Short title:
STRIDE: Acceptability study

Full title:
STructured Rehabilitation and InDividulaised Exercise and education (STRIDE): A single arm acceptability study of a rehabilitation programme to improve post-operative walking in people with neurogenic claudication

Sponsor:	King's College Hospital NHS Foundation Trust (KCH) & King's College London
Funder (s):	Dunhill Medical Trust
IRAS Reference	333622
ISRCTN / Clinicaltrials.gov no:	TBC

Protocol Version and Date **v1.0 01/09/2023**

KEY ROLES AND RESPONSIBILITIES

SPONSOR: The sponsor is responsible for ensuring before a study begins that arrangements are in place for the research team to access resources and support to deliver the research as proposed and allocate responsibilities for the management, monitoring and reporting of the research. The Sponsor also has to be satisfied there is agreement on appropriate arrangements to record, report and review significant developments as the research proceeds, and approve any modifications to the design.

FUNDER: The funder is the entity that will provide the funds (financial support) for the conduction of the study. Funders are expected to provide assistance to any enquiry, audit or investigation related to the funded work.

CHIEF INVESTIGATOR (CI): The person who takes overall responsibility for the design, conduct and reporting of a study. If the study involves researchers at more than once site, the CI takes on the primary responsibility whether or not he/she is an investigator at any particular site.

The CI role is to complete and to ensure that all relevant regulatory approvals are in place before the study begins. Ensure arrangements are in place for good study conduct, robust monitoring and reporting, including prompt reporting of incidents, this includes putting in place adequate training for study staff to conduct the study as per the protocol and relevant standards.

The Chief Investigator is responsible for submission of annual reports as required. The Chief Investigator will notify the R&I Office of the end of the study, including the reasons for the premature termination. Within one year after the end of study, the Chief Investigator will submit a final report with the results, including any publications/abstracts to the REC.

PRINCIPAL INVESTIGATOR (PI): Individually or as leader of the researchers at a site; ensuring that the study is conducted as per the approved study protocol, and report/notify the relevant parties – this includes the CI of any breaches or incidents related to the study.

OTHER:

Academic Supervisors:

Dr Sam Norton Reader in Research Methods & Statistics Health Psychology, 5th Floor Bermondsey Wing Guy's Hospital, Pond Lane London SE1 9RT sam.norton@kcl.ac.uk 020 7188 0198	**Prof. Lindsay Bearne** Professor of Physiotherapy and Rehabilitation Population Health Research Institute St George's, University of London 1st floor Jenner Wing, Cranmer Terrace, London SW17 0RE lbearne@sgul.ac.uk 020 8725 0135 (ext 50135)	**John Weinman** Professor of Psychology as applied to Medicines School of Cancer & Pharmaceutical Sciences King's College London Guy's Hospital, Pond Lane London SE1 9RT john.weinman@kcl.ac.uk

DECLARATIONS

The undersigned confirm that the following protocol has been agreed and accepted and that the investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the UK Policy framework for health and social care research, the Trust Data & Information Governance policy, Sponsor and other relevant SOPs and applicable Trust policies and legal frameworks.

I (investigator) agree to ensure that the confidential information contained in this document will not be used for any other purposes other than the evaluation or conduct of this research without the prior written consent of the Sponsor.

I (investigator) also confirm that an honest accurate and transparent account of the study will be given; and that any deviations from the study as planned in this protocol will be explained and reported accordingly.

Chief Investigator:

Signature:..... **.....** **Date.01/09/2023**

Print Name(in full):.....Suzanne McIlroy

Position:....Consultant Physiotherapist.....

CONTENTS

KEY WORDS

Rehabilitation, Walking, Lumbar Spinal Stenosis, Neurogenic claudication, Behaviour change

LIST OF ABBREVIATIONS

AE	Adverse Event

CI	Chief Investigator
CRF	Case Report Form
HRA	Health Research Authority
PI	Principal Investigator
REC	Research Ethics committee
SAE	Serious Adverse Events

Trial personnel

Chief Investigator	Suzanne McIlroy e-mail: Suzanne.McIlroy@nhs.net tel: 02032998220
Lead Sponsor	King's College Hospital The R&I Office, King's College Hospital NHSFT 161 Denmark Hill, London, SE5 9RS
Co-sponsor	Professor Bashir Al-Hashimi Vice President (Research and Innovation) King's College London Room 8.11, 8th Floor Melbourne House 44-46 Aldwych London WC2B 4LL Tel: 02078487306 Email vpri@kcl.ac.uk
Statistician (if applicable)	Dr Sam Norton e-mail: Sam.Norton@kcl.ac.uk tel: 02071880198

STUDY SUMMARY

STUDY OVERVIEW	
Full title	STructured Rehabilitation and InDividulaised Exercise and education (STRIDE): A single arm acceptability study of a rehabilitation programme to improve post-operative walking in older people with neurogenic claudication
Objectives	1. To explore the acceptability of the STRIDE intervention 2. To evaluate adherence and engagement to the STRIDE intervention 3. To evaluate study recruitment and retention of participants

