UNIVERSITY OF EXETER

COLLEGE OF MEDICINE AND HEALTH

TITLE PAGE

Full/long title of the study

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

Short study title / acronym

BOOST-IS

Protocol version number and date

V1.1 15th July 2022

Research reference numbers

IRAS Number:	315731
SPONSORS Number:	2021-22-31
FUNDERS Number:	NIHR203301

HRA PROTOCOL COMPLIANCE DECLARATION

This protocol has regard for the HRA guidance and order of content.

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature:
.....

Date:
...../...../.....

Name (please print):

Pam Baxter

Position:

Research Governance Manager (Health and Social Care)

Chief Investigator:

Signature:
.....

Date:
...../...../.....

Name: (please print):

Professor Sallie Lamb
.....

LIST OF CONTENTS

KEY STUDY CONTACTS

Chief Investigator	**Professor Sallie Lamb**, Associate Dean (Research), Mireille Gillings Professor of Health Innovation, College of Medicine and Health, University of Exeter. Tel: 01392 725585 Email: S.E.Lamb@exeter.ac.uk
Study Co-ordinator	**Dr Helen Richmond-Davies**, College of Medicine and Health, University of Exeter. Tel: 07834 074221 Email: h.richmond@exeter.ac.uk
Sponsor	**Pam Baxter** Research Governance Manager (Health & Social Care) University of Exeter Tel: 01392 723588 Ext: 3588 Mobile: 07485042117 http://www.exeter.ac.uk/cgr/researchethics/ Research Ethics and Governance Office, Lafrowda House, St Germans Road, Exeter, Devon, EX4 6TL
Joint-sponsor(s)/co-sponsor(s)	Not applicable
Funder(s)	NIHR programme development grant. Email: programme.grants@nihr.ac.uk
Key Protocol Contributors	**Dr Esther Williamson**, Senior Research Fellow (esther.williamson@ndorms.ox.ac.uk) **Dr Helen Richmond**, Postdoctoral researcher (h.richmond@exeter.ac.uk) **Dr Christine Comer**, Postdoctoral researcher (c.comer@nhs.net) **Professor Krysia Dziedzic**, Professor of Musculoskeletal Therapies (k.s.dziedzic@keele.ac.uk) **Dr Laura Swaithes**, Postdoctoral Knowledge Mobilisation Fellow (l.swaithes@keele.ac.uk) **Professor William Henley**, Medical Statistician (email: W.E.Henley@exeter.ac.uk) **Dave Rogers**, MSK Clinical Programme Lead (david.rogers4@nhs.net)
Committees	Not applicable

STUDY SUMMARY

This is a two-stage longitudinal cohort study centred on the implementation of the BOOST programme, a clinically effective, group-based education and exercise programme for older people with symptomatic lumbar spinal stenosis.

Study Title	Evaluating the optimisation and impact of the BOOST programme: an implementation study
Internal ref. no. (or short title)	BOOST-IS
Study Design	A two-stage longitudinal cohort study with embedded qualitative interview studies.
Study Participants	Patients: any patient presenting with symptomatic lumbar spinal stenosis to outpatient departments in NHS trusts across England and Wales that go on to receive the BOOST programme. Therapists: any therapist that manages (or plans to manage) patients with symptomatic lumbar spinal stenosis wanting to learn how to deliver the BOOST programme in their practice.
Planned Size of Sample (if applicable)	Stage 1: minimum of 24 participants across 4 departments. Stage 2: minimum of 60 participants across 10 departments.
Follow up duration (if applicable)	6 months
Planned Study Period	July 2022 – Sept 2023
Research Question/Aim(s)	**Primary Objectives** For stage 1, the primary objective is to evaluate the effect of optimising the BOOST programme on walking capacity as measured by the ODI walking item and the 6-minute walk test. Our primary objective for stage 2 is to again evaluate the effect of the BOOST programme on walking capacity, as measured by the ODI walking item and the 6-minute walk test, when delivered by therapists that have received the BOOST training online via the BOOST MOOC. **Secondary Objectives** • Evaluate the effect of the optimised BOOST programme on patient reported pain-related disability, quality of life, physical activity, and satisfaction (stage 1 and 2). • Interview the therapists delivering the optimised BOOST programme to explore their experiences. The exact number of interviews will depend on the number of staff delivering each group (estimated number: 5). • Evaluate learning outcomes and implementation intentions on completion of the BOOST MOOC.

	• Evaluate therapist self-reported implementation outcomes 6 months after completion of the BOOST MOOC. • Interview the therapists who have delivered the BOOST programme after completing training via the BOOST MOOC to understand their experiences (estimated number: 10).

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
NIHR programme development grant	Financial

ROLE OF STUDY SPONSOR AND FUNDER

Role of sponsor

The study sponsor will ensure that the research team has access to resources and support to deliver the research as proposed and that responsibilities for management, monitoring and reporting of the research are in place prior to the study commencing. The sponsor will ensure that there is agreement on recording, reporting, and reviewing significant developments as the research proceeds and approve any modifications to design, obtaining requisite regulatory authority approval.

The sponsor will assume responsibility for operating the management and monitoring systems of the research.

Prior to the study commencing the sponsor will be satisfied that:

- The research will respect the dignity, rights, safety and well-being of participants and the relationship with healthcare professionals.
- Where appropriate the research has been reviewed and approved by an NHS Research Ethics Committee and/or the Health Research Authority Approval Programme.
- The Chief Investigator, and other key researchers have the requisite expertise and have access needed to conduct the research successfully.
- The arrangements and resources proposed for the research will allow the collection of high quality, accurate data and the systems and resources will allow appropriate data analysis and data protection.
- Organisations and individuals involved in the research agree the division of responsibilities between them.

- Arrangements are in place for the sponsor and other stakeholder organisations to be alerted to significant developments during the study, whether in relation to the safety of individuals or scientific direction.
- There are arrangements for the conclusion of the study including appropriate plans for the dissemination of findings.

The sponsor plays no role in the design of this study and will have no role in data analysis, interpretation, or writing up of findings of the study.

Role of funder
The research funder has the responsibility to ensure that there is a proper use of the funds they control. The study is funded as part of an NIHR research programme grant. The Funder has reviewed the programme the research and established that the research is worthwhile, of high scientific quality and represents good value for money. The research funder has assessed the experience and expertise of the Chief Investigator and other key researchers on the programme and has deemed that there is appropriate infrastructure for the research to be carried out.

