Service
RES	Research Ethics Service
OXTREC	Oxford Tropical Research Ethics Committee
PI	Principal Investigator
PIL	Participant/ Patient Information Leaflet
R&D	NHS Trust R&D Department
REC	Research Ethics Committee
SOP	Standard Operating Procedure

5. BACKGROUND AND RATIONALE

In recent years the number of elective hip and knee joint arthroplasties has been steadily increasing with the National Joint Registry reporting 97,792 primary hip replacements and 102,944 primary knee replacements were carried out in the year 2018 alone[1]. Older patients who have undergone a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA) or Uni-compartmental Knee Arthroplasty (UKA) are known to be at an increased risk of falls. Studies have reported an incidence rate of falls of up to 40%[2] following TKA and 36% post THA[3] whereas the prevalence of falls for community dwelling older adults is 28%[4]. This increase in risk of falls for patients following joint arthroplasty is thought to be present due to the reduction in joint proprioception and a short term increase in pain alongside a reduction in muscle strength[2,5]. These factors in combination with hospital admission itself predispose those older adults who are likely to have less physical reserves than their younger counterparts to falls[6].

Falls have a multifactorial aetiology and there are several physiotherapy interventions developed to help target these contributing factors including gait re-education and strength and balance training[7]. However, the majority of conventional physiotherapy programmes currently fail to include a backwards

walking (BW) element to improve balance and decrease the risk of falls. The ability to take multi directional protective steps when exposed to forward, backward and lateral perturbations can decrease your risk of falls. However to effectively sustain balance, steps must be appropriately directed, timed, and executed to arrest the motion of the body's centre of mass by altering the base of support [8]. Without practice of BW patients following joint arthroplasty with their known reduction in strength and proprioception are less likely to be able to take a protective backwards step to prevent falls.

BW is a form of closed kinetic chain exercise which is known to be more functional, safe and effective than open kinetic chain exercises due to the reduced compressive forces at the patellofemoral joint [9]. Compared to forward walking, lower limb muscle activity during backward walking is greater due to the higher recruitment of motor units[10]. In addition, BW has been seen to increase cardio-pulmonary demand[11] helping to improve the cardiovascular fitness of patients. The absence of visual cues also increases the spatial and temporal gait parameters[12]. BW does not require any specific equipment thus is a cost effective and easy mode of rehabilitation. Additionally once it has been completed under supervision a BW programme can be continued as part of a home exercise programme. Taking into consideration all of these factors BW could form an important functional and strengthening role in the rehabilitation of patients post THA and TKA/UKA.

There have been a number of studies looking at BW for different musculoskeletal conditions. A recent literature review and meta-analysis concluded that although there was sufficient evidence to recommend a BW programme as part of a rehabilitation programme for patients with knee osteoarthritis, other conditions still required further evidence [13]. Patients following hip and knee arthroplasty differ from the populations with knee OA as they have greater strength deficits [14] and lower activity levels post operatively[15] making them more at risk of falls. To date there are no randomised controlled trials (RCT) looking at a BW programme for this population. It is therefore pertinent that we look at the effectiveness of BW post hip and knee arthroplasty in reducing the risk of falls and improving balance and physical function in a RCT. This feasibility pilot will be the first step to delivering the RCT and will test the procedures and acceptability of a BW programme for patients following THR/TKA/UKA.

6. OBJECTIVES AND OUTCOME MEASURES

Objectives	Outcome Measures	Timepoint(s) of evaluation of this outcome measure (if applicable)
Primary Objective To test the procedures and processes of the trial and to estimate parameters for the main trial sample size calculation	• Berg Balance Scale (BBS) (to calculate sample size) – Static and dynamic balance activities of varying difficulty are performed to provide a measure of falls risk and balance • Participant recruitment figures • Participant retention figures • Randomisation acceptability • Number of protocol violations from fidelity checks • BW programme diary to provide a measure of adherence • Participant safety through recording any falls and injuries whilst completing the BW programme • Qualitative interviews to determine acceptability of intervention and delivery with participants and physiotherapists	Baseline and 3 months
Secondary Objectives To examine the consistency of the effects of the backwards walking programme on falls risk, balance, strength and gait speed following hip and knee joint arthroplasty	• Four Square Step Test (FSST)- a test of dynamic balance that clinically assesses a person's ability to step over objects forward, sideways, and backwards • 2 minute walk test (2MWT)- assesses walking distance • 30 second chair rise test - assesses sit to stand ability and provides a measure of lower limb strength and dynamic balance. • Activities-specific Balance confidence scale (ABC) - self-reported measure of confidence in performing various ambulatory activities without falling • Falls diary - records the frequency of falls	Baseline and 3 months