Type of trial	Multi methods acceptability study
Trial design and methods	Up to 15 adults waiting for surgery for neurogenic claudication will be recruited. They will be asked to complete three assessments, that will consist of measures of walking capacity (six-minute walk test) and performance (mean daily step count measured with a thigh worn accelerometer for 7 days), lower limb performance, and self-rated questionnaires. They will also be asked to complete a questionnaire to assess acceptability of the STRIDE. A focus group to explore their experiences and suggestions for refinement of STRIDE and the research processes will be conducted. A topic guide will be developed a priori and will be informed by the Theoretical Framework of Acceptability.
Health condition(s) or problem(s) studied	Patients waiting for surgery to treat neurogenic claudication
Target sample size	Up to 15
Trial duration per participant:	6 months
Main inclusion/exclusion criteria:	Inclusion Criteria: 1. ≥50 years old 2. Symptoms of neurogenic claudication 3. Radiographic evidence of degenerative lumbar spinal stenosis 4. On the waiting list for elective lumbar decompressive surgery (+/- fixation) in >10 weeks time, to treat lumbar spinal stenosis 5. Conversational English or willing to use an interpreter Exclusion Criteria: 1. Lumbar spinal stenosis caused by tumour or fracture. 2. People who report other conditions as the primary reason that inhibits their walking 3. Unwilling or unable to give informed consent 4. >2 level instrumentation
Statistical methodology and analysis:	Quantitative data: Descriptive statistics will summarise the characteristics of participants. The number of patients referred, approached and consented to participate, fidelity to the intervention (number of appointments attended, completion of planned exercise prescription and walking goals recorded in diary, and proportion of patients that completed the study will be collected and summarised. In keeping with the study design, clinical outcome data will be summarised descriptively, and effect sizes calculated. Qualitative data will be analysed using thematic content analysis.

STUDY TIMELINES	
Study Duration/length	12 months
Expected Start Date	November 2024
End of Study definition and anticipated date	Last data collection with last participant and participant focus group has been conducted
Key Study milestones	study submission: 15/9/23 Finalisation of budget already completed first patient recruitment: xxs
STORAGE of SAMPLES (if applicable)	
Human tissue samples	Not applicable
Data collected / Storage	

1 INTRODUCTION

Neurogenic claudication (NC) affects 1:10 older people and reduces walking and quality of life. It is the main indication for spinal surgery in older people yet following surgery, up to 40% report walking disability and 90% do not achieve physical activity recommendations. Changing behaviour is challenging without appropriate guidance and support. Rehabilitation could improve walking but current provision is inconsistent and ineffective. We have recently developed STRIDE: **ST**ructured **R**ehabilitation and **I**n**D**ividulaised **E**xercise and education, a rehabilitation programme aimed at increasing patients walking before and after surgery. Prior to undertaking a future trial we need to understand how acceptable the intervention is to patients and understand how it can be optimised for delivery in clinical practice.

2 BACKGROUND AND RATIONALE

Neurogenic claudication caused by lumbar spinal stenosis occurs in 10% of older people [1]. This degenerative condition causes compression of the nerves and blood vessels within the lumbar spine and pain, numbness and/or weakness in the legs[2]. It has wide ranging consequences on an

individual including reduced walking, physical activity[2, 3] and quality of life[4-6], increased dependence[5] and social isolation[4].

Surgery is recommended for people who have had ineffective response to conservative management (analgesics, physiotherapy) to improve pain and walking [7, 8]. Lumbar spinal stenosis is the most common reason for spinal surgery in older people[9] and 23% of people undergo further surgery[10]. Consequently, there is a large personal and healthcare cost [9, 11] and this burden is expected to increase with the ageing population.

Whilst surgery decompresses the spinal nerves and blood vessels the correlation between spinal canal size and walking ability is poor[12]. Following surgery, approximately 40% of people with LSS report ongoing pain and walking disability and 90% do not meet evidence-based physical activity recommendations[13]. Thus, people are at risk of the negative consequences associated with low levels of physical activity such as cardiovascular disease, falls and cognitive decline[14]. The reasons for persistent walking disability are multi-factorial and include biopsychosocial and behavioural factors. If these modifiable factors are identified and targeted in a rehabilitation programme outcomes, such as walking, may be improved.

We have completed a series of three studies to identify the salient factors associated with walking improvement after surgery for NC. A systematic review (35 studies, n=10,078 participants, manuscript in preparation) of pre-operative prognostic factors for walking ability after surgery for NC identified there was moderate evidence that greater pre-operative walking ability predicts better post-operative walking and that spondylolisthesis (vertebral slip) is not associated with walking ability post-operatively but there was weak or inconclusive evidence that other factors were associated with post-operative walking[15].

A prospective longitudinal study (n=134) assessed walking capacity and performance pre and post-surgery for NC and a comprehensive battery of biopsychosocial variables were collected pre- and 6 and 12 weeks post-operatively. The findings demonstrated pre-operative walking capacity and performance explained a large proportion of the change in walking improvement. A number of biopsychosocial variables were associated with pre-operative walking (history and fear of falls, fear of movement, illness perceptions, self-regulation of exercise, lower limb function) but not change in post-operative walking. In addition, patients with fear of falling or movement post-operatively at 6-weeks post-operative demonstrated less improvement in walking at 12-weeks post-operative. The results indicated that pre-operative rehabilitation targeting walking, balance and psychosocial factors may be required to optimise surgical outcomes with additional support for people demonstrating fear of falling or movement post-operatively[16].

The third study completed interviews with 16 people (>3 months after surgery for NC) to explore their experience of recovery and post-operative walking and their preferences for post-operative rehabilitation. All participants reported that their experience of surgery and their recovery was a major event for them. They all expressed a degree of satisfaction and gratitude for their surgery however, the extent of this varied considerably. Three themes were developed that described the experience of walking recovery and rehabilitation. The first theme 'making sense of recovery and walking rehabilitation using a biomedical model' identified that patient's perception of NC and recovery was shaped using a biomedical model rather than holistic approach. The second theme 'the mismatch between expectation and recovery' had two subthemes: 'the unanticipated burden of the recovery journey' illustrated the long and effortful period of recovery; 'expectations of outcome' explored expectations of life after surgery and considered how these aligned with treatment outcomes. The third theme 'one size doesn't fit all: the need for tailored rehabilitation' illustrated how participants navigated the complex requirements of walking rehabilitation and largely had to

assume responsibility for their own rehabilitation. Many participants were dissatisfied with the lack of tailored care following discharge from hospital. Participants preferred in-person, tailored, supervised rehabilitation that commenced 2-6 weeks post-surgery[17].