The funding review process provided feedback on the design of the programme. The funder plays no further role in the design of this individual study and will have no role in data analysis, interpretation or writing up of findings of the study. The funder will be sent all outputs prior to dissemination but has no role in the decision to submit for publication.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Study Management Group
The management group is made up of the CI and collaborators listed under ‘Key Contacts’ in this protocol. This group will oversee the day-to-day running of the cohort studies and will meet regularly throughout the lifetime of the research.

Patient & Public Involvement (PPI) Group
PPI has been and will continue to be central to the optimisation and implementation of the BOOST programme. We have established a diverse community of practice (COP) consisting of physiotherapists from the original BOOST trial, patients who received the BOOST programme in the original trial, physiotherapy managers, clinical commissioners, and clinicians with expertise in symptomatic lumbar spinal stenosis (LSS). This COP has iteratively co-produced the optimised elements of the BOOST programme with the study team. We will continue to utilise this COP to help champion the BOOST programme and establish an impactful implementation strategy. Furthermore, all patient facing materials have been reviewed by our two PPI representatives who supported the original BOOST RCT.

Protocol contributors
Professor Sallie Lamb, Dr Esther Williamson and Dr Helen Richmond-Davies have co-written this protocol. Professor William Henley has provided expertise on the statistical analysis sections of this protocol. Professor Krysia Dziedzic and Dr Laura Swaithes have provided expertise on the theorical framework unpinning the implementation study and will input into the development of the BOOST Massive Online Open Course (MOOC) materials. Dr Chistine Comer and Dave Rogers have provided clinical expertise on the optimisation of the BOOST programme and will input into the development of the BOOST MOOC materials.

Key words: Lumbar spinal stenosis; low back pain; physiotherapy; group education and exercise; cognitive behavioural approach; frailty.

STUDY FLOW CHART

A Gantt chart of activity outlining the timing of study management can be found below, in Table 1. Timings of events may change depending on when approvals are obtained and when sites have capacity around staff holidays over the summer months.

Table 1. Study Gantt chart for stages 1 and 2

	2022							2023									
Activity	**May**	**Jun**	**Jul**	**Aug**	**Sept**	**Oct**	**Nov**	**Dec**	**Jan**	**Feb**	**Mar**	**Apr**	**May**	**Jun**	**Jul**	**Aug**	**Sept**
S1: Therapist Training																	
S1: Deliver BOOST																	
S1: Data collection																	
S1: Therapist interviews																	
S1: Analysis																	
S2 Develop + launch MOOC																	
S2: Deliver BOOST																	
S2: Data collection (therapist and patient)																	
S2: Therapist interviews																	
S2: Analyse + report																	

STUDY PROTOCOL

Evaluating the optimisation and impact of the BOOST programme.

1 BACKGROUND

Neurogenic claudication (NC) is one of the most disabling spinal conditions in older people. Approximately 11% of community dwelling older adults report symptoms consistent with NC (1, 2). It presents as pain, discomfort or other symptoms radiating from the spine into the buttocks and legs, which is provoked by walking or prolonged standing and relieved by sitting or lumbar flexion (3). Other signs and symptoms include weakness, altered sensation, fatigue and gait changes (3). Back pain is common but not always present. The symptoms of NC are thought to arise from pressure on nerves and blood vessels in the spinal canal caused by degenerative changes narrowing the volume of the spinal canal. Narrowing may or may not be evident on imaging (3, 4). When evident, the condition is termed lumbar spinal stenosis (LSS). The burden of symptoms is substantial, affecting an individual's confidence and ability to walk and is associated with adverse health outcomes and reduced quality of life (1, 5, 6).

1.1 Treatment options for people with NC / symptomatic LSS

There are few treatment options for this population. Both surgical interventions and use of medications come with the risk of substantial side-effects (7, 8). Evidence for non-operative care has been reported as low to very low quality, precluding any clinical recommendations from being made (9). Problems include trials with small sample sizes and often short term follow up, interventions focusing on spinal stenosis mechanics with little regard to the psychological impact of pain or aging, and an omission of (i) cognitive behavioural approaches (CBA) to pain management, (ii) behavioural strategies to increase adherence to exercise and (iii) strategies to address age-related issues such a falls or age-related muscle weakness.

1.2 The BOOST randomised controlled trial (RCT)

The BOOST RCT was one of the first trials to explore the effectiveness of group-based education, informed by a CBA, combined with exercise for people with symptomatic LSS (10). The programme consisted of 12 group sessions over 12 weeks with two support phone calls over the following 12 weeks. Content included progressive resistance exercises, balance, and mobility training, along with education about pain and tips on behaviours to enhance pain self-management (11). We found that, compared to best practice advice (up to three sessions with a physiotherapist), the BOOST programme significantly improved walking distance and self-reported walking at 6 and 12 months, and significantly reduced the risk of falling during the 12-month follow-up period (10). In terms of pain, the programme resulted in a modest, statistically significant improvement in the overall Oswestry Disability Index (ODI) at 6 months, with only a minor difference that was not statistically significant between the groups at 12 months. The programme was cost-effective from an both an NHS and personal social service perspective and a wider societal perspective (10).

1.3 The BOOST RCT process evaluation and embedded longitudinal qualitative study

The longitudinal qualitative study and process evaluation provided important insights (papers currently under review). The experience of living with symptomatic LSS was distressing and limiting. Participants highlighted the importance of mobility and the highly unpredictable and disabling nature of their pain, which was described as "attacks" that could leave them unable to move and fearful of walking too far. Participants enjoyed the sociability of the BOOST programme, and many described

increased walking confidence. Once the group sessions finished, some participants experienced a withdrawal effect, and this may explain why the improvements in pain and disability lessened.

1.4 Other emerging evidence

Two recent trials have been published that both tested programmes consisting of structured and progressive exercises to improve trunk and lower limb mobility, strength, and fitness (12, 13). Participants also received manual therapy treatment to increase spinal movement. The Ammendolia programme is most like the BOOST programme, including a CBA for pain management and a structured walking programme delivered over 12 sessions (12). Compared to self-directed exercise (one session), the intervention programme resulted in lasting improvements in walking, providing further support for implementing these types of programmes. The Schneider programme did not have a focused walking element or use a CBA (13). This study found no difference in walking between the 6-week experimental arm and control arm of medical care, suggesting these elements are important to achieve walking improvements.