7. STUDY DESIGN

This study is a mixed methods design. The quantitative study will be a randomised single blinded design. Up to 40 participants will be recruited from a single site at the Nuffield Orthopaedic Centre in Oxford. After recruitment baseline outcome measures will be taken. Block randomisation will then be used to balance stratification factors (hip or knee arthroplasty) into either the intervention or control group. The participant will receive their physiotherapy intervention or control at the Nuffield Orthopaedic Centre which will last up to 12 weeks. Once the first 5 participants randomised into the intervention arm have been recruited the study will be halted whilst all adverse event data is collected to ensure participants have not fallen when completing the intervention. If the study team is happy the intervention is not causing any adverse events, then the next five participants will be recruited and again the study will halt whilst their adverse event data is collected. This will continue until all 20 participants for the intervention group are recruited. Outcome measures will be repeated at 12 weeks once the treatment has ceased. This will be the final data collection point for the study.

The qualitative element of the study will involve semi structured interviews. This will take place after the participants have completed their 12 week follow up and physiotherapists have completed the intervention delivery. We will interview to a point of theoretical saturation[16], and anticipate that up to 10 participants and 5 physiotherapists will allow us to develop useful themes.

8. PARTICIPANT IDENTIFICATION

8.1. Study Participants

Patients who have undergone either hip or knee arthroplasty will be eligible for inclusion if they meet the following criteria:

8.2. Inclusion Criteria

- Men and women aged 65 or older
- Participant is willing and able to give informed consent for participation in the study.
- Participants who have received a primary unilateral hip or knee arthroplasty due to osteoarthritis

8.3. Exclusion Criteria

- Post-operative weight bearing restrictions
- Post-operative complications such as infection, a deep vein thrombosis or pulmonary embolism, or failure of the wound to heal.
- Inability to undertake a backwards walking programme due to conditions such as severe cardiovascular or pulmonary disease (New York Heart Association III-IV).
- Severe dementia or communication difficulties that would prevent completion of study assessments.
- Any neurological condition.
- Further planned treatment on the same or contralateral hip or knee within next 6 months
- Registered as visually impaired

9. PROTOCOL PROCEDURES

9.1. Recruitment

Patients who have had a hip or knee replacement at the Nuffield Orthopaedic Centre in Oxford attend a 6 week post discharge clinic appointment. These patients will be screened for eligibility by their direct care team (Nuffield Orthopaedic Centre Physiotherapists). They will be introduced to the study by either a letter in the post from their direct care team (which will be sent alongside their clinic appointment letter) with information about the study and invitation letter and reply slip, or they will be introduced to the study and given the study information by their direct care team during their routine clinical appointment. Patients will be given ample time to consider taking part in the study. If they express an interest in the study the investigator will review the study details and answer any questions they may have. They will then be screened for eligibility and those who meet the criteria will take part in the study. If they agree to take part an appointment will be made to obtain consent and record baseline data and outcome measures with a trial research clinician at the Nuffield Orthopaedic Centre. Once patients have completed their baseline assessment they will be randomised according to the procedure set out below. Those who do not wish to take part will be asked if they can provide a reason for declining so that recruitment onto the trial can be analysed. The trial research clinician will also record the number of responders to the study information. As detailed in the study design section after the first 5 participants have been recruited to the intervention arm the study will stop whilst adverse event data is collected to ensure participants are not falling during the intervention. Providing this is not the case the study will resume and continue to stop and evaluate adverse event data for every 5 participants in the intervention arm.

9.2. Screening and Eligibility Assessment

The maximum time between screening and randomisation will be 2 months. During the screening process no exceptions will be made regarding eligibility and each participant must satisfy all the approved inclusion and exclusion criteria stated in section 8.

The healthcare professional that carried out the clinic appointment will screen the participant using the criteria provided. This will involve reviewing the patients' medical notes.

9.3. Informed Consent

Informed consent will be taken by an experienced physiotherapy researcher who has completed specific training in taking consent including Good Clinical Practice Training and has experience taking consent for participating in physiotherapy research.

The participant must personally sign and date the latest approved version of the Informed Consent form before any study specific procedures are performed.