Subsequently we co-designed STRIDE: STructured Rehabilitation and Individualised Exercise and education, a patient-centred, complex rehabilitation programme. This used the findings from the previous studies and was informed by the intervention development approaches of Experience-based co-design [18] and the Behaviour Change Wheel [19] and aligns with the Medical Research Council recommendations [20] to consider context, stakeholders perspectives and for the incorporation of theoretical and empirical evidence when designing complex interventions to change behaviours, such as walking. Ten people who had undergone surgery for NC, 3 family members and 20 clinicians (physiotherapists = 12; physiotherapy assistant =2; nurse =2; spine surgeon = 3; health psychologist =1) participated in a series of 4 workshops and small group meetings. Using interactive exercises the group identified priorities for the rehabilitation programme, explored intervention options, content and modes of delivery. The acceptability, practicality, effectiveness, affordability, safety and equity (APEASE criteria [19]) of the intervention options and prototypes were considered before consensus was sought on the final design.

STRIDE is a physiotherapy led, behaviour change programme that aims to provide wraparound (i.e. delivered before and after surgery) rehabilitation for people undergoing surgery for NC. It consists of a pre-operative phase and a post-operative phase. Both phases have three core individual sessions, delivered over a 12-week period. In additional there are up to 3 optional sessions available for people who may require additional support (figure 1). The sessions will incorporate behaviour change techniques, be delivered by a physiotherapist using a motivational interviewing approach to encourage self-management and engagement and adherence to a personalised exercise and walking programme. Two of the sessions will be delivered face to face within the physiotherapy clinic, the remaining sessions may be delivered face to face, or via telephone or video calls depending upon patient preference. All patients will be provided with a pedometer and a personalised workbook which will include information about their condition, their surgery, their exercise programme and a diary to record their walking and exercises. In addition, participants will receive access to educational videos.

Acceptability is a necessary condition for effectiveness of an intervention[21], without it patients are less likely to adhere to treatment recommendations. Therefore before testing the efficacy of the new rehabilitation programme in a randomised controlled trial the acceptability of the developed rehabilitation programme and research processes needs to be assessed[22]. Specifically, we need to understand if STRIDE is acceptable to patients and explore how it can be refined and optimised for clinical delivery.

3 OBJECTIVES

To assess the acceptability undertaking the STRIDE rehabilitation programme in older people receiving surgery for neurogenic claudication. In particular the objectives are to

1) Explore the perceived acceptability of the STRIDE rehabilitation programme
2) Estimate adherence and engagement with the STRIDE rehabilitation programme
3) Estimate the willingness of eligible patients to participate in the study and feasibility of recruiting for a future larger study

4 STUDY DESIGN

Study Design: Multiple methods acceptability study consisting of:

1. Single arm acceptability study
2. Qualitative focus group

- **Setting:** Single site; participants will be recruited from King's College Hospital NHS Foundation Trust, a tertiary centre for spinal surgical services.

Study Population for Walk Study: Adults ≥50 years old with lumbar spinal stenosis and symptoms of neurogenic claudication, listed for surgery, who meet the eligibility criteria will be invited to participate in the study.

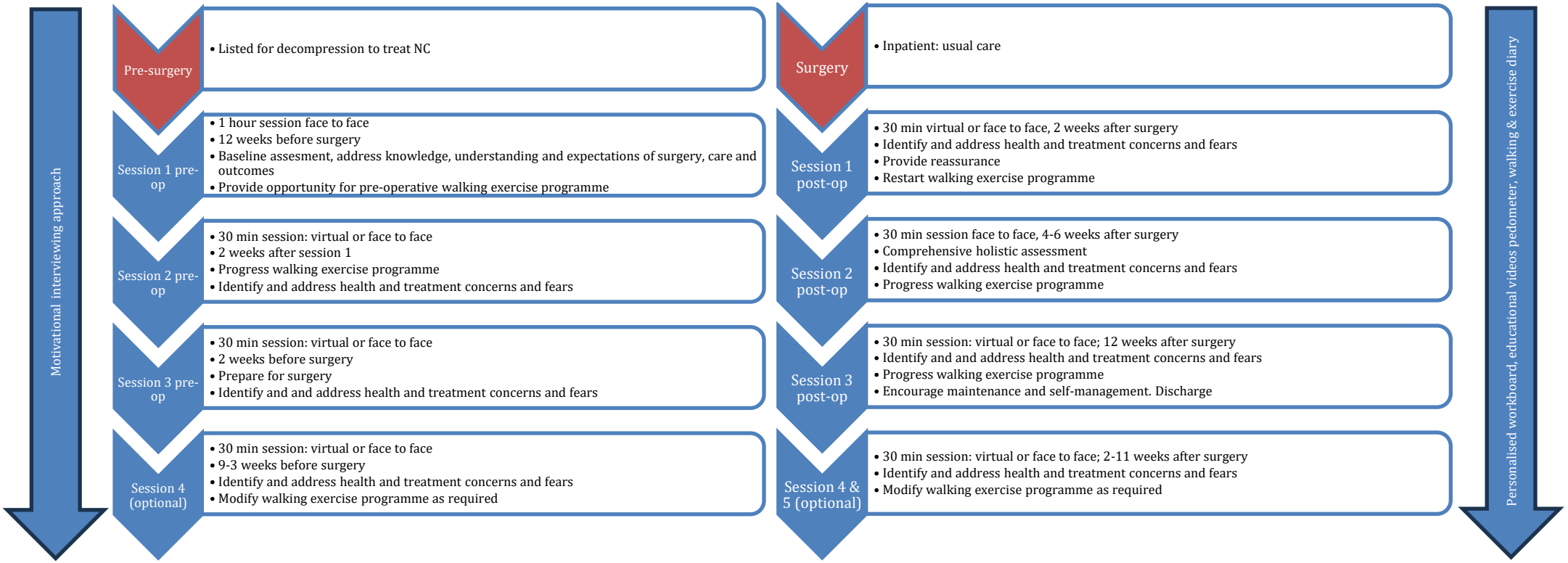
Method:

