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Better outcomes for older people with spinal trouble

Submission date
10/11/2015

Recruitment status
No longer recruiting

Registration date
03/05/2016

Overall study status
Completed

Last Edited
24/06/2025

Condition category
Nervous System Diseases

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] 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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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

Study design
Multi-centre randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

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

Secondary outcome measures
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.

Overall study start date
01/04/2015

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

Age group
Senior

Lower age limit
65 Years

Sex
Both

Target number of participants
A minimum of 402 participants will be recruited into the RCT.

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
England

United Kingdom

Study participating centre
The Royal Orthopaedic Hospital
Royal Orthopaedic Hospital NHS Foundation Trust
Bristol Road South
Northfield
Birmingham
United Kingdom
B31 2AP

Study participating centre
Nuffield Orthopaedic Centre
Oxford University Hospitals NHS Foundation Trust
Windmill Road
Oxford
United Kingdom
OX3 7HE

Sponsor information

Organisation
Oxford University Hospitals NHS Foundation Trust

Sponsor details
Joint Research Office
Block 60
Churchill Hospital
Old Road
Headington
Oxford
England
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OX3 7LE

Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan

The results of the trial will be reported first to trial collaborators. The main report will be drafted by the research team and subject to external peer review prior to publication. The trial will be reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines. Findings from the research will be disseminated at conferences and via a dedicated website. A summary of the study outcomes will also be available to study participants on relevant websites and directly circulated by way of study newsletters.

Intention to publish date
31/12/2021

Individual participant data (IPD) sharing plan
Not provided at time of registration

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?
Protocol article	protocol	18/10/2018	30/10/2019	Yes	No
Statistical Analysis Plan	statistical analysis plan	21/07/2020	24/07/2020	No	No
Protocol article	protocol for causal mediation analysis	02/09/2020	07/09/2020	Yes	No
Other publications		14/09/2022	15/09/2022	Yes	No
Results article		12/08/2022	30/09/2022	Yes	No
Other publications	Economic evaluation	08/02/2023	10/02/2023	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Development and delivery of the BOOST intervention	07/02/2019	06/06/2024	Yes	No
Results article		01/12/2023	06/06/2024	Yes	No
Other publications	A causal mediation analysis	20/06/2025	24/06/2025	Yes	No