

Better Outcomes for Older People with Spinal Trouble (BOOST) Research Programme

Background

Low back pain (LBP) is now recognised as the leading disabling condition in the world. LBP is a highly variable condition, with many different causes and patterns of presentation. Over 70% of people will suffer with LBP in their lifetime, and the chance of having the most serious forms of LBP is greatest in later life. LBP is associated with mobility decline and falls in older people, and in turn, loss of independence and frailty. Conversely, this is the time in life when GPs and patients are least likely to target LBP for treatment. The reasons are complicated. In later life people are much more likely to have other health conditions which they think are a greater priority for treatment. Some older people just grin and bear the pain accepting it as part of ageing. GPs and older people may not recognise the importance of LBP to the development of frailty and decline in later life. 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. We suspect older people respond and react differently to the common treatments for LBP.

Research Objectives

There are 2 parts to this programme of research.

1. The Oxford Pain, Activity and Lifestyle (OPAL) Cohort study:
 - We will conduct a primary care survey of 4000 older people to identify the role of LBP in determining important health outcomes in older adults. Outcomes of interest are falls, the development of frailty and disability and loss of mobility.
 - We hope to improve the primary care management of LBP in older people by developing a prognostic tool to identify when LBP should be prioritised as a treatment target.
 - We will also use the survey to identify people to take part in for clinical trials of musculoskeletal conditions in later life, starting with lower back and leg pain.
2. The BOOST Randomised Controlled Trial (RCT): We will focus on the condition of neurogenic claudication due to spinal stenosis which is a common spinal condition of old adults.
 - We will evaluate the clinical and cost-effectiveness of a group physiotherapy programme for people with neurogenic claudication compared to best practice advice.
 - We will also explore whether MRI scan parameters and other baseline factors predict a response to physiotherapy treatment.

Randomised Controlled Trial of Physiotherapy for Older People with Neurogenic Claudication

The RCT forms the major part of this programme of work and we are looking for centres to be involved in recruitment of participants to the study and in provision of the physiotherapy treatment. We have chosen NC because it is a common spinal syndrome which is poorly recognised in primary care, and the symptoms are substantial and distressing. NC is defined as pain or other discomfort with walking or standing that radiates into one or both legs and is relieved by rest or lumbar flexion [1]. It is usually accompanied by low back pain (LBP). It is serious because it impairs the ability to walk and stand. The condition arises from a narrowing of the spinal canal, which may or may not be seen on radiological/MRI imaging [1, 2]. When narrowing is evident radiologically, the condition is termed Lumbar Spinal Stenosis (LSS). Narrowing places pressure on nerves and blood vessels in the spine. LSS is very common as people age but not all people with radiological narrowing are symptomatic [2]. Therefore, we will focus on people with NC rather than those with radiological evidence of LSS. NC can be identified from simple self-report questions [1, 2]: worsening of symptoms when standing or walking and improvement in symptoms when bending forward or sitting.

We will also explore whether MRI scans and other baseline factors (e.g. frailty and behavioural factors such as fear avoidance beliefs, intentions and self-efficacy) can help determine who will and will not respond to physiotherapy treatment. Participants will be referred for an MRI scan unless they have had one in the last 12 months.

There is a strong theoretic underpinning and limited evidence from clinical practice, cohort studies and small randomised controlled trials for a physiotherapy intervention for NC. Experts hypothesise that stretching and mobilising the spine (lumbar flexion, and hip extension) can relieve pressure on spinal nerves and blood vessels and aerobic exercises will improve circulation within spinal blood vessels alleviating ischaemic changes [3]. Clinicians use these treatments in clinical practice [4, 5] despite the recommendations not being substantiated by high quality evidence [3]. The recent Cochrane systematic literature review reports that the current evidence from non-operative care is very low to low quality thus prohibiting recommendations to guide clinical practice [6]. Trials to date have been small. Only 2 small studies report outcomes beyond 6 months. We would also suggest that the approach taken by research studies to date has focused predominantly on the mechanics of spinal stenosis with little regard to the psychological impact of pain or ageing on participants.