2 RATIONALE

This is a challenging time for implementing interventions, however, the NHS is experiencing substantial demand for orthopaedic procedures, and for many older people whose mobility is deteriorating, a conservative treatment will have a strong place in the offerings the NHS can make. While we consider the BOOST programme worthwhile for implementation in its original format, optimisation is identified as an important element of the MRC complex intervention pathway, including during the final implementation of an intervention (14). Based on feedback from qualitative interviews, PPI representatives and clinicians, data from mediation analyses, and a review of the current literature, we have optimised BOOST to improve its effect on pain related disability and to help participants make a transition to long-term exercise.

We will evaluate the optimised BOOST programme to ensure it is feasible to deliver and clinically effective prior to implementing and evaluating the programme more broadly. Thus, this protocol describes a two-stage approach to implementation:

Stage 1

During stage 1 we have established a community of practice (COP) consisting of PPI representatives, physiotherapists, and other stakeholders, who have worked with us to iteratively optimise the BOOST programme for implementation. We will now evaluate this optimised programme in a prospective cohort with 4 sites and a minimum of 24 patients, collecting outcomes at baseline and 6 months. Three sites will deliver the programme in the NHS and one site will deliver the programme in the community utilising a community provider. We will use a synthetic control method to evaluate the probability that the optimisation has improved the intervention. We will interview the therapists to explore their experiences of implementing the optimised programme.

Stage 2

For stage 2, we will launch a Massive Online Open Course (MOOC), hosted by FutureLearn, to provide physiotherapists and other care providers with the knowledge, skills, and motivational framework to implement the optimised BOOST programme in their own regions and settings. In stage 2, we will conduct a second prospective cohort study to evaluate participant learning outcomes and implementation intentions after completing the MOOC. We will also evaluate patient outcomes from the BOOST programme when delivered in routine practice with at least 10 therapists and 60 patients. Therapists can be from NHS sites that participated in stage 1, providing they are naive to the BOOST

programme prior to completing the BOOST MOOC. We will interview the 10 therapists to explore their experiences of implementing BOOST following training via the MOOC.

3 THEORETICAL FRAMEWORK

The integrated Promoting Action on Research Implementation in Health Services (i-PHARiS) framework, a knowledge mobilisation theory, will guide this study (15). This framework will guide four key elements: the context, recipients, facilitation, and the innovation. A theoretically informed approach is advocated to develop and explain findings and plan future implementation (14). The i-PARIHS framework was selected as being particularly relevant to this research due to the prominent focus on context, which we have previously highlighted to be important in the implementation of evidence based musculoskeletal practice (15).

4 RESEARCH QUESTION/AIM(S)

4.1 Aims

Stage 1

Stage 1 aims to evaluate the feasibility and effectiveness of the optimised BOOST programme in relation to the results from the BOOST RCT.

Stage 2

Stage 2 aims to i) develop and launch the BOOST MOOC and assess therapist learning and implementation outcomes and ii) evaluate patient outcomes in a subset of learners that commit to implementing the BOOST programme, to ensure outcomes are the same or better than the original BOOST programme.

4.2 Objectives

For stage 1, the primary objective is to evaluate the effect of optimising the BOOST programme on walking capacity as measured by the ODI walking item and the 6-minute walk test. Our primary objective for stage 2 is to again evaluate the effect of the BOOST programme on walking capacity, as measured by the ODI walking item and the 6-minute walk test, when delivered by therapists that have received the BOOST training online via the BOOST MOOC.

Secondary objectives are to:

- Evaluate the effect of the optimised BOOST programme on patient reported pain-related disability, quality of life, physical activity, and satisfaction (stage 1 and 2).
- Interview the therapists delivering the optimised BOOST programme to explore their experiences. The exact number of interviews will depend on the number of staff delivering each group (estimated number: 5).
- Evaluate learning outcomes and implementation intentions on completion of the BOOST MOOC.
- Evaluate therapist self-reported implementation outcomes 6 months after completion of the BOOST MOOC.
- Interview the therapists who have delivered the BOOST programme after completing training via the BOOST MOOC to understand their experiences (estimated number: 10).

5 STUDY INTERVENTION

5.1 The BOOST Programme

The BOOST programme has been published in detail (11) 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 MOOC.

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.

5.2 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 COP. 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.

6 STUDY DESIGN AND METHODS OF DATA COLLECTION AND DATA ANALYIS

Two sequential longitudinal implementation cohort studies with embedded qualitative interview studies. BOOST-IS assesses change in patient reported outcome measures after receiving the BOOST programme, as well as ascertaining the effectiveness and impact of the BOOST MOOC on knowledge and implementation of the BOOST programme.

6.1 Data Collection

Patient participants

A reduced set of outcome measures from the original BOOST RCT will be used to evaluate the effect of implementation on patient outcomes (Table 1). Participants will complete a baseline questionnaire consisting of demographic information (age, sex, ethnicity, household income, education attainment, place of residence, marital status, and employment status), medication use, co-morbidities and patient reported outcomes (Oswestry Disability Index (ODI), Health-related quality of life (EQ-5D-5L), 4-items from the CSEP-PATH: Physical activity and sedentary behaviour questionnaire (PASB-Q), and a single item question on how troublesome their symptoms have been). The therapist will also complete the 6-minute walk test at baseline and record this in the participant's baseline questionnaire. Participants will attend an additional clinic appointment at 6 months to complete a follow-up questionnaire consisting of patient reported outcomes (ODI, EQ-5D-5L, 4 items from the PASB-Q, a single item question on how troublesome their symptoms have been, and an 8-item satisfaction questionnaire). The therapist will repeat the 6-minute walk test and record this in the participant's follow-up questionnaire.

In addition, we will collect an objective measure of activity over time, utilising a CE marked wrist worn accelerometer provided by the Activity Informatics team at the University of Exeter. The research device is a black 'watch' and does not present any data to participants. Participants will wear the device for 16 days to capture two weekends at baseline and at the 6-month follow-up timepoint. Participants will receive the wearable via post, along with instructions on how to wear it and how to return it in the pre-paid envelope provided. While using the device, participants will complete an activity log to record i) the date they put the device on, ii) the date they removed the device, iii) details of why they have removed the device for any period during the 16 days and for how long, and iv) to facilitate accuracy of the data analysis, the time they went to sleep and woke up. Assessment time points are outlined in Table 2.

