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Getting an education and exercise programme for older adults with neurogenic claudication (the BOOST programme) into clinical practice: a research study.

Submission date
24/10/2022

Recruitment status
No longer recruiting

Registration date
07/11/2022

Overall study status
Completed

Last Edited
09/06/2025

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
A recent randomised controlled trial found the BOOST programme significantly improved walking ability and reduced falls risk at 12 months in people with symptomatic lumbar spinal stenosis (LSS). Spinal stenosis happens when the space inside the backbone is too small. This can put pressure on the spinal cord and nerves that travel through the spine. The programme consisted of an individual session and 12 group-based sessions of education and exercise. Before widespread implementation of the BOOST programme, we want to optimise it to achieve maximum effectiveness on clinical outcomes and uptake by healthcare providers. We have formed a 'community of practice' with patients and health professionals to provide feedback on the original programme and to iteratively coproduce content for optimisation.

Who can participate?
Patients aged 65 years or older, with symptomatic LSS, and health professionals and exercise therapists aged 21 years or older, providing treatment for symptomatic LSS.

What does the study involve?
This protocol describes two sequential observational studies with embedded interview studies. The first study aims to evaluate the clinical effectiveness of the optimised BOOST programme. To do this, we will collect data from patients before they start the optimised BOOST programme and in six months' time. We will measure pain-related disability, quality of life, walking capacity, and satisfaction. We will interview the health professionals delivering the optimised programme to understand their experiences. Data from the first study will inform the wider implementation in stage two.
In stage two, we will develop a digital resource to provide health professionals with knowledge, skills, and tools to implement the BOOST programme. We will evaluate learning and implementation outcomes to ensure the digital resource is effective. For a subset of health professionals delivering BOOST to patients, we will collect the same patient data (pain-related disability, quality of life, walking capacity, and satisfaction) at baseline and six months. Health

professionals, or level four exercise therapists, treating people with LSS can take part in the digital resource evaluation. Patients taking part in the clinical evaluation will have been referred for NHS physiotherapy and have symptoms of LSS. The BOOST programme can be delivered in an NHS or community setting, in partnership with an NHS Trust.

What are the possible benefits and risks of participating?
The advice, information, and exercises received as part of the BOOST programme may help patients back and leg symptoms. In the multi-centre trial that evaluated the BOOST programme, patients significantly improved their waking capacity and physical function, and reduced their falls risk by 40% compared to usual care.
Patients are unlikely to be harmed by the BOOST programme. The therapist will have assessed the patient to make sure that the exercises are at the right level for them. However, participants may experience normal muscle soreness after completing some of the exercises. This is expected and the therapist will provide participants with advice on how to manage this.

Where is the study run from?
University of Exeter (UK)

When is the study starting and how long is it expected to run for?
May 2022 to January 2024

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
Dr Cynthia Srikesavan, c.srikesavan2@exeter.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

315731

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 53283, NIHR203301, IRAS 315731

Study information

Scientific Title
Evaluating the optimisation and impact of the BOOST programme: an implementation study

Acronym
BOOST-IS v1.0

Study objectives
We can optimize outcomes for people with neurogenic claudication in a real-world setting, achieving outcomes equal to those achieved in the context of a multi-centered clinical trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/07/2022, London - Surrey Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 2071048388; surrey.rec@hra.nhs.uk), ref: 22/PR/0776

Study design
Inteverntional non-randomized

Primary study design
Interventional

Secondary study design
Non randomised study

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
Symptomatic lumbar spinal stenosis

Interventions

The BOOST programme has been published in detail and is described in brief below.

Dose and method: BOOST is predominantly a group-based intervention. It consists of one 60-minute individual session followed by 12 x 90-minute group sessions over 12 weeks. Participants complete a home exercise programme twice weekly during and beyond the formal programme. At 1 and 2 months after completion of the formal programme, participants receive a support phone call.

Provider: Each session is delivered by a therapist who has specific training in the BOOST programme. For stage 1, this training will be delivered face-to-face where possible. For stage 2, this training will be solely via the BOOST online training platform.

Initial individual session: Participants receive:
• Provision of advice on diagnosis and prognosis.
• Individually tailored exercises to complete in the group sessions.
• Provision of a patient workbook containing education and exercises.