Participants will be asked to complete three assessments: at baseline before STRIDE, before surgery and (after completing the pre-operative phase of STRIDE) and 12-weeks after surgery after completing STRIDE (figure 2). The assessment will consist of measures of walking capacity (six-minute walk test) and performance (mean daily step count measured with a thigh worn accelerometer for 7 days), lower limb performance and balance tests, and self-rated questionnaires. Measures are detailed on table 1. The objective assessments will take approximately 30 min to complete and will be conducted in person. The accelerometers will be returned by post using a stamped addressed envelope. The self-reported measures will be completed either at home or in person, electronically or on paper (and may be returned by post using a stamped addressed envelope), dependent upon patient preference.

After completing the STRIDE rehabilitation programme, to assess the acceptability of the rehabilitation programme a questionnaire informed by the constructs of Theoretical Framework of Acceptability[21] will be provided to all participants that are recruited to the study (appendix). In addition, after each rehabilitation session, participants will be invited to provide feedback on the perceived effectiveness of the session by completing a very brief questionnaire feedback measure informed by a single item of the Theoretical Framework of Acceptability.

A qualitative focus group study (up to 8 participants) will be conducted to explore participants' experiences and suggestions for refinement of STRIDE and the research processes. A semi-structured topic guide (appendix) developed a priori will cover key questions of the experiences of the participants, what they liked about the programme, what changes they recommend, what stopped them from completing the programme etc. The topic guide will be refined iteratively as new areas of interest arise. The focus groups will allow participants to share, build on and discuss each other's experiences and views of the programme and the research process. Focus group data will be transcribed verbatim, anonymised and analysed thematically[23].

Consent:
Consent will be obtained and assessments completed either by the Chief Investigator or a member of the participants direct care team. Any members of the direct care team involved in the research will be trained by the CI and their roles will be recorded in the Site Signature and delegation log.



4.1 Figure 1: STRIDE programme

4.2 Table 1 Measures for feasibility study

Table 1: Measures for acceptability study				
Measures	Description	Data Collection Schedule		
		Baseline, prior to STRIDE	After completion of pre-operative phase of STRIDE	After post-operative phase/ completion of STRIDE
Sociodemographic and clinical data:	Age (years), body mass index (kg/m^2), sex, ethnicity, education, employment, social support, social deprivation, co-morbidities, anxiety and depression, smoking history, number and type of medications used in the last week, falls history, and reasons for surgery.	●		
Objective walking capacity	6 minute walking distance will be assessed by the six-minute walk test[24]. Participants will be asked to walk as far as possible around two cones, placed 10m apart in a straight corridor, in 6 minutes. The total distance walked (in metres) in 6 minutes will be recorded. The six-minute walk test is reliable and responsive to change in older people with long term conditions[25].	●	●	●
Objective walking performance	Walking performance will be measured using a tri-axial accelerometer (ActivPal 3). Participants will be requested to wear the small device on their thigh continuously or during waking hours for seven continuous days[26]. Walking performance (daily step count), walking intensity and periods of activity are recorded. Accelerometers will be returned (by post), data downloaded and analysed to see if participants wore the device for ≥14 hours per day for ≥5 days. The use of continuous activity monitoring devices has been found to be acceptable by older people with LSS [3, 13].	●	●	●
Objective lower extremity function[1]	Reliable and valid measures of lower limb function will include: 5 times chair stand test incorporates assessment of lower limb strength and transitional movements in older adults. It is based on the amount of time a person rakes to move from a sitting position, to standing, back to a sitting position 5 times without using their hands.[27, 28] 4-stage balance test will be used to assess static balance and a participant's risk of falling. It is based on the persons ability to hold four progressively more challenging positions.[29]	●	●	●
Fear of falling[6]	The Short Falls Efficacy Scale International[30] will be used to measure fear of falling. Participants rate their confidence in performing 7 activities of daily living on a four-point scale. Individual scores are summed and a higher score indicates greater fear of falling.	●	●	●

Pain	Pain intensity will be measured using a Numerical rating scale (0-10). Numerical rating scales are recommended for use to measure pain in older people[31].	●	●	●
Back related disability	Oswestry Disability Index will be used to back related disability. Participants rate their pain and functional ability on 10 domains. It has been shown to be valid and reliable and responsive to change. [32, 33]	●	●	●
Illness perceptions[2,5]	The Brief Illness Perceptions Questionnaire (B-IPQ) is reliable and valid, nine-item scale designed to rapidly assess the cognitive and emotional representations of illness. It consists of nine constructs: beliefs about consequences, timeline, personal control, treatment control, identity, coherence, emotional representation, illness concern and cause [34].	●	●	●
Fear of moving[6]	The Valid and reliable Tampa Scale of Kinesiophobia will be used to assess fear of movement [35, 36]. It is 17-item checklist using a four-park Likert Scale	●	●	●
Expectations[5]	A modified version of the "expectations scale" of the North American Spine Society (NASS) Lumbar Spine Questionnaire will assess what changes participants expect to experience as a result of the operation for 8 items (leg pain, back pain, walking capacity, independence is everyday activities, sporting activities, general physical capacity, frequency and quality of social contacts and mental wellbeing) rated on a 5-point Likert scale. Additionally, it asks what the single most important change occurring as a result of the operation would make them say that the operation helped, or was a success. Parallel questions are asked to assess fulfilment of expectations at the STRIDE rehabilitation programme, the results of which will be analysed descriptively.[37]	●	●	●
Impression of change	The second item from the Patient Global Impression of change will be used to assess the participant's perception of the amount of change they have had since starting their rehabilitation and after their surgery on a scale from -5: much worse to +5: much better[38]		●	●
Acceptability	A questionnaire informed by the constructs of Theoretical Framework of Acceptability[21] will be provided to all participants that are recruited to the study.	●	●	●
Key: COM-B domains: 1- physical capability; 2- psychological capability; 3- social opportunity; 4-physical opportunity; 5-reflective motivation; 6-automatic motivation				

Sample Size:

This is an acceptability study therefore a formal power calculation is not appropriate.
A target sample size of up to 15 participants accommodates the available timeframe for recruitment and is aligned to recommendations to achieve the study objectives [39, 40].