Table 2: Patient participant outcomes and assessment time points

	Timepoint	
Stages 1 and 2	**Baseline**	**6-months follow-up**
Informed consent	**x**	
Demographics	**x**	
Medications and co-morbidities	**x**	
ODI	**x**	**x**
EQ-5D-5L	**x**	**x**
PASB-Q	**x**	**x**
6-minute walk test	**x**	**x**
10-point managing symptoms item	**x**	**x**
Satisfaction		**x**
Single item physical activity question		**x**
Activity over 16 days (wearable)	**x**	**x**
Activity log	**x**	**x**
Sleep efficiency	**x**	**x**

Therapist participants

All therapist data will be collected during stage 2 using JISC online surveys. Therapist demographics will be collected prior to starting the BOOST MOOC and will include name, email, sex, age, occupation, professional qualification, work setting, years of experience treating symptomatic LSS patients and average number of patients treated per month (if applicable). We will collect learning

outcomes and implementation intentions online at the end of the BOOST MOOC. Learning outcomes include self-reported course completion, perceived confidence (in their own ability) and capability (given wider external factors such as necessary space and equipment) to deliver the BOOST programme. Implementation outcomes align with the taxonomy proposed by Proctor et al (16) and include implementation intention (Adoption), satisfaction with the training (Acceptability) and potential barriers to implementation (Appropriateness) and actual use in practice (Adoption). Therapists will be emailed a link to a brief follow up questionnaire by the study team 6 months after completing the baseline assessment to assess additional implementation outcomes. We will again ask participants about self-reported course completion and actual use in practice (Adoption as well as asking them about the number of BOOST sessions delivered (Fidelity), perceived patient satisfaction with the BOOST programme (Acceptability), perceived clinical usefulness of the BOOST programme, helpful and unhelpful aspects of the BOOST programme with regards to implementation, and reasons for non-implementation (Appropriateness). Outcomes and timepoints are detailed in Table 3.

Table 3: Therapist participant outcomes and assessment time points

	Timepoint		
Stage 2	**Start of MOOC**	**On completion of MOOC**	**6 months from MOOC enrolment**
Informed consent	**x**		
Therapist demographics	**x**		
Course completion		**x**	**x**
Satisfaction with training		**x**	
Confidence to deliver the BOOST programme		**x**	**x**
Capability to deliver the BOOST programme		**x**	**x**
Implementation intention		**x**	**x**
Potential barriers to implementation		**x**	**x**
Actual use in practice		**x**	**x**
Perceived patient satisfaction			**x**
Number of BOOST programme cycles delivered			**x**
Perceived clinical usefulness of BOOST			**x**
Helpful / unhelpful aspects of BOOST			**x**
Reasons for non-implementation			**x**

Interview study

Therapist interviews in stages 1 and 2 will follow a semi-structured format. As per standard practice, these interviews will be guided by a pre-specified set of open-ended questions, allowing the use of interviewer prompts to further investigate participant responses, and allow the participant the scope to explore additional areas of the topic they feel relevant to their situation (17, 18). The interview guide will be informed by two frameworks: i) the integrated Promoting Action on Research Implementation in Health Services (i-PHARiS) and ii) the Theoretical Domains Framework (TDF) (15, 19). We will conduct interviews via MS Teams, use audio-visual recording and automated transcription. Interviews will be conducted at a convenient time for the participants, as close to the completion of the BOOST group sessions as possible.

Intervention fidelity

To ensure that the optimised BOOST programme is being delivered as intended, a BOOST study researcher will observe at least one individual and group treatment session at each site. An intervention checklist will be used to ensure that key session components have been delivered and feedback will be provided to the therapist where applicable. Additionally, we will collect the anonymised BOOST individual session logs, attendance and exercise logs, and phone call logs, to understand how the BOOST programme was delivered.

6 SAMPLE AND RECRUITMENT

Patient participants

7.1 Eligibility Criteria

Patients with symptomatic LSS.

7.1.1 Inclusion criteria

- Able to give informed consent
- Aged 65 years and over
- Symptoms include:
    - 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.
    - Standing or walking makes symptoms in the buttocks or legs worse.
    - Sitting or bending forward relieves symptoms.

Feedback from our COP members highlighted that insufficient numbers, or an inconsistent flow, of patients with symptomatic LSS, can result in long delays for the commencement of the group-based sessions. Thus, being pragmatic and cognisant of these important considerations, in stage 2 we will allow sites the flexibility to offer the BOOST programme to other older populations with back pain where the responsible therapist feels it would benefit the patient. In this situation, the same exclusion criteria would still apply, helping to ensure the patient is suitable for the group-based programme. These patients would still be invited to participate in the research study, completing the baseline and follow-up assessments.

7.1.2 Exclusion criteria

The participant may not enter the cohort study if ANY of the following apply:

- Nursing home resident.
- Inability to walk 3 meters independently.
- Awaiting surgery.
- Cauda equina syndrome or signs of serious pathology.
- Cognitive impairment (where applicable, the assessing physiotherapist will complete the Abbreviated Mental Test score, where the patient will need to score more than 6).
- Registered blind.
- Unable to follow instructions in a group setting.

Therapist participants

7.1.3 Inclusion Criteria

- Be either a qualified a health professional or a level 4 exercise therapist.
- Provide treatment (or plan to provide treatment in the near future) to patients with symptomatic lumbar spinal stenosis.

- Be based in the UK.
- 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).
- Aged 21 years and over.

7.1.4 Exclusion Criteria

- Not meeting the inclusion criteria.

7.2 Recruitment

Stage 1

Site recruitment

All physiotherapists who took part in the BOOST RCT will be contacted via email to inform them about an opportunity to participate in stage 1 and/or stage 2 of the BOOST programme optimisation and implementation. If this does not result in 4 NHS sites for stage 1, we will seek additional new sites (that did not participate in the BOOST RCT) based on our clinical networks. For 3 of the NHS sites, the BOOST programme will be delivered within the NHS as it was in the original RCT. For the forth NHS site, the BOOST programme will be delivered in the community with a local provider who has a good existing relationship with the NHS Trust.

We will conduct semi-structured interviews with all the therapists (n=4) delivering the optimised BOOST programme to understand the impact of the changes made to the programme.