Written and verbal versions of the Participant Information and Informed Consent will be presented to the participants detailing no less than: the exact nature of the study; 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 as much time as wished to consider the information, and the opportunity to question the Investigator, their GP or other independent parties to decide whether they will participate in the study. Written Informed Consent will then be obtained by means of participant dated signature and dated signature of the person who presented and obtained the Informed Consent. A copy of the signed Informed Consent will be given to the participant. The original signed form will be retained at the study site.

9.4. Randomisation

Participants will be randomised once informed consent has been gained. A randomisation list will be generated using the web-based randomisation system Sealed Envelope[17] by an independent researcher

at the study site who is not part of the study team. Randomisation will be stratified by arthroplasty type. Permuted block randomisation will be used to ensure the strata are balanced between the groups. The independent researcher will then follow the sequence list generated to write each individual allocation in an opaque sealed envelope which will be labelled on the outside in number order from 1-20 with each stratum beside it (knee or hip arthroplasty). When a participant has completed the baseline study assessment a second independent researcher will take the opaque sealed envelope in number sequence, based on the participant's type of arthroplasty, to determine that participant's treatment allocation. This treatment allocation will then be passed onto the treating physiotherapist via a referral form and the participant will be informed of their group allocation when they attend their physiotherapy sessions. The second independent researcher will also complete a randomisation log to document each participant's allocation.

9.5. Blinding and code-breaking

The trial research clinician who is completing the study assessments will remain blinded to the participant allocation and will not be involved in any part of the randomisation procedure to ensure that they are not able to bias the group allocation. Due to the nature of the intervention it is not possible to blind the participant or treating clinician.

As participants and treating clinicians are not blinded to the treatment allocation it is not necessary to have a code-breaking procedure.

9.6. Description of study intervention(s), comparators and study procedures (clinical)

9.6.1. Description of study intervention(s)

This group will undertake a routine course of one to one out-patient physiotherapy which will include a BW programme. The BW programme will be prescribed by a physiotherapist and the participant will carry it out, along with other prescribed exercises, in their own home. Aside from the BW programme the physiotherapy treatments offered in the initial and review sessions will not be restricted but will be recorded in treatment logs. Each participant will initially be prescribed a 5 minute BW programme to be completed once a day. Participants will score the intensity of their backwards walking based on the BORG rating of perceived exertion scale. The aim will be for participants to be working at the light to somewhat hard level on the scale (11-14) (see appendix 1). The length of the BW programme and intensity will be progressed or regressed as deemed appropriate by the treating clinician with the aim for patients to achieve at least 10 minutes of BW every day of the week by the end of the programme. The

programme will be issued for completion over the course of 12 weeks and up to four review appointments will be made with the participant to monitor the BW programme and other prescribed exercises. To promote adherence a BW programme diary will be issued to participants to complete each time they carry out the programme in their own homes.

The intervention was developed in line with the MRC developing complex intervention guidelines [18]. The guidelines state a three stage process should be used to develop interventions including identifying existing evidence, identifying and developing theory and modelling process and outcomes. The initial stage of identifying evidence was conducted by reviewing a recent literature review which appraised 11 studies with a backwards walking programme for musculoskeletal conditions[13]. The studies ran over no more than 4 weeks and each session lasted between 5 to 10 minutes. From this we surmised that as these patients would have recently had joint replacement surgery they may struggle with the intensity of a 10 minute programme used in other musculoskeletal conditions. It was determined therefore that initially the sessions should start at 5 minutes and that the treating therapists should clinically reason when to progress each participant up to the maximum 10 minute BW programme. All the studies were conducted in a supervised environment with some participants returning daily to complete the BW programme under supervision. This was not deemed feasible in an NHS setting where clinical resources are limited and so along with consultation from clinical specialists it was determined that the programme should initially be prescribed by a physiotherapist and once the patient could complete this safely this should be issued for completion at home over 12 weeks. This formed the identifying and developing theory process. The final stage is modelling and outcomes which will be tested in this feasibility pilot study.

9.6.2. Description of comparator(s)

This group will undertake a routine course of one to one out-patient physiotherapy over 12 weeks. To allow comparison between the two groups the control group will also have up to four review appointments where their home exercise programme can be progressed or regressed. The physiotherapy treatments will not be restricted (apart from no BW programme) to allow for a pragmatic approach based on the treating clinician's clinical judgement, however their content will be recorded on treatment logs.