5 STUDY SCHEDULE

Figure 5.1 illustrates the study schedule.

Potential participants will be identified and screened for eligibility by the direct care team either in clinic or by screening the surgical waiting lists. Potential participants will be invited to find out more about the study either in clinic or via telephone and be provided with a patient information sheet. Potential participants will be asked for verbal consent to be contacted by a researcher.

We will offer potential at least 24hours to consider whether they wish to participate before we invite the participant to provide consent. Given the low risk of the study, the limited mobility, age and comorbidities of some of the potential participants, patients can consent on the day they are informed of the trial, or if they prefer, they can take the participant information sheet home and decide whether to join or not at a later date. It is envisaged that all participants will have >24 hours to consider whether they wish to take part.

After verbally indicating they would like to participate, participants will be made an appointment to complete the baseline assessment and initial STRIDE session. Participants will be sent the consent form and baseline questionnaires either electronically or via post (patient preference) and requested to complete and return them either prior to or at the initial appointment. Following consent being obtained the baseline objective measures will be assessed. The initial STRIDE appointment will occur >1 week following baseline assessment to allow for sufficient accelerometery data collection.

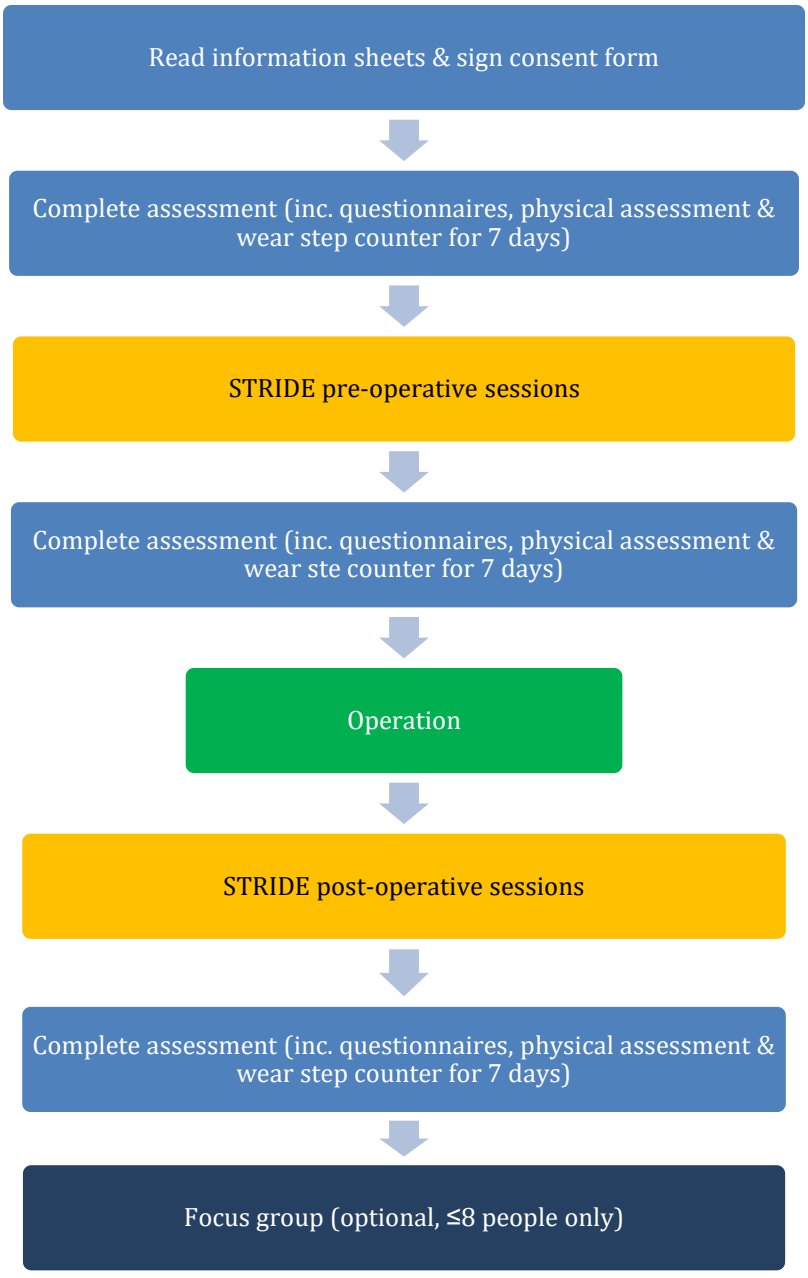
Following the pre-operative phase of STRIDE before surgery, and 12 weeks post-operative, after their final STRIDE appointment, the participants will be invited to the hospital for objective, physical assessment.

Self-rated questionnaires will be sent to participants at baseline, end of pre-operative phase, and 12 weeks following surgery (after final STRIDE session). These will be sent electronically or via post (patient preference) and returned electronically or by post.