Patient participant recruitment

Potentially eligible patients will be identified either from (i) physiotherapy waiting lists or (ii) from an initial consultation with a physiotherapist. Where identified from a waiting list, the patient will be sent the patient information sheet via post or email, depending on their preference, with a follow up phone call to ascertain if the patient would be interested in taking part. Where identified in an initial consultation with a physiotherapist, the physiotherapist will screen the patient for eligibility and provide the patient information sheet to the patient. Depending on the set up at each site, either a research physiotherapist in the NHS physiotherapy outpatient department, or the physiotherapist who conducted the initial consultation with the patient, will consent patients for the study, complete the study enrolment form (containing the participants contact details) and carry out the baseline assessment. For the site where BOOST will be delivered in the community, participants will be booked an individual appointment with the community provider to complete their baseline outcome measures and receive the first individual BOOST session. While the programme is running in the community, the referring physiotherapist will hold a consulting role, supporting the community provider as and when needed.

Stage 2

Therapist participant recruitment

Therapists who manage (or plan to manage) patients with symptomatic LSS in the UK will be invited to participate in a soft launch of the BOOST MOOC. This will not be publicly available, and therapists will need to agree to participate in the cohort study to gain access to it. We will target a minimum of 30 therapists and will recruit them through special interest groups and networks, conferences, University of Exeter, Keele and Oxford research group contact lists, Applied Research Collaboration regional websites, social media platforms, and personal contacts. Interested therapists will be asked to contact the BOOST study team to express their interest. Interested therapists will be sent a link to a webpage containing a participant information sheet, consent form and a baseline questionnaire prior to enrolment in the course. After providing informed consent and completing the baseline questionnaire, therapists

will be sent a link to enrol in the BOOST MOOC with instructions on how to create an account on FutureLearn. Once enrolled, therapists will have full access to the BOOST MOOC content. Therapists will be asked to complete the course within a six-week period from the date of registration.

Therapists who have completed the BOOST MOOC will be invited to participate in a cohort study to evaluate patient outcomes. We will target 10 NHS sites. Site can choose to deliver the BOOST programme within an NHS setting or to partner with a community provider for the delivery of the BOOST programme.

We will email the first 10 therapists to deliver the optimised BOOST programme in their practice to invite them to participate in a semi-structured interview.

Patient participant recruitment
Patient recruitment and study procedures are the same as those described in stage 1 above.

7.3 Consent
Stage 1 and 2: Patient Participants
The consent process will vary by site, depending on local staff and procedures. Patients will with be sent a patient information sheet by post or email or, provided with one during their initial consultation with a physiotherapist in clinic. With either route, written and verbal versions of the PIS and informed consent form (ICF) will be presented to patients detailing the exact nature of the cohort study, what it will involve for the patients, and how their data will be handled. Where patients have been sent the PIS via post/email, the departmental research physiotherapist or other member of the patient's clinical team will call them to discuss the PIS and answer any questions.

It will be clearly stated that the participant is free to withdraw from the cohort study at any time, for any reason, without prejudice to future care, and with no obligation to give the reason for withdrawal. Data contributed to the study up until the point of withdrawal will remain with the study group, unless stated by the withdrawing participant.

A copy of the signed ICF will be given to the participant, and one copy will be sent to the BOOST study team. The original signed form will be retained by the site in the Investigator Site File and a copy placed in the participant's medical notes. The participant's GP will be sent a letter by the study team, informing them of the participant's involvement in the cohort study.

Stage 1 and 2: Therapist Participants
Interviews
Therapists will be sent an invitation to take part in an online interview via an email containing the PIS and ICF. The PIS clearly states the nature of the study and that they are free to withdraw at any time, for any reason, and with no obligation to give a reason for withdrawal. Therapists will be offered the opportunity to ask any questions using the contact information provided. Interviews will be conducted via MS Teams and will be audio-video recorded and automatically transcribed. Those willing to take part will be asked to sign and return their consent form via email. On commencement of the interview, verbal consent will also be taken.

MOOC evaluation
Therapists expressing an interest in the BOOST MOOC will be emailed a link to a webpage containing the PIS and ICF, detailing the exact nature of the cohort study and informing them that their data will be shared with the BOOST study team. It will be clearly stated that the participant is free to withdraw from the cohort study at any time, for any reason, and with no obligation to give a reason for withdrawal. Data

contributed to the study up until the point of withdrawal will remain with the study group, unless stated by the withdrawing participant.

8 STATISTICS AND ANALYSES

8.1 Sample Size

Stage 1

We will recruit a minimum of 24 participants and 3 therapists from NHS sites, and a minimum of 6 participants and 1 therapist from a community provider linked to an NHS Trust.

Stage 2

We will recruit a minimum of 60 patients and 10 therapists.

8.2 Data Analysis

Outcome hierarchy

Primary outcomes: ODI walking item and the 6-minute walk-test

Secondary outcomes listed in order of priority: ODI standing item, ODI pain item, ODI overall, followed by all remaining outcome measures.

Stage 1

We will use a synthetic control method to evaluate the probability that the optimisation has improved the intervention (20). Synthetic controls are a method of using historical control data, and contemporary data on the natural history of a condition, to form the counterfactual element needed to draw inferences on the improvement cycles. The counterfactual state is one which estimates what would happen if the improvements were not made, or no intervention was made. The rich data set from the BOOST trial will allow us to create a counterfactual that accounts for context, and to draw a comparison with the BOOST group intervention as well as a comparison to the control arm of the BOOST trial (best practice advice).

Two different analytical approaches will be used to enable synthetic control comparisons. First, propensity score methods will be employed to balance measured covariates at baseline between the group receiving the optimised programme and the control arm of the BOOST trial (21). We will consider a broad list of demographic and baseline clinical characteristics as covariates. The effectiveness of the optimised intervention will be estimated in generalised linear mixed models for the study outcome measures with inverse probability of treatment weighting (IPTW) on the propensity score (PS). Previous studies have shown that IPTW can produce valid estimates of treatment effects in small samples if relevant confounders are included in the PS model, but sensitivity analyses will be conducted to explore the impact of model specification and missing data (22). Random effects will be included to account for any heterogeneity in response due to the recruitment centre. As a second approach, Bayesian hierarchical linear models will be used to compare the optimised intervention to each arm of the BOOST trial, with commensurate and power priors to determine the degree of borrowing of information from the historical trial data. Models will be adjusted for key baseline characteristics to account for measured confounders (23). We will guard against baseline differences generating confounded effect estimates by recruiting in a similar way to the original trial and ensuring a representative population.