9.7. Baseline Assessments

After written informed consent is taken, the baseline assessment measurements will commence. The research clinician will take general demographic information, relevant medical history, falls history, type of arthroplasty and height and weight. They will then carry out the following physical measures:

BBS – The BBS is a validated measure of balance for patients with osteoarthritis with normative data for post hip and knee replacement available[19]. The participant is asked to complete fourteen different balance test including sit to stand, stand to sit, unsupported standing, unsupported sitting, transfers, standing with eyes closed, standing with feet together, reaching forward, picking up an object from the floor, turning to look behind, 360 degree turn, step onto stool, tandem stance and single leg stance. Each task is marked out from 0 to 4 with 4 being the best score. The test is totalled out of 56 with higher scores indicating lower falls risk.

FSST - This clinical test is a valid and reliable measure of dynamic balance in older adults[20]. The participant is timed during multi-directional stepping into four different quadrants separated by walking sticks. The participant will step forward over a stick, step to the right sideways over a stick, step backwards over a stick and step to the left sideways over a stick; the sequence will immediately be repeated in reverse. The participant will start over if he/she touches a stick with his/her foot or if it is completed in the wrong sequence. The total time taken to complete this test will be recorded.

2MWT – Provides a measure of gait speed and distance[21]. The participant will walk 20-metre laps for two minutes. The distance completed during the two minutes will be recorded to provide a measure of endurance. Assistive devices can be used but must be consistent between testing.

30s Chair rise test – This is a validated clinical measure of lower body strength and dynamic balance which is recommended as one of the best physical performance tests following joint arthroplasty by OARSI[22]. The participant is asked to sit in a straight back chair of 17" seat height without arms. From the sitting position, the participant stands up completely up so hips and knees are fully extended, then completely back down, so that the bottom fully touches the seat. This is repeated for 30 seconds and the participant should not use their hands to get up. If the participant is unable to do this they are allowed to place their hands on their knees or use their regular mobility aid to rise from the chair and this is recorded as an adapted score.

Following the collection of the physical outcome measures the participants will be asked to complete the ABC questionnaire. This provides a measure of balance confidence whilst performing certain tasks and is a 16 item self-report measure. Each question is scored out of 100 with 0 representing no confidence and 100 representing total confidence. The average of all scores is used to provide a final score and normative data is available for older adults[23].

At the end of the assessment the participant will be issued with a falls diary to complete for the 3 months whilst they are taking part in the study. For those randomised to the intervention arm a diary of adherence to the BW programme will also be issued at the initial physiotherapy appointment.

9.8. Subsequent Visits

As this is a feasibility pilot study the main aims are not to assess the effectiveness of the intervention but to trial the acceptability and feasibility of the study protocol and pilot its delivery at the Nuffield Orthopaedic Centre in Oxford. For this reason the main assessments for the study relate to recruitment, retention and acceptability. The research clinician will therefore collect data throughout the trial on the number of patients screened, the number that consented, the reason for not consenting, the number of drop outs, the availability of the outcome measure data and the standard deviation of the BBS in order to estimate the sample size. The acceptability of the intervention will be measured through collection of the BW programme diary which will provide a measure of adherence. Participants will also be invited to take part in an interview to determine the study acceptability.

Fidelity checks

Fidelity checks will be made by a member of the study team who is not blinded to treatment allocation to ensure adherence to the study protocol from the recruiting and treating clinicians. These will take place mid-way through study recruitment once approximately 20 participants have been randomised.

12 week follow up

Participants will be followed up at 12 weeks for the final assessment. Participants will be asked to return to the physiotherapy clinic or where possible this appointment will tie in with their final physiotherapy appointment at 12 weeks. The outcome measure assessments will be the same as at baseline and the research clinician will ensure they collect in the falls diary and if applicable BW programme diary.

Qualitative interviews

Patients taking part in the study, and treating clinicians, will be invited to take part at the in a semi-structured interview to determine if the study procedures and trial design were acceptable to participants. This will take place after the participants have completed their 12 week follow up and physiotherapists have completed the intervention delivery.

9.9. Sample Handling

No samples will be taken.

9.10. Early Discontinuation/Withdrawal of Participants

Each participant has the right to withdraw from the study at any time. In addition, the Chief Investigator (CI) may discontinue a participant from the study interventions at any time if the investigator considers it necessary for any reason including:

- Ineligibility (either arising during the study or retrospectively having been overlooked at screening)
- A significant protocol deviation
- A significant non-compliance with treatment regimen or study requirements
- An adverse event which requires discontinuation of the study intervention or results in inability to continue to comply with trial procedures

It will be the sole responsibility of the CI to determine whether investigator-led discontinuation occurs or not.