After each STRIDE session (or after ceasing to attend STRIDE rehabilitation sessions) participants will be invited to complete a questionnaire assessing the acceptability of STRIDE and the research processes. The questionnaire, informed by the Theoretical Framework of Acceptability, will enquire about the perceived effectiveness of the session – matched to the learning objectives of the session, and how the session could be improved. To further explore acceptability, some participants will be invited to take part in a 60-90 min focus group (target sample ≤8 participants). The focus group will be conducted via a Video call or in person, dependent upon majority participants preference.

Reminders to non-responders will be sent by post, telephone and/or email (twice each), or until the participant requests to withdraw from the study.

5.1 Figure 2: Study schedule



6 CONSENT

Consent will be obtained by the CI or a member of the clinical or research team who has completed training in the consent procedure for the study. Prior to gaining consent the participant will be provided time to read the participant information sheet, discuss it with family or friends and ask questions.

Consent process:

- The consent form will be sent to the potential participant ahead of their initial appointment, either electronically or by post.
- Participants will have the choice to complete electronically or return it in person at their initial, baseline appointment.
- Prior to completing the baseline assessment the researcher will ensure the consent form has been completed and any queries answered.
- A copy will be filed in the medical notes, a copy filed in the Site File by the research team and a copy given to the participant.

7 ELIGIBILITY CRITERIA

7.1 Inclusion Criteria:

- ≥50 years old
- Symptoms of neurogenic claudication
- Radiographic evidence of degenerative lumbar spinal stenosis
- On the waiting list for elective lumbar decompressive surgery (+/- fixation) in >10 weeks time, to treat lumbar spinal stenosis
- Conversational level English or willing to use an interpreter

7.2 Exclusion Criteria:

- Lumbar spinal stenosis caused by tumour or fracture
- People who report other conditions as the primary reason that inhibits their walking
- Unwilling or unable to give informed consent
- >2 level instrumentation

8 RECRUITMENT

Potential participants will be identified by searching electronic patient records and screening for eligibility or identified in outpatient clinics by one of the clinical team. If in clinic, the clinician will invite the potential participant to find out more about the study ad seek approval for the research team to contact them, they will also provide with the patient information sheet.

All potential participants will be telephoned or emailed by a member of the research team and invited to participate. If interested they will be sent (electronically or by post) the participant information sheet, consent form, questionnaires and, if required, a stamped addressed envelope to return the completed questionnaires.

A screening log will be maintained to record reasons for ineligibility and non-participation.

9 STATISTICAL METHODS

Descriptive statistics will summarise baseline characteristics of patients. Continuous variables will be described as mean and standard deviation. Categorical variables will be described as frequency and percentages. The number of patients referred, approached and consented and the proportion of patients that were compliant with the intervention (number of appointments attended) and proportion of patients that completed the study will be collected and summarised.

In keeping with the study design, clinical outcome data will be summarised descriptively and effect sizes calculated as indicated.

Thematic content analysis will be used to analyse the qualitative data from the focus group.

10 Public Involvement

The project was developed with patients. They highlighted the lack of access to physiotherapy. A co-design study was used to develop the STRIDE programme to ensure the needs of patients were at the centre of the programme and that patients had an equal voice in the design.

A patient advisory group has been developed with people with NC who have had spinal surgery. We have discussed with them the research processes, measures, topic guides and questionnaires for this study. In addition they have reviewed and helped refine the patient information sheet. They considered the research proposed to be acceptable and not burdensome. They have helped develop the questionnaire to assess acceptability as, they found after reviewing two validated questionnaires, the questions to be difficult to understand and answer.

The patient advisory group have agreed to support the research on an ongoing basis.

During the study, the patient advisors will meet six monthly to contribute to the planning and review the progress of each study stage.

The patient advisors will be provided with a honourarium (£150/day) and all expenses will be reimbursed, as per the NIHR guidance. These payments are a form of reward and recognition offered for the contribution that public contributors make to NIHR and to health and care research.

11 FUNDING AND SUPPLY OF EQUIPMENT

The study is funded by the Dunhill Medical Trust. Suzanne McIlroy (CI) has been awarded a research fellowship, the costs of the research and the equipment is covered by the award.

12 DATA HANDLING AND MANAGEMENT

All participants will be allocated a unique patient identifier number.

Any data sent via email will be sent via secure NHS.net email accounts.

All electronic data will be collated and stored in an Excel spreadsheet in such way that data can be easily exported to the data analysis packages with minimal effort. All electronic data will be stored on NHS computers or encrypted external hard drives and comply with KCH Information Governance Policies.

Any paper identifiable data will be kept within a locked filing cabinet within a locked secure room. At the end of the fellowship this will be securely archived.

Identifiable data will not be shared outside the research team.

13 MATERIAL/SAMPLE STORAGE

No tissue samples or materials will be collected in this study.

14 PEER AND REGULATORY REVIEW

The study has been peer reviewed in accordance with the requirements outlined by KCH R&I.

The study has been peer reviewed within King's College London and a Project Approval Form issued. The study has also been peer reviewed by the funding body.

The study was deemed to require regulatory approval from the following bodies. Each approval will be obtained before the study commences.

- HRA
- REC

15 ASSESMENT AND MANAGEMENT OF RISK

There are minimal risks of participating in this research. The risk of sustaining an injury during physical tests and assessment is low, reflects usual care and will be conducted by an experienced physiotherapist.

Many of the participants will have mobility problems and therefore may at risk of falling during the timed walk and balance tests. The participants will be supervised closely the whole time and the tests stopped if the participant appears unsafe.

The adhesive dressing to attach the accelerometer to the participants' thigh may cause an irritation. Participants will be asked if they are allergic to dressings before use and advised to monitor for signs of irritation. They will be provided with additional dressings so that they can reposition the accelerometer as required. They will be advised that if more than a mild irritation occurs to discontinue use and inform their clinical team and/or the research team. The Tagaderm dressing used has been found to be acceptable to most people.

