

Better outcomes for older people with spinal trouble

Submission date 10/11/2015	Recruitment status No longer recruiting	☒ Prospectively registered ☒ Protocol
Registration date 03/05/2016	Overall study status Completed	☒ Statistical analysis plan ☒ Results
Last Edited 18/09/2026	Condition category Nervous System Diseases	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Low back pain (LBP) is the leading cause of disability worldwide. Over 70% of people will suffer with LBP in their lifetime, and the chance of having the most serious forms of LBP increases with age. It is associated with loss of mobility and falls in older people leading to loss of independence and frailty, however, this is the time in life when GPs and patients are least likely to prioritise treatment for LBP. In later life people are much more likely to have other health conditions which they think are more important than LBP. Some older people just grin and bear the pain, accepting it as part of ageing. Although there is a large body of research in LBP, this has focused almost exclusively on younger people. Hence there is little guidance appropriate to older people. Lumbar spinal stenosis is a common back condition in older adults where the spinal cord is compressed due to narrowing of the spinal canal. This leads to a range of symptoms including pain, tingling, numbness or heaviness spreading from the back into one or both legs, together known as neurogenic claudication. Neurogenic claudication is a common symptom of lumbar spinal stenosis (narrowing of the spine leading to compression of the spinal cord), a leading cause of LBP in the aging population. Neurogenic claudication affects a person's ability to walk and stand which impacts on their ability to remain independent. There is little research to help us know what type of physiotherapy is best for people with neurogenic claudication. The aim of this study is to compare the effectiveness of two different approaches to physiotherapy which have been designed to help older adults with neurogenic claudication to stay mobile and remain independent.

Who can participate?

Adults aged 65 years or over who live at home and report symptoms of neurogenic claudication.

What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group take part in a 12-week group physiotherapy programme. This involves weekly hour-and-a-half long sessions of exercises and group discussions about ways to manage symptoms and be more physically active. Those in the second group receive an individual session with a physiotherapist in which they are provided with information about exercises and how best to manage their symptoms. These

participants can receive two follow up sessions if required. Participants in both groups complete a number of questionnaires and physical assessments at the start of the study and again 6, 12 and 24 months later in order to find out if their symptoms have improved.

What are the possible benefits and risks of participating?

Participants may benefit from an improvement to their back and leg symptoms because of the advice, information and exercises given to them by the physiotherapist. There is a risk of muscle soreness after completing some of the exercises however this is normal and the physiotherapist will provide advice on how to manage this. Some participants may feel uncomfortable answering certain questions about their health during the study, but they will be advised that they are not obliged to answer any questions they are not comfortable with.

Where is the study run from?

1. The Royal Orthopaedic Hospital, Birmingham (UK)
2. Nuffield Orthopaedic Centre, Oxford (UK)

When is the study starting and how long is it expected to run for?
April 2015 to April 2020

Who is funding the study?

National Institute for Health Research (UK)

Who is the main contact?

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Contact information

Type(s)

Public

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Study information

Scientific Title

Better Outcomes for Older People with Spinal Trouble (BOOST) Randomised Controlled Trial

Acronym

BOOST RCT

Study objectives

The aim of this study is to evaluate the clinical and cost-effectiveness of a group physiotherapy programme for people with neurogenic claudication due to spinal stenosis compared to best practice advice.

Ethics approval required

Old ethics approval format

Ethics approval(s)

London - Brent Research Ethics Committee, 10/03/2016, ref: 16/LO/0349

Primary study design

Interventional

Study design

Multi-centre randomized controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Neurogenic claudication, spinal stenosis

Interventions

Participants are randomly allocated to one of two groups.

Intervention group: Participants take part in a 12-week group physiotherapy programme comprising of a progressing exercise programme underpinned by cognitive behavioural strategies to promote engagement and adherence with the programme. Each class lasts for 1.5 hours and will involve exercises and group discussions about ways to manage symptoms and be more physically active.

Control group: Participants receive one individual session to provide information about exercise and self-management with two optional follow up sessions if required.

After treatment, participants will be invited to two follow-up appointments with the researcher (6 and 12 months after they join the study). They will also receive a questionnaire in the post 2 years after joining the study which we will ask them to complete and return to the BOOST Trial Team.

Intervention Type

Behavioural

Primary outcome(s)

Functional Disability is measured using the Oswestry Disability Index at baseline, 6, 12, 24 months.