Inclusion criteria:

- Registered with a primary care practice
- 65 years and over
- Living in the community, including sheltered or supported housing
- Participant is willing and able to give informed consent for participation in the randomised controlled trial
- Reports symptoms consistent with neurogenic claudication

Exclusion criteria:

- Living in a residential care or nursing home
- Has a terminal condition with a life expectancy of less than 6 months
- 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.
- Unable to walk 3m without the help of another person
- On a surgical waiting list
- Presents with cauda equina syndrome or signs of serious pathology requiring immediate referral for investigations
- Cognitive impairment
- Registered blind
- 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 (e.g. English comprehension)

Recruitment of Participants:

We plan to recruit a minimum of 402 participants to the RCT across 8-10 centres. Participants will be recruited into the RCT via 2 routes (See Flow Diagram).

Firstly, potentially eligible participants will be identified from the primary care survey (OPAL cohort study) – we will invite people 65 years or above to complete a survey that cover a variety of topics including questions related to LBP and leg symptoms. Those responding positively to questions suggestive of neurogenic claudication will be invited to attend for an eligibility assessment for the BOOST RCT

Secondly, we will recruit participants through spinal clinics. The spinal clinics may be based in primary or secondary care, and can be physiotherapy-led clinics or spinal consultant clinics, depending on models of service delivery in each area.

Interventions:

We will compare the clinical and cost-effectiveness of a group physiotherapy programme with best practice advice. We will provide training and support to deliver the interventions.

Interventions may be delivered in primary or secondary settings depending on the models of physiotherapy provision in each area.

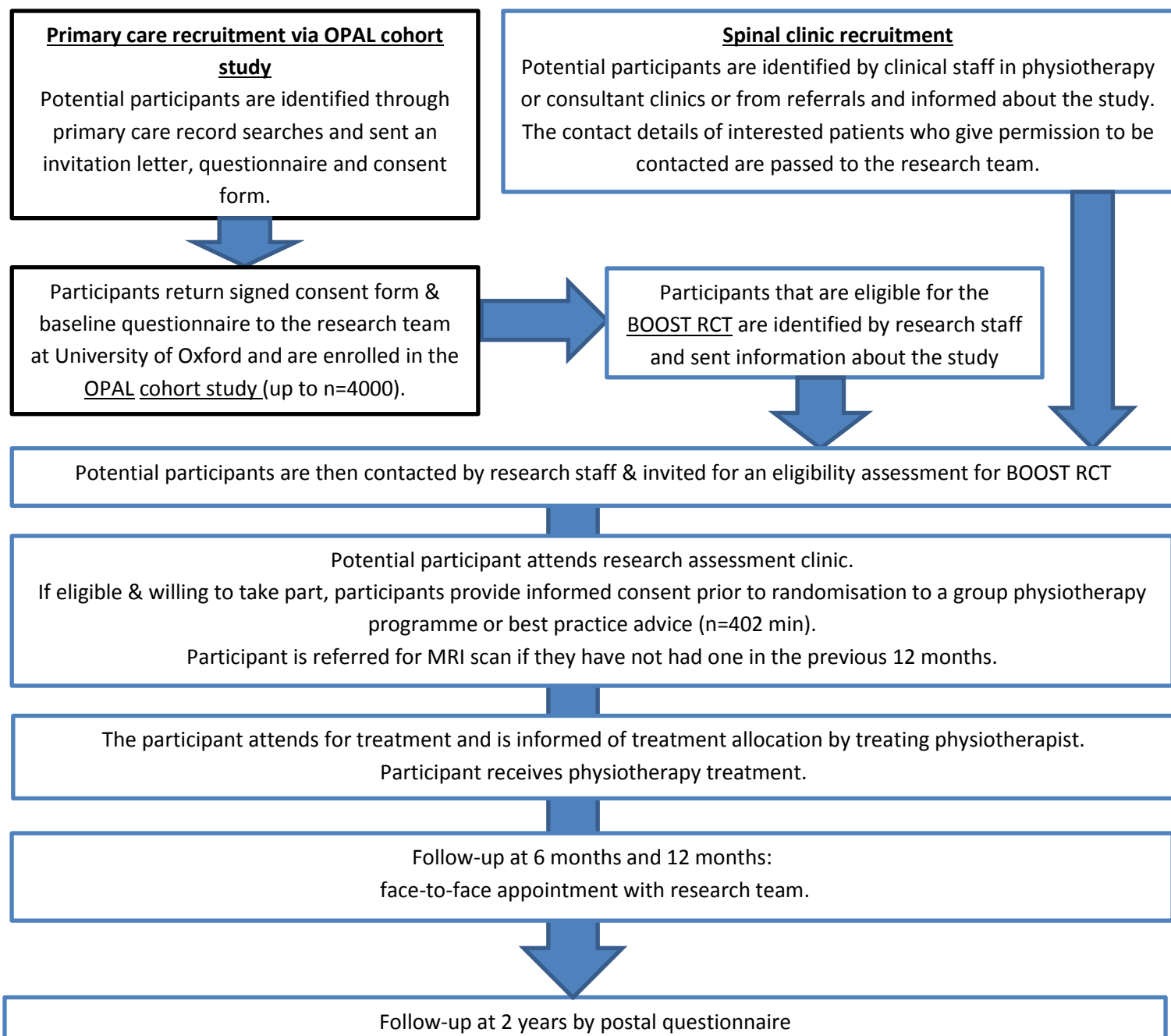
The group physiotherapy programme will consist of spinal exercises (ROM and strengthening), lower limb strengthening and stretching exercises and aerobic exercise. The programme will be underpinned by a cognitive behavioural framework to address potential barriers to engagement (such as unhelpful beliefs about ageing, pain or exercise) and to promote adherence to the home exercise programme. Short duration programmes (6 weeks or less) with minimal supervision appear ineffective at improving mobility in people with NC [7] or increasing muscular strength. We plan to deliver a progressive, individually tailored programme that aims for an exercise dose of at least moderate intensity in 12 sessions over 12 weeks. This will ensure that participants receive a