Whilst it is unlikely, the focus group may inadvertently cause distress, if this is the case, it will be stopped and support will be offered by the interviewer or the academic supervisors, who are all qualified health professionals.

The PPI meetings conducted indicates that the outcome measures are not too burdensome. Visits to the hospital for assessment will be minimised and where possible will coincide with routine visits.

No serious adverse events are expected within this research study. However, if they occur they will be recorded and processes in the following sections followed.

16 RECORDING AND REPORTING OF EVENTS AND INCIDENTS

16.1 Definitions of Adverse Events

Term	Definition
Adverse Event (AE)	Any untoward medical occurrence in a patient or study participant, which does not necessarily have a causal relationship with the procedure involved.
Serious Adverse Event (SAE).	Any adverse event that: • results in death, • is life-threatening*, • requires hospitalisation or prolongation of existing hospitalisation**, • results in persistent or significant disability or incapacity, or • consists of a congenital anomaly or birth defect
*A life- threatening event, this 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. ** Hospitalisation is defined as an in-patient admission, regardless of length of stay. Hospitalisation for pre-existing conditions, including elective procedures do not constitute an SAE.	

16.2 Assessments of Adverse Events

No adverse events are expected. Each adverse event will be assessed for severity, causality, seriousness and expectedness as described below.

16.2.1 Severity

The generic categories below are given for use as a guide.

Category	Definition
Mild	The adverse event does not interfere with the participant's daily routine, and does not require further procedure; it causes slight discomfort

Moderate	The adverse event interferes with some aspects of the participant's routine, or requires further procedure, but is not damaging to health; it causes moderate discomfort
Severe	The adverse event results in alteration, discomfort or disability which is clearly damaging to health

16.2.2 Causality

The assessment of relationship of adverse events to the procedure is a clinical decision based on all available information at the time of the completion of the case report form.

If a differentiated causality assessment which includes other factors in the study is deemed appropriate, please add/amend the following wording to specify:

The differentiated causality assessments will be captured in the study specific CRF/AE Log and/or SAE form (amend as required).

The following categories will be used to define the causality of the adverse event:

Category	**Definition**
Definitely:	There is clear evidence to suggest a causal relationship, and other possible contributing factors can be ruled out.
Probably:	There is evidence to suggest a causal relationship, and the influence of other factors is unlikely
Possibly	There is some evidence to suggest a causal relationship (e.g. the event occurred within a reasonable time after administration of the study procedure). However, the influence of other factors may have contributed to the event (e.g. the participant's clinical condition, other concomitant events).
Unlikely	There is little evidence to suggest there is a causal relationship (e.g. the event did not occur within a reasonable time after administration of the study procedure). There is another reasonable explanation for the event (e.g. the participant's clinical condition).
Not related	There is no evidence of any causal relationship.
Not Assessable	Unable to assess on information available.

16.2.3 Expectedness

Category	Definition
Expected	Nil expected, retrospective study. Patient reported outcome measures only

Unexpected	Non- applicable, retrospective study. Patient reported outcome measures only

* this includes listed events that are more frequently reported or more severe than previously reported

16.3 Recording adverse events

All adverse events will be recorded in the medical records in the first instance.

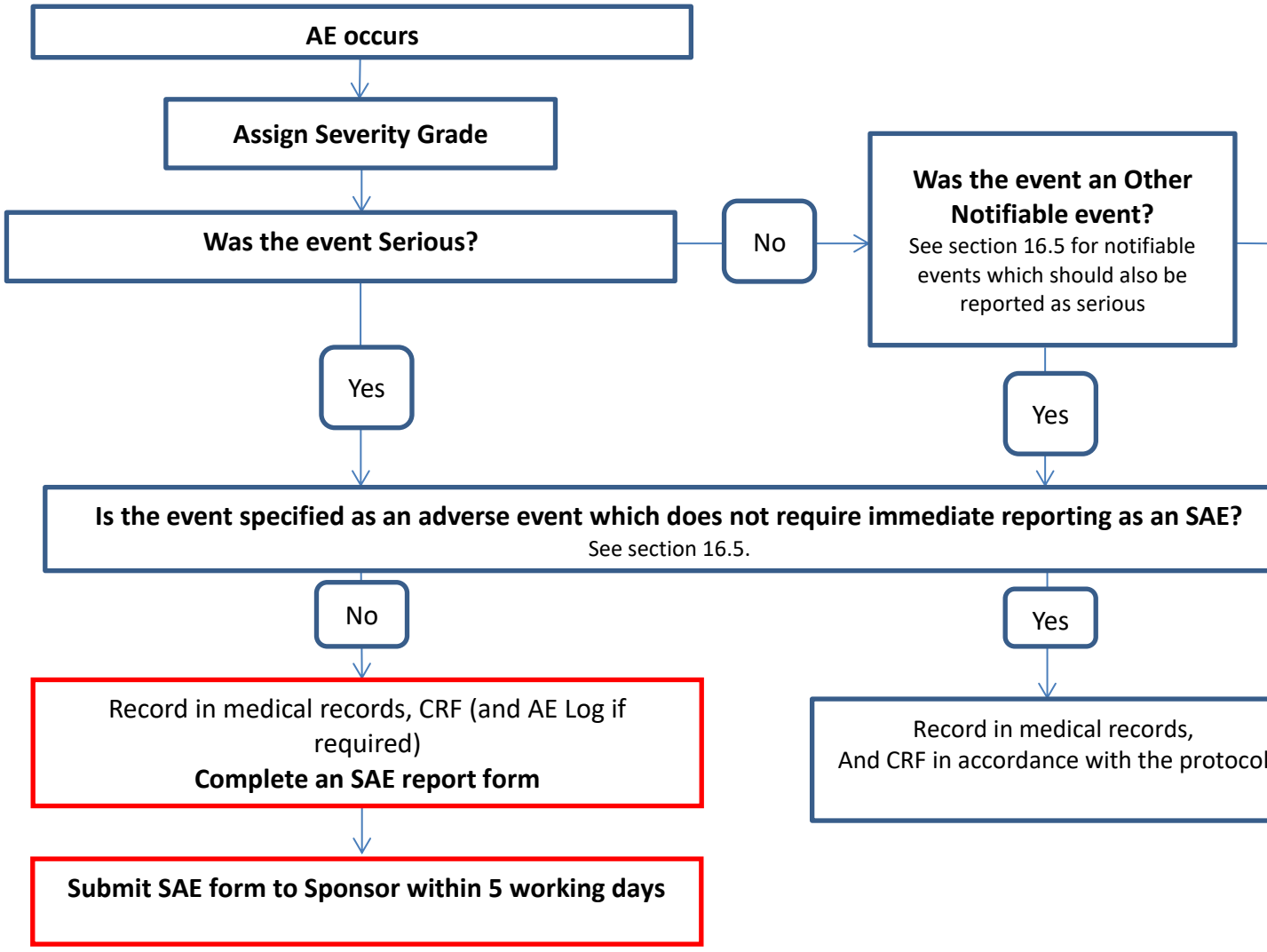
16.4 Procedures for recording and reporting Serious Adverse Events