Key secondary outcome(s)

1. Back pain and leg symptoms is measured using the Swiss Spinal Stenosis Questionnaire (symptom subscale) at baseline, 6, 12 and 24 months
2. Physical activity is measured using Rapid Assessment Disuse Index (modified) at baseline, 6, 12 and 24 months
3. Mobility is measured using a 6 minute walk test and short physical performance battery at baseline 6, 12 and 24 months
4. Frailty, fatigue and sleep is measured using the Tilberg Frailty Index at baseline, 6, 12 and 24 months
5. Falls and falls related injuries are measured using self-report at baseline, 6, 12 and 24 months, and Short Physical Performance Battery (SPPB) at baseline.
6. Disability and health related quality of life is measured using the EQ5D-5L at baseline, 6, 12 and 24 months
7. Perceived change is measured using the Global rating of perceived change scale at 6, 12 and 24 months
8. Self-efficacy is measured using Self-efficacy recovery and maintenance related to performing home exercises and Single item from the Modified Gait Self-Efficacy Scale at baseline, 6, 12 and 24 months and the Exercise self-efficacy scale (short version) at baseline.
9. Fear avoidance is measured using the Fear avoidance beliefs questionnaire at baseline, 6, 12 and 24 months
10. Habit is measured using Index of habit (short version) at 6, 12 and 24 months
11. Satisfaction with attempts to increase physical activity is measured using 5 point scale questionnaire at 6, 12 months
12. Satisfaction with treatment is measured using 5 point scale questionnaire at 6, 12 months
13. Adherence to home exercise programme is measured through self-reporting at 6, 12 months
14. Sagittal alignment of the spine is measured using occiput to wall measure at baseline, 6, 12 months and MRI scan parameters at baseline.
15. Health resource use and treatment costs is measured using self-report and structured interview at 6, 12 months.
16. Other pain measured by Nordic pain questionnaire at baseline and 24 months.

Completion date

29/08/2020

Eligibility

Key inclusion criteria

1. Aged 65 years and over
2. Registered with a primary care practice
3. Living in the community, including sheltered or supported housing
4. Willing and able to give informed consent for participation in the trial
5. Reports symptoms consistent with neurogenic claudication

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Lower age limit

65 Years

Upper age limit

100 Years

Sex

All

Total final enrolment

435

Key exclusion criteria

1. Living in a residential care or nursing home
2. Has a terminal condition with a life expectancy of less than 6 months
3. Any substantial health or social concern that, in the opinion of the patient's general practitioner, would place the patient at increased risk or inability to participate including known inability to provide informed consent e.g. Dementia
4. Unable to walk 3 meters without the help of another person
5. On a surgical waiting list
6. Presents with cauda equina syndrome or signs of serious pathology requiring immediate referral for investigations
7. Cognitive impairment (defined as an Abbreviated Mental Test score of 6 or less)
8. Registered blind
9. Unable to follow verbal instructions which would make participation in the exercise group impractical including severe hearing impairment not corrected by a hearing aid or inability to follow simple safety instructions (eg English comprehension)

Date of first enrolment

25/07/2016

Date of final enrolment

29/08/2018

Locations

Countries of recruitment

United Kingdom

England

Study participating centre**The Royal Orthopaedic Hospital**

Royal Orthopaedic Hospital NHS Foundation Trust

Bristol Road South

Northfield

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Study participating centre**Nuffield Orthopaedic Centre**

Oxford University Hospitals NHS Foundation Trust

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Sponsor information**Organisation**

Oxford University Hospitals NHS Foundation Trust

ROR

<https://ror.org/03h2bh287>

Funder(s)**Funder type**

Government

Funder Name

National Institute for Health 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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Protocol for causal mediation analysis	12/08/2022	30/09/2022	Yes	No
Results article		01/12/2023	06/06/2024	Yes	No
Protocol article		18/10/2018	30/10/2019	Yes	No
Protocol article		02/09/2020	07/09/2020	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Economic evaluation	14/09/2022	15/09/2022	Yes	No
Other publications		08/02/2023	10/02/2023	Yes	No
Other publications		07/02/2019	06/06/2024	Yes	No
Other publications	Causal mediation analysis	20/06/2025	24/06/2025	Yes	No
Other publications	Secondary analysis	17/09/2026	18/09/2026	Yes	No
Statistical Analysis Plan	Statistical analysis plan	21/07/2020	24/07/2020	No	No