Group session content: Each group session consists of 30 minutes of education and discussion based on a CBA, followed by 60 minutes of exercise. The exercise component includes:
• Seated warm-up.
• Individually tailored strength, balance, and flexibility exercises.
• A 20-minute supervised walking programme.
Optimisation
We have optimised the BOOST programme to improve its effect on pain-related disability and to maximise conversion to long term exercise/activity. We have iteratively co-produced these enhancements with our community of practice consisting of patients and physiotherapists. Enhancements to the programme include:
• Addition of an upper quadrant exercise in standing.
• Delivering the BOOST programme in partnership with the voluntary, community, and social enterprise sector (VCSE). Sites will have the flexibility to decide how they partner with the VCSE, for example, some may choose to provide a consulting role while the BOOST programme itself is delivered by an accredited and trained community provider, while others may choose to invite a community provider to one of the BOOST sessions to provide awareness of suitable local activities running in the community.
• Enhancing education on the management of pain flare ups and on managing symptoms when standing.
• Engaging with a clinical pharmacist to provide more detailed education on medication and improve awareness that patients can request medication reviews from their clinical pharmacist without the need for a GP appointment.
• Offering the patient workbook digitally.
• Providing participants with a ‘business card’ containing education about their condition with exercise recommendations.

Intervention Type

Behavioural

Primary outcome measure

Walking capacity is measured using the patient-reported Oswestry Disability Index (ODI) walking item and the objective 6 minute walk test at baseline and at 6 months

Secondary outcome measures
1. Pain related disability is measured by the ODI at baseline and at 6 months
2. Health related quality of life is measured by the EQ-5D-5L at baseline and at 6 months
3. Troublesomeness is measured using a single item measuring how troublesome back and leg symptoms have been over the past 4 weeks at baseline and at 6 months
4. Satisfaction is measured at 6 months
5. Physical activity is measured using 4 items from the physical activity and sedentary behaviour questionnaire (CSEP-PATH) at baseline and at 6 months
6. Activity measured from a wrist worn accelerometer will be measured over 16-days at baseline and at 6 months
7. Sleep efficacy will be measured from a wrist worn accelerometer will be measured over 16-days at baseline and at 6 months

Overall study start date
02/05/2022

Completion date
31/01/2024

Eligibility

Key inclusion criteria
Patient participants:
1. Able to give informed consent
2. Aged 65 years and over
3. Symptoms consistent with symptomatic lumbar spinal stenosis:
3.1. A report of back pain and/or pain or other symptoms such as tingling, numbness or heaviness that travels from their back into their buttocks or legs in the last 6 weeks.
3.2. Standing or walking makes symptoms in the buttocks or legs worse.
3.3. Sitting or bending forward relieves symptoms.

Therapist participants:
1. Be either a qualified a health professional or a level 4 exercise therapist.
2. Provide treatment (or plan to provide treatment in the near future) to patients with symptomatic lumbar spinal stenosis.
3. Be based in the UK.
4. Employed by either the NHS or a community health provider (depending on local business models, exercise therapists can be self-employed if they are providing services for a community provider).
5. Aged 21 years and over.

Participant type(s)
Patient, Health professional

Age group
Adult

Lower age limit
65 Years

Sex

Both

Target number of participants
Planned Sample Size: 114; UK Sample Size: 114

Total final enrolment
142

Key exclusion criteria
Patient participants:
1. Nursing home resident.
2. Inability to walk 3 meters independently.
3. Awaiting surgery.
4. Cauda equina syndrome or signs of serious pathology.
5. Cognitive impairment (defined as a score of 6 or lower on the Abbreviated Mental Test score.)
6. Registered blind.
7. Unable to follow instructions in a group setting.

Therapist participants: Not meeting the inclusion criteria.

Date of first enrolment
08/08/2022

Date of final enrolment
30/06/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Birmingham Community Healthcare NHS Foundation Trust
3 Priestley Wharf
Holt Street
Birmingham Science Park, Aston
Birmingham
United Kingdom
B7 4BN

Study participating centre
Oxford University Hospitals NHS Foundation Trust
John Radcliffe Hospital
Headley Way
Headington

Oxford
United Kingdom
OX3 9DU

Study participating centre
Leeds Community Healthcare NHS Trust
Stockdale House
8 Victoria Road
Leeds
United Kingdom
LS6 1PF

Study participating centre
Active Leeds
Leeds City Council
John Charles Centre for Sport
Middleton Grove
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United Kingdom
LS11 5DJ

Study participating centre
Aneurin Bevan University Health Board
Lodge Road
Caerleon
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Sponsor information

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Sponsor type
University/education

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ROR
https://ror.org/03yghzc09

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/07/2024

Individual participant data (IPD) sharing plan
At the end of the study and once all analyses are complete, data will be uploaded into the University of Exeter's institutional repository, Open Research Exeter (ORE), which stores and preserves research data securely for the long-term. Data will not be publicly available, but anyone interested in accessing the data can request access from the chief investigator (Professor Sallie Lamb, s.e.lamb@exeter.ac.uk).

IPD sharing plan summary
Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.1	15/07/2022	07/11/2022	No	No
HRA research summary			28/06/2023	No	No
Other unpublished results			09/06/2025	No	No