All serious adverse events will be recorded, by the direct care team, in the medical records.

All SAEs (except those specified in section 16.5 as not requiring reporting to the Sponsor) must be recorded on a serious adverse event (SAE) form. The CI/PI or designated individual will complete an SAE form and the form will be preferably emailed to the Sponsor within 5 working days of becoming aware of the event. The Chief or Principal Investigator will respond to any SAE queries raised by the sponsor as soon as possible.

Where the event is unexpected and thought to be related to the procedure this must be reported by the Investigator to the Health Research Authority within 15 days.

Flow Chart for SAE reporting



16.5 Serious Adverse Events that do not require reporting

Not applicable

16.6 Reporting Urgent Safety Measures

If any urgent safety measures are taken the CI/ PI shall immediately and in any event no later than 3 days from the date the measures are taken, give written notice to the relevant REC and Sponsor of the measures taken and the circumstances giving rise to those measures.

16.7 Protocol deviations and notification of protocol violations

A deviation is usually an unintended departure from the expected conduct of the study protocol/SOPs, which does not need to be reported to the sponsor. The CI will monitor protocol deviations.

A protocol violation is a breach which is likely to effect to a significant degree –

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

The CI and sponsor will be notified immediately of any case where the above definition applies during the study conduct phase.

16.9 Reporting incidents involving a medical device(s) (if applicable)

Not applicable

16.10 Trust incidents and near misses

An incident or near miss is any unintended or unexpected event that could have or did lead to harm, loss or damage that contains one or more of the following components:

a. It is an accident or other incident which results in injury or ill health.
b. It is contrary to specified or expected standard of patient care or service.
c. It places patients, staff members, visitors, contractors or members of the public at unnecessary risk.
d. It puts the Trust in an adverse position with potential loss of reputation.
e. It puts Trust property or assets in an adverse position or at risk.

Incidents and near misses must be reported to the Trust through DATIX as soon as the individual becomes aware of them.
A reportable incident is any unintended or unexpected event that could have or did lead to harm, loss or damage that contains one or more of the following components:

a) It is an accident or other incident which results in injury or ill health.
b) It is contrary to specified or expected standard of patient care or service.
c) It places patients, staff members, visitors, contractors or members of the public at unnecessary risk.
d) It puts the Trust in an adverse position with potential loss of reputation.
e) It puts Trust property or assets in an adverse position or at risk of loss or damage.

17 MONITORING AND AUDITING

The Chief Investigator will ensure there are adequate quality and number of monitoring activities conducted by the study team. This will include adherence to the protocol, procedures for consenting and ensure adequate data quality.

The Chief Investigator will inform the sponsor should he/she have concerns which have arisen from monitoring activities, and/or if there are problems with oversight/monitoring procedures.

18 TRAINING

The Chief Investigator will review and provide assurances of the training and experience of all staff working on this study. Appropriate training records will be maintained in the study files

19 INDEMNITY ARRANGEMENTS

KCH will provide NHS indemnity cover for negligent harm, as appropriate and is not in the position to indemnify for non-negligent harm. NHS indemnity arrangements do not extend to non-negligent harm and NHS bodies cannot purchase commercial insurance for this purpose; it cannot give advance undertaking to pay compensation when there is no negligence attributable to their vicarious liability. The Trust will only extend NHS indemnity cover for negligent harm to its employees, both substantive and honorary, conducting research studies that have been approved by the R&D Department. The Trust cannot accept liability for any activity that has not been properly registered and Trust approved. Potential claims should be reported immediately to the Joint Research Office.

20 ARCHIVING

At the end of the study period all project documents will be archived for 7 years through the Research and Innovation department using Iron Mountain. The storing facility is secure, with appropriate environmental controls and adequate protection from fire, flood and unauthorised access.

21 PUBLICATION AND DISSEMINATION POLICY

Results will be reported as per the CONSORT extension guidelines, adapted for use in non-randomised trials [41] and disseminated via internal and local audit and training meetings and written for publication in peer reviewed scientific journals and presentation at scientific conferences. A public meeting will be held at the end of the training fellowship to share the findings.

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23 APPENDICES

. **Appendix 1:** Pre and post-operative data collection packs including self-rated questionnaires

Appendix 2: Topic guide for stage 2

Appendix 3: Patient information sheet

PROTOCOL VERSIONS

Version Stage	Versions No	Version Date	Appendix No detail the reason(s) for the protocol update