sufficient dose that is consistent with thresholds required for cardiovascular and strength conditioning [8] and that adequate supervision is provided to promote adherence with exercises.

The control intervention of best practice advice will consist of a one hour session to promote self-management and provision of a home exercise programme. A maximum of 2 follow up appointments is permitted if required.

Participants will be followed up at 6 and 12 months in a face to face appointment. Outcomes will include disability, mobility, pain, quality of life and health resource use. They will receive a postal questionnaire at 2 years follow up.

Study flow chart



Please contact the BOOST Trial Team for further information

Chief Investigator: Professor Sallie Lamb

Project Lead: Dr Esther Williamson

Host Institution: University of Oxford

Funded by: NIHR Programme Grants for Applied Research

Email: BOOST@ndorms.ox.ac.uk

References

1. 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 Dec; 304(23):2628-2636.
2. de Schepper EI, Overvest 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 Apr; 38(8):E469-E481.
3. Backstrom KM, Whitman JM, Flynn TW. Lumbar spinal stenosis-diagnosis and management of the aging spine. Man Ther. 2011 Aug; 16(4):308-317.
4. Comer CM, Redmond AC, Bird HA, Conaghan PG. Assessment and management of neurogenic claudication associated with lumbar spinal stenosis in a UK primary care musculoskeletal service: a survey of current practice among physiotherapists. BMC Musculoskelet Disord. 2009; 10:121.
5. Tomkins CC, Dimoff KH, Forman HS, Gordon ES, McPhail J, Wong JR, et al. Physical therapy treatment options for lumbar spinal stenosis. J Back Musculoskelet Rehabil. 2010; 23(1):31-37.
6. Ammendolia C, Stuber KJ, Rok E, Rampersaud R, Kennedy CA, Pennick V, et al. Nonoperative treatment for lumbar spinal stenosis with neurogenic claudication. Cochrane Database Syst Rev. 2013; 8:CD010712.
7. Comer C, Redmond AC, Bird HA, Hensor EM, Conaghan PG. A home exercise programme is no more beneficial than advice and education for people with neurogenic claudication: results from a randomised controlled trial. PLoS One. 2013; 8(9):e72878.
8. American College of Sports Medicine. Guidelines for exercise testing and prescription. 5th Edition ed. Baltimore: Williams and Wilkins 1995.