The treating clinician may withdraw a participant from the study if they feel it would not be clinically appropriate for them to continue.

If the participant has withdrawn from study treatment then they will be encouraged to continue with the follow-up.

Participants who wish to withdraw consent for the study or whose participation from the trial is discontinued will have de-identifiable data collected up to the point of that withdrawal of consent, included in the analyses, unless the participant specifically asks for all data collected to be destroyed. The participant will not contribute further data to the trial and the withdrawal CRF will be completed which documents the level of withdrawal. The reason for withdrawal will also be recorded. Participants who withdraw once they have been randomised will not be replaced.

9.11. Definition of End of Study

The end of study is the point at which all the study data has been entered and queries resolved.

10. SAFETY REPORTING

The safety reporting window will start from the time of consent to the point that the participant completes the study. The investigator will follow up SAEs until event resolution or stabilisation for related events only.

10.1. 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 a serious adverse event when, based upon appropriate medical judgement, the event may jeopardise the participant and may require medical or surgical intervention to prevent one of the outcomes listed above.

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.

10.2. Reporting Procedures for Serious Adverse Events

A serious adverse event (SAE) occurring to a participant should 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).

11. STATISTICS AND ANALYSIS

11.1. Statistical Analysis Plan (SAP)

The plan for the statistical analysis of the study is outlined below. There is not a separate SAP document in use for the trial.

11.2. Description of the Statistical Methods

This is a feasibility pilot RCT, therefore the aim of this study is not to provide a measure of efficacy but to determine whether it is possible to run a large scale RCT. Participant demographics will be summarised using standard descriptive statistics. The following components will also be analysed:

- The mean and SD of the primary outcome measure the BBS will be analysed to provide a sample size calculation for a larger RCT
- Recruitment – The number of recruited participants in the recruitment window, the number of participants screened to allow for the recruitment target to be met and the reason for non-entry into the trial which will 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 fail to complete the intervention? Adherence to the prescribed BW programme will be measure through a collection of a diary. These issues will also 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 - Fidelity checks will be conducted, this will involve observing treatment sessions to check adherence to the protocol.

Qualitative interviews:

The data from the interviews will be analysed using thematic analysis, using six steps proposed by Braun and Clarke 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 the process of data analysis NVIVO 10 (or later version) software will be used, this computer programme is design for the analysis of qualitative data. It allows the collection, sorting and analysing of data from qualitative methods such as interviews.

11.3. Sample Size Determination

The sample size for the feasibility randomised controlled trial will be 40 participants, allowing for 20 participants per group. Whitehead et al[24] suggests that feasibility trials recruit 20 participants per group for an 80% powered main trial, assuming a small effect size of 0.1 to 0.3.

12. DATA MANAGEMENT

The plan for data management is outlined below. There is not a separate Data Management document in use for the study.

12.1. Source Data

Source documents are where data are first recorded, and from which participants' CRF data are obtained. These include, but are not limited to, hospital records (from which medical history and previous and concurrent medication may be summarised into the CRF), clinical and office charts, laboratory and pharmacy records, diaries, microfiches, radiographs, and correspondence.

CRF entries will be considered source data if the CRF is the site of the original recording (e.g. there is no other written or electronic record of data). All documents will be stored safely in confidential conditions. On all study-specific documents, other than the signed consent, the participant will be referred to by the study participant number/code, not by name.

12.2. 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.

12.3. Data Recording and Record Keeping

All trial data will be entered onto paper CRFs, then entered onto Microsoft Excel 2010 or newer or SPSS computer software (SPSS version 26.0 or newer) using password protected files on password protected OUH FT computers. Any study documents and data, such as the signed consent form will be stored in a lockable secure room in the Physiotherapy Research Unit at the Nuffield Orthopaedic Centre. The participants will be identified by a unique study specific participant number in any database. The name and any other identifying detail will NOT be included in any trial data electronic file. Qualitative transcripts will use pseudo initials and all identifiable information regarding people or place will be removed from transcripts. Personal data will be kept for 1 year after the study has finished and the study data will be stored on the OUH FT server for 5 years.

For participants who agree in their Informed Consent to be contacted for future research, the consent form will be retained as the basis for retention of details and future approach. Those contact details will be held securely, separately from the research data, and kept updated. They will be held for an indeterminate period of time.

13. QUALITY ASSURANCE PROCEDURES

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

13.1. Risk assessment

There will be no formal risk assessment plan due to the nature of this small, low risk feasibility pilot study.

