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Acceptability of STRIDE: a new rehabilitation programme to improve walking after low back surgery

Submission date
24/10/2023

Recruitment status
No longer recruiting

Registration date
20/11/2023

Overall study status
Completed

Last Edited
09/02/2024

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Lumbar spinal stenosis causes symptoms called neurogenic claudication. This causes pain, weakness and/or numbness down both legs resulting in difficulty walking. Lumbar spinal stenosis is the most common reason for spinal surgery but many people do not increase their walking after their operation. Rehabilitation and physiotherapy have the potential to improve people's walking, outcomes and experiences after surgery for lumbar spinal stenosis. There are no structured rehabilitation programmes within the NHS. A new rehabilitation programme has been developed called STructured Rehabilitation and InDividulaised Exercise and education (STRIDE). STRIDE aims to improve walking, outcomes and experiences in people who have low back surgery for lumbar spinal stenosis. The purpose of this study is to investigate the experiences of people who receive STRIDE. They will be asked if they find it acceptable and how it can be improved. The study will also assess whether it is possible to run a future research trial investigating if STRIDE works. Therefore, the study will evaluate how many people agree to take part and how many people complete the study. This will provide important information that will help with the planning of future studies.

Who can participate?
People aged 50 years old and over on the waiting list for surgery to treat neurogenic claudication

What does the study involve?
Participants will be invited to complete the STRIDE rehabilitation programme, which is a physiotherapy-led programme that lasts for 12 weeks before their surgery and 12 weeks after their surgery. Participants will be invited to three research assessments, the first will occur after signing up for the study, the second will be about 12 weeks later and the last one will be 12 weeks after their operation. At the assessments, walking and lower limb function will be assessed. In addition, participants will be requested to complete some questionnaires at each of these time points. Participants will also be requested to wear an accelerometer (step counter) on their thigh for 7 days after each of the research assessments.

What are the possible benefits and risks of participating?
The study team hope that the STRIDE programme is helpful. It aims to improve people's walking and outcomes after surgery for lumber spinal stenosis. There are minimal risks of taking part, some people may find the assessment mildly uncomfortable or hard work however participants can have breaks or ask to stop at any time. There is a very low risk that the step counter or dressing on their thigh causes irritation, if this happens it can be taken off easily.

Where is the study run from?
King's College Hospital NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
July 2023 to January 2025

Who is funding the study?
1. The Dunhill Medical Trust (UK)
2. National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Suzanne McIlroy, suzanne.mcilroy@nhs.net (UK)

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
333622

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 59148, IRAS 333622

Study information

Scientific 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

Acronym
STRIDE

Study objectives
The STRIDE rehabilitation programme is acceptable to people before and after surgery for neurogenic claudication

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 18/12/2023, London - Bloomsbury Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)2071048171; Bloomsbury.rec@hra.nhs.uk), ref: 23/LO/0913

Study design
Non-randomized interventional study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Home, Internet/virtual, Other therapist office, Telephone

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Rehabilitation after surgery for lumbar spinal stenosis

Interventions
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 addition, there are up to 3 optional sessions available for people who may require additional support. The sessions will incorporate behaviour change techniques, and be delivered by a physiotherapist using a motivational interviewing approach to encourage self-management, 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.

Design: Multiple methods acceptability study:
1. Single-arm feasibility and acceptability study
2. Nested qualitative focus group
3. Single-arm acceptability study

Sample: Up to 15 adults due to undergo surgery to treat neurogenic claudication due to lumbar spinal stenosis will be recruited. Inclusion criteria: People aged ≥50 years, on the waiting list for surgery for lumbar spinal stenosis with symptoms of neurogenic claudication. Exclusion criteria: People who report other conditions as the primary reason that inhibits their walking, are unwilling or unable to give informed consent.

Participant identification and recruitment: Potential participants will be identified by the direct care teams either in outpatient clinics or from surgical waiting lists. The direct care team will discuss the research with the potential participants and provide them with an information sheet. Verbal consent will be requested for the research team to contact the participant to discuss the project, confirm eligibility and invite them to participate. Appointments will then be made for the patient to attend either the hospital or physiotherapy department where consent will be gained and assessment completed.

Procedure: Participants will be asked to complete three assessments, before and after completing STRIDE and after completing the pre-operative phase of STRIDE. 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. 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.