Evidence from the counterfactual analyses will help inform assessment of whether the improvements in the intervention should be accepted. An attraction of the Bayesian framework is that it provides a

basis for making direct probability statements about whether a greater proportion of people achieve clinically significant outcomes in pain and walking with the improvements.

Data from the wrist worn accelerometer will be merged into the study dataset with all other participant outcome measures and will be included in the statistical modelling detailed above. We will also report descriptive summaries of all participant outcome measures.

Final decisions
Using data from a relatively smaller number of participants will not be definitive but will be reasonable to inform clinical practice. If our estimates from the propensity score analysis demonstrate that the point estimate of the optimised intervention is lying within the upper half of the distribution of the confidence interval of the original trial, we will take that as a positive marker. We will also consider the estimated posterior probability that the optimised intervention has improved outcomes from the Bayesian analysis and accept the new intervention if this is above 50%. If this probability estimate is below 50% or the point estimate from the propensity score analysis is lying below the original lower limit, then we will continue with the original intervention. If the two analyses diverge, the Bayesian approach will be taken as the primary analysis as it will be more sensitive. We will use qualitative interviews from the therapists delivering the optimised programme to determine whether the changes are manageable and appear effective. We will triangulate this data.

Stage 2: patient participant outcomes
We will collect outcome data from a minimum of 60 participants and follow the same data analysis plan as described for Stage 1. For implementation to be deemed successful and be launched widely via the FutureLearn BOOST MOOC, using comparison to the synthetic controls from the original trial, the benchmark will be that the estimates of changes in pain-related disability and walking are not significantly worse than the original trial.

Stage 2: therapist participant outcomes
Data will be analysed descriptively using IBM SPSS Statistics, version 28.0.1.0. Cases with missing values will excluded using listwise deletion. Free text responses will be coded using the TDF.

Interview studies (stage 1 and 2)
The interview studies in stage1 and 2 are separate studies but will follow the same analysis methods. Data will be analysed using framework methodology. The first stage of analysis is familiarisation of the raw data, listening to audiotapes and reading transcripts, to identify key ideas and recurrent themes (18). Data will then be coded and charted into a matrix under the four constructs of the Promoting Action on Research Implementation in Health Services (i-PHARIS) framework (context, innovation features, individual characteristics, and implementation processes) (15). Charting refers to the rearrangement and summarisation of data, with each column being a theme (i-PHARIS construct) and each row being a case (therapist interviewed) (18). To provide further granularity, data within each of the i-PHARIS constructs will be independently categorised by two members of the research team into determinants of behaviour change using the Theoretical Domains Framework (TDF) (19). The TDF consists of a set of 14 domains covering the main factors believed to influence clinicians' behaviour change, for example, knowledge, skills, beliefs about capabilities, beliefs about consequences, optimism, and professional identity (19). This framework has been well validated and applied successfully in both primary and secondary care contexts (24, 25). Any differences in coding will be resolved through discussion between the two researchers.

9 ETHICAL AND REGULATORY CONSIDERATIONS

9.1 Declaration of Helsinki and Guidelines for Good Clinical Practice

The investigator will ensure that this study is conducted in accordance with the principles of the declaration of Helsinki, any relevant regulations and that the study is consistent with the guidelines for good clinical practice (last amended Fortaleza, Brazil, October 2013).

9.2 Assessment and management of risk

9.2.1 Serious Adverse Events

A serious adverse event is any untoward medical occurrence that:

- Results in death
- Is immediately life-threatening
- Requires hospitalisation or prolongation of existing hospitalisation
- Results in persistent or significant disability or incapacity
- Is a congenital abnormality or birth defect

Other ‘important medical events’ may also be considered serious if they jeopardise the participant or require an intervention to prevent one of the above consequences.

NOTE: The term "life-threatening" in the definition of "serious" refers to an event in which there was a 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.

9.2.2 Adverse Events

Serious adverse events are likely to be very rare and highly unlikely to occur as a result of the exercise programme being delivered in this cohort study.

Given the age range of the study population and the nature of physical interventions, foreseeable occurrences (adverse events) that may occur during the study period which do not require specific time critical reporting, but may be collected as part of standard data collection are (refs):

- acute infections (e.g. viral)
- medical instability (e.g. diabetic control – becomes hypoglycaemic, deterioration in control of heart failure)
- vestibular disorders and stroke
- fall-related injuries

However, if any of the above occur as the result of an incident during, or within two hours of completing, the exercise sessions or follow-on physical activities or are related to the intervention and categorised as an SAE according to 9.2.1, then they should be reported to the BOOST-IS Team as a suspected SAE as per section 9.2.3.

It is likely that participants taking part in an exercise programme may experience:

- transient increases in symptoms of neurogenic claudication (≤ 72 hours)
- delayed onset of muscle soreness (≤ 72 hours)

If either of these do not resolve in 72 hours, are assessed as being related to the study intervention, and are categorised as an SAE according to 9.2.1, then they should be reported to the BOOST-IS

Team as a suspected SAE as per section 9.2.3. Under these conditions, these events will be considered as unexpected, since they are more severe and longer lasting than what is expected.

9.2.3 Reporting Procedures for Serious Adverse Events
Serious adverse events (SAEs) which occur as the result of an incident during, or within two hours of completing, the exercise sessions or follow-on physical activities, and are considered related to the study, will be reported in a pre-defined and time-critical process. The site PI or delegated team member must assess causality of any suspected SAEs and report them to the BOOST-IS Team within 24 hours of becoming aware of the event, using the Serious Adverse Event Form for non-CTIMPs. Completed forms will be scanned and emailed to the BOOST-IS Team, who will assess causality and expectedness, and ensure that all SAEs are followed up to resolution. Any unexpected SAE which is deemed related to the study interventions will be reported to the REC that gave a favourable opinion of the study by the BOOST-IS Team within 15 working days of the Chief Investigator becoming aware of the event, using the Health Research Authority (HRA) report of serious adverse event form (see HRA website).