13.2. Study monitoring

Not applicable

13.3. Study Committees

There will be no oversight committees since this study is small, logistically simple and low risk.

14. PROTOCOL DEVIATIONS

A study related deviation is a departure from the ethically approved study protocol or other study document or process (e.g. consent process or administration of study intervention) or from Good Clinical Practice (GCP) or any applicable regulatory requirements. Any deviations from the protocol will be documented in a protocol deviation form and filed in the study master file.

15. SERIOUS BREACHES

A "serious breach" is a breach of the protocol or of the conditions or principles of Good Clinical Practice which is likely to affect to a significant degree –

(a) the safety or physical or mental integrity of the trial subjects; or

(b) the scientific value of the research.

In the event that a serious breach is suspected the Sponsor must be contacted within 1 working day. In collaboration with the C.I., the serious breach will be reviewed by the Sponsor and, if appropriate, the Sponsor will report it to the approving REC committee and the relevant NHS host organisation within seven calendar days.

16. ETHICAL AND REGULATORY CONSIDERATIONS

16.1. Declaration of Helsinki

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

16.2. Guidelines for Good Clinical Practice

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

16.3. Approvals

Following Sponsor approval the protocol, informed consent form, participant information sheet will be submitted to an appropriate Research Ethics Committee (REC), and HRA (where required) and host institutions 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.

16.4. Other Ethical Considerations

This study does not involve vulnerable participants or participants who are unable to consent for themselves.

16.5. 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, Sponsor and funder (where required). In addition, an End of Study notification and final report will be submitted to the same parties.

16.6. Participant Confidentiality

The study will comply with the General Data Protection Regulation (GDPR) and Data Protection Act 2018, which require data to be de-identified as soon as it is practical to do so. The processing of the personal data of participants will be minimised by making use of a unique participant study number only on all study documents and any electronic database(s), 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 staff will safeguard the privacy of participants' personal data.

16.7. 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.

17. FINANCE AND INSURANCE

17.1. Funding

The project is funded by the Physiotherapy Research Unit, Nuffield Orthopaedic Centre. The Clinical Investigator is in receipt of a preparatory fellowship to cover their salary whilst conducting the study from the NIHR Biomedical Research Centre, based at Oxford University Hospitals Trust, Oxford.

17.2. 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.

17.3. Contractual arrangements

Appropriate contractual arrangements will be put in place with all third parties.

18. PUBLICATION POLICY

The Investigators will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authors will acknowledge that the study was supported by NIHR Biomedical Research Centre, based at Oxford University Hospitals Trust, Oxford. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged.

19. DEVELOPMENT OF A NEW PRODUCT/ PROCESS OR THE GENERATION OF INTELLECTUAL PROPERTY

Not applicable

20. ARCHIVING

Identifiable information will be kept for 1 year after the completion of the study. De-identified research data and research documents, and any research documents with personal information, such as consent forms, will be securely archived within the OUHFT for 5 years.

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22. Appendix 1

Scale Instructions

While exercising we want you to rate your perception of exertion, i.e., how heavy and strenuous the exercise feels to you. The perception of exertion depends mainly on the strain and fatigue in your muscles and on your feeling of breathlessness or aches in the chest.

Look at this rating scale; we want you to use this scale from 6 to 20, where 6 means "no exertion at all" and 20 means "maximal exertion."

6	No exertion at all
7	
8	Extremely light
9	Very light
10	
11	Light
12	
13	Somewhat hard
14	
15	Hard (heavy)
16	
17	Very hard
18	
19	Extremely hard
20	Maximal exertion

Borg RPE scale
© Gunnar Borg, 1970, 1985, 1994, 1998

Figure 7.1 The Borg RPE scale for perceived exertion.

9 corresponds to "very light" exercise. For a normal, healthy person it is like walking slowly at his or her own pace for some minutes.

13 on the scale is "somewhat hard" exercise, but it still feels OK to continue.

17 "very hard" is very strenuous. A healthy person can still go on, but he or she really has to push him- or herself. It feels very heavy, and the person is very tired.

19 on the scale is an extremely strenuous exercise level. For most people this is the most strenuous exercise they have ever experienced.

Try to appraise your feeling of exertion as honestly as possible, without thinking about what the actual physical load is. Don't underestimate it, but don't overestimate it either. It's your own feeling of effort and exertion that's important, not how it compares to other people's. What other people think is not important either. Look at the scale and the expressions and then give a number.

Any questions?