To assess the acceptability of the rehabilitation programme and research processes a questionnaire informed by the constructs of the Theoretical Framework of Acceptability will be provided to all participants who are recruited to the study. The self-reported measures will be completed either at home or in person, electronically or on paper (and maybe returned by post using a stamped addressed envelope), depending upon patient preference.

Qualitative focus group study:
Participants and recruitment: A purposive sample of up to 8 participants from stage one will be recruited.
Method: A focus group will be conducted via video call (Teams) or in person (dependent upon majority participant preference) to allow for further exploration of the acceptability of the STRIFE programme and the research processes. A semi-structured topic guide developed a priori will cover key questions about 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.

Intervention Type
Behavioural

Primary outcome measure
Acceptability measured using questionnaires based on the theoretical framework of acceptability after the pre-operative and post-operative phases of STRIDE. In addition, a focus group will be undertaken after the completion of the STRIDE programme.

Secondary outcome measures
1. Feasibility measures of recruitment, adherence and fidelity will be collected at the end of the intervention
2. Walking capacity will be measured with the six-minute walk test at baseline, 12 weeks and end of STRIDE intervention
3. Lower limb performance will be measured with timed 5-chair stands at baseline, 12 weeks and end of STRIDE intervention
4. Balance will be measured with the 4-pint balance test at baseline, 12 weeks and end of STRIDE intervention
5. Walking performance will be measured with the mean daily step count, collected over 7 days, using an accelerometer at baseline, 12 weeks and end of STRIDE intervention
6. Back-related disability will be measured with the Oswestry Disability Index at baseline, 12 weeks and end of STRIDE intervention
7. Fear of falling will be measured with the Short Falls Efficacy Scale International at baseline, 12 weeks and end of STRIDE intervention
8. Pain severity will be measured with the numerical rating scale at baseline, 12 weeks and end of STRIDE intervention
9. Illness perceptions will be measured with the Brief Illness Perceptions Questionnaire at baseline, 12 weeks and end of STRIDE intervention
10. Fear of movement will be measured with the Tampa Scale of Kinesiophobia at baseline, 12 weeks and end of STRIDE intervention
11. Satisfaction with the outcome of treatment will be measured with the Satisfaction scale from the valid Zurich Claudicant Scale at baseline, 12 weeks and end of STRIDE intervention
12. Impression of change will be measured with the Patient's Global Impression of change at baseline, 12 weeks and end of STRIDE intervention

Overall study start date
01/07/2023

Completion date
31/01/2025

Eligibility

Key inclusion criteria

1. > = 50 years old
2. Symptoms of neurogenic claudication (defined as as pain/ aching/ heaviness/ weakness/ tingling/ numbness in one or both buttocks and/ or legs (with or without back pain), precipitated by walking/ prolonged standing and eased by sitting /bending forwards)
3. Radiographic evidence of degenerative lumbar spinal stenosis
4. On the waiting list for lumbar decompressive surgery (+/- fixation) to treat lumbar spinal stenosis
5. Conversational level English or willing to use an interpreter

Participant type(s)
Patient

Age group
Adult

Lower age limit
50 Years

Sex
Both

Target number of participants
Planned Sample Size: 15; UK Sample Size: 15

Key exclusion criteria
1. Lumbar spinal stenosis caused by tumour or fracture or significant deformity
2. Patients requiring urgent surgery (e.g. with cauda equina syndrome)
3. People who report other conditions as the primary reason that inhibits their walking
4. Unwilling to give informed consent
5. > 2 level instrumentation
6. < 10 weeks prior to surgery

Date of first enrolment
19/12/2023

Date of final enrolment
31/01/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
King's College Hospital NHS Foundation Trust
Denmark Hill

London
United Kingdom
SE5 9RS

Sponsor information

Organisation
King's College Hospital NHS Foundation Trust

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The R&D Office, First Floor Coldharbour Works
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+44 (0)20 3299 1980
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Sponsor type
Hospital/treatment centre

Website
https://www.kch.nhs.uk/

ROR
https://ror.org/01n0k5m85

Funder(s)

Funder type
Government

Funder Name
Dunhill Medical Trust

Alternative Name(s)
The Dunhill Medical Trust, DMT

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal. In addition, the study will be written up as part of PhD thesis.

Intention to publish date
01/12/2024

Individual participant data (IPD) sharing plan
The datasets generated during and analysed during the current study will be available upon request from Suzanne McIlroy, suzanne.mcilroy@nhs.net. Any data shared will be anonymised.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.0	01/09/2023	17/11/2023	No	No