9.3 Research Ethics Committee (REC) and other Regulatory review & reports
Before the start of the study, a favourable opinion will be sought from the UK Health Departments Research Ethics Service (NHS REC and HRA assessment) for the study protocol, informed consent forms and other relevant documents. We will ensure that:

- Substantial amendments requiring review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at site.
- All correspondence with the REC will be retained.
- The Chief Investigator will notify the REC of the end of the study.
- The CI shall submit, on request, an Annual Progress report to the REC Committee, host organisation and Sponsor.
- If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination.
- Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

9.3.1 Regulatory Review & Compliance
Before any site can enrol patients into the study, we will ensure that appropriate approvals from participating organisations are in place. For any amendment to the study, we will, in agreement with the sponsor, submit information to the appropriate body in order for them to issue approval for the amendment. We will work with sites (R&D departments at NHS sites as well as the study delivery team) so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

9.3.2 Amendments
The Investigator will submit and, where necessary, obtain approval from the Research Ethics Committee and Sponsor for all substantial amendments to the original approved documents. It is the sponsor's responsibility to decide whether an amendment is substantial or non-substantial for the purposes of submission to the REC.

9.4 Patient & Public Involvement

PPI has been and will continue to be central to the optimisation and implementation of the BOOST programme. We have established a diverse community of practice (COP) consisting of physiotherapists from the original BOOST trial, patients who received the BOOST programme in the original trial, physiotherapy managers, clinical commissioners, and clinicians with expertise in symptomatic lumbar spinal stenosis (LSS). This COP has iteratively co-produced the optimised elements of the BOOST programme with the study team. We will continue to utilise this COP to help champion the BOOST programme and establish an impactful implementation strategy. Furthermore, all patient facing materials have been reviewed by patients in this COP.

9.5 Protocol compliance

Accidental protocol deviations can happen at any time. They must be adequately documented on the relevant forms and reported to the Chief Investigator and Sponsor immediately. Deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach.

9.6 Data protection and participant confidentiality

9.6.1 Participant confidentiality

The study staff will ensure that participants' anonymity is maintained. Participants will be identified by a unique personal identification (ID) code on all outcome measures and in any electronic database holding study data. Participants will not be named on the qualitative interview transcripts and care will be taken to remove any identifying information given in interviews.

All documents will be stored securely at the University of Exeter study offices and only accessible by study staff and authorised personnel. The study will comply with the Data Protection Act and any personal details (e.g. addresses for posting follow-up questionnaires) held by the study team will be stored separately from any participant study data. All study data will only be accessed by authorised personnel. The consent form includes consent for this data to be held. Data linking participants with their unique ID will be stored in separate locations using encrypted digital files with password protected folders.

For the activity informatics team at the University of Exeter to send the wrist worn accelerometer to patient participants at baseline, the BOOST study team will send them a link to a file on OneDrive that contains the participants name and postal address. The activity informatics team will write the details on the envelopes for posting and will then email the BOOST study team to confirm that the data has been received. The link to the OneDrive file will then be removed. We will repeat this process to send the accelerometers to participants at the 6-month follow-up time point.

9.6.2 Data processing

The Chief Investigator (CI) will be responsible for the management of the research data throughout the life of the project. Local Principal Investigators at each institution will be responsible for research data management at that institution. The CI will have overall responsibility for data management. Documentation from the cohort studies will be retained for 5 years after completion of cohort-related activities. Collaborating sites are delegated the responsibility of archiving local essential documents (including the Investigator Site File) in an appropriate secure environment. The study team will archive all documents according to University of Exeter policy. A master copy of the data will be stored. No analysis will be run on this copy so if the working copy gets corrupted, lost or becomes unusable we will be able to create an identical working copy. Only fully anonymised data will be shared at the end of the

project.

Patient participants
We will ask the therapist delivering the BOOST programme to scan and email the study enrolment form (containing the participants contact details), consent form and the baseline/follow-up questionnaire (PROM and 6MWT) to the study team's secure NHS email. These will be stored in the University's Research Data Storage (RDS) platform, a large object store that replicates across three sites allowing for high resilience and reliability. Data will be inputted into Excel files stored on the University's RDS platform. We will double check ten percent of data for errors. If a participant does not attend their 6-month follow-up appointment and is therefore unable to complete the outcome measures, the study team will post these to the participant along with a self-addressed, pre-paid envelope. On return, these will be scanned and stored on the same secured network drive, with the paper copies securely destroyed. Files will only be accessed by designated members of the study team.

Data from the original BOOST RCT that will be used to generate the synthetic controls will also be stored on the University's RDS secure platform.

Data from the wrist worn accelerometer is stored locally on the device. On receipt of the devices return, the activity informatics team at the University of Exeter will transfer data from the device to their research grade, secure cloud server. Once analysed, the activity informatics team will transfer the pseudo-anonymised output files to the BOOST study team using the University's secure OneDrive. These files will then be downloaded into the University's RDS storage and merged with the remaining study data by the study's statistician. The anonymised monitoring log that participants return with their wrist worn accelerometer will be used to facilitate data analysis by the activity informatics team and will be stored securely in locked filing cabinets at the University of Exeter.

Therapist participants
Data from the BOOST MOOC evaluation will be collected using JISC online surveys. Each participant will have a unique ID that links their anonymised survey responses. Data will be downloaded from JISC and stored securely in the University's RDS platform. Files will only be accessed by designated members of the study team.

Therapist interviews will be conducted on MS Teams and will be audio-video recorded and automatically transcribed. These files will be automatically downloaded to the University of Exeter's cloud-based storage solution (OneDrive) and will be manually moved onto the University's RDS platform for secure storage.

9.7 Indemnity
The University of Exeter maintains public liability and professional liability insurance which will operate in this respect. NHS indemnity operates in respect of the clinical treatment that is provided.

9.8 Access to the final study dataset
The CI, along with the collaborators listed in this protocol, will have access to the full dataset where necessary.

9.9 Expenses and Benefits
No payments will be made to individuals for their participation this research.

10 DISSEMINATION POLICY

10.1 Dissemination policy

The data from this study will be owned by the University of Exeter. On completion of the study, the data will be analysed and tabulated, and a Final Study Report prepared. This report will be available from the repository at the University of Exeter and publicly in line with the funder's requirements. We will also publish this work in one or more publications in peer reviewed journals. Any of the investigators listed on this protocol will be able to publish from the study data. We will write to patient participants at the end of this study to inform them of the results. 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.

10.2 Authorship eligibility guidelines and any intended use of professional writers

The BOOST study team at the University of Exeter will be involved in reviewing drafts of manuscripts, abstracts, press releases and any other publications arising from the cohort studies. Authorship will be determined in accordance with the ICMJE guidelines. Funders and other contributors will be acknowledged in all publications of this work.

11 REFERENCES

1. Williamson E, Sanchez Santos MT, Morris A, Garrett A, Conway O, Boniface G, et al. The Prevalence of Back and Leg Pain and the Cross-sectional Association With Adverse Health Outcomes in Community Dwelling Older Adults in England. Spine (Phila Pa 1976). 2021;46(1):54-61.
2. Ishimoto Y, Yoshimura N, Muraki S, Yamada H, Nagata K, Hashizume H, et al. Prevalence of symptomatic lumbar spinal stenosis and its association with physical performance in a population-based cohort in Japan: the Wakayama Spine Study. Osteoarthritis Cartilage. 2012;20(10):1103-8.
3. Suri P, Rainville J, Kalichman L, Katz JN. Does this older adult with lower extremity pain have the clinical syndrome of lumbar spinal stenosis? JAMA. 2010;304(23):2628-36.
4. de Schepper EI, Overdevest GM, Suri P, Peul WC, Oei EH, Koes BW, et al. Diagnosis of Lumbar Spinal Stenosis: An Updated Systematic Review of the Accuracy of Diagnostic Tests. Spine (Phila Pa 1976). 2013;38(8):E469-E81.
5. Battié MC, Jones CA, Schopflocher DP, Hu RW. Health-related quality of life and comorbidities associated with lumbar spinal stenosis. Spine J. 2012;12(3):189-95.
6. Winter CC, Brandes M, Müller C, Schubert T, Ringling M, Hillmann A, et al. Walking ability during daily life in patients with osteoarthritis of the knee or the hip and lumbar spinal stenosis: a cross sectional study. BMC Musculoskelet Disord. 2010;11:233.
7. Zaina F, Tomkins-Lane C, Carragee E, Negrini S. Surgical versus non-surgical treatment for lumbar spinal stenosis. The Cochrane database of systematic reviews. 2016(1):Cd010264.
8. Jensen RK, Harhangi BS, Huygen F, Koes B. Lumbar spinal stenosis. BMJ. 2021;373:n1581.
9. Ammendolia C, Stuber KJ, Rok E, Rampersaud R, Kennedy CA, Pennick V, et al. Nonoperative treatment for lumbar spinal stenosis with neurogenic claudication. The Cochrane database of systematic reviews. 2013;8:CD010712.
10. Williamson E, Boniface G, Marian IR, Dutton SJ, Garrett A, Morris A, et al. The Clinical Effectiveness of a Physiotherapy Delivered Physical and Psychological Group Intervention for Older Adults With Neurogenic Claudication: The BOOST Randomized Controlled Trial. The Journals of Gerontology: Series A. 2022.
11. Ward L, Williamson E, Hansen Z, French DP, Boniface G, Rogers D, et al. Development and delivery of the BOOST (Better Outcomes for Older adults with Spinal Trouble) intervention for older adults with neurogenic claudication. Physiotherapy. 2019;105(2):262-74.
12. Ammendolia C, Côté P, Southerst D, Schneider M, Budgell B, Bombardier C, et al. Comprehensive Nonsurgical Treatment Versus Self-directed Care to Improve Walking Ability in Lumbar Spinal Stenosis: A Randomized Trial. Arch Phys Med Rehabil. 2018;99(12):2408-19.e2.
13. Schneider MJ, Ammendolia C, Murphy DR, Glick RM, Hile E, Tudorascu DL, et al. Comparative Clinical Effectiveness of Nonsurgical Treatment Methods in Patients With Lumbar Spinal Stenosis: A Randomized Clinical Trial. JAMA Netw Open. 2019;2(1):e186828.
14. O'Cathain A, Croot L, Duncan E, Rousseau N, Sworn K, Turner KM, et al. Guidance on how to develop complex interventions to improve health and healthcare. BMJ Open. 2019;9(8):e029954.
15. Swaithes L, Dziedzic K, Finney A, Cottrell E, Jinks C, Mallen C, et al. Understanding the uptake of a clinical innovation for osteoarthritis in primary care: a qualitative study of knowledge mobilisation using the i-PARIHS framework. Implement Sci. 2020;15(1):95.
16. Proctor E, Silmere H, Raghavan R, Hovmand P, Aarons G, Bunger A, et al. Outcomes for Implementation Research: Conceptual Distinctions, Measurement Challenges, and Research Agenda. Administration and Policy in Mental Health and Mental Health Services Research. 2011;38(2):65-76.
17. Britten N. Qualitative Research: Qualitative interviews in medical research. BMJ. 1995;311(6999):251-3.
18. Green J, Thorogood N. Qualitative methods for health research: sage; 2018.
19. French SD, Green SE, O'Connor DA, McKenzie JE, Francis JJ, Michie S, et al. Developing theory-informed behaviour change interventions to implement evidence into practice: a systematic approach using the Theoretical Domains Framework. Implementation Science. 2012;7(1):38.
20. Thorlund K, Dron L, Park JJH, Mills EJ. Synthetic and External Controls in Clinical Trials - A Primer for Researchers. Clin Epidemiol. 2020;12:457-67.
21. Austin PC. An Introduction to Propensity Score Methods for Reducing the Effects of Confounding in Observational Studies. Multivariate Behav Res. 2011;46(3):399-424.

22. Pirracchio R, Resche-Rigon M, Chevret S. Evaluation of the propensity score methods for estimating marginal odds ratios in case of small sample size. BMC Med Res Methodol. 2012;12:70.
23. Hobbs BP, Carlin BP, Mandrekar SJ, Sargent DJ. Hierarchical commensurate and power prior models for adaptive incorporation of historical information in clinical trials. Biometrics. 2011;67(3):1047-56.
24. Cane J, O'Connor D, Michie S. Validation of the theoretical domains framework for use in behaviour change and implementation research. Implementation Science. 2012;7(1):37.
25. Atkins L, Francis J, Islam R, O'Connor D, Patey A, Ivers N, et al. A guide to using the Theoretical Domains Framework of behaviour change to investigate implementation problems. Implementation Science. 2017;12(1).

12. APPENDICIES

12.1 Appendix 1- Required documentation

Local documentation required prior to initiating a participating site: CVs of the research team, Patient Information Sheet (PIS) and consent form (ICF) on headed paper.

12.2 Appendix 2 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made