Project Title: PRESS - Development of a prehabilitation intervention for lumbar spinal stenosis

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Plain English Summary

Background

People with leg pain due to lumbar spinal stenosis (LSS) cannot walk very far. Although surgery can help, current UK waiting times are long. We wanted to find out the best way to improve patients' health while waiting for surgery to improve recovery after surgery (known as prehabilitation).

Methods

We had five objectives to understand:

1. what care was offered for people waiting for surgery (survey of large hospitals),
2. who was undergoing surgery (analysis of British Spinal Registry data),
3. what contexts, mechanisms and outcomes were most important when designing a prehabilitation intervention (using a realist review)
4. what prehabilitation components were most effective (using a systematic review).
5. and agree the intervention components of a prehabilitation intervention.

Key Findings

1. 15/25 Trusts responded to the survey and only 13% provided prehabilitation. Most reported they were unsure what to deliver.
2. People undergoing surgery in the UK were on average 70 years old, with many comorbidities, and moderate to severe pain and function before undergoing surgery.
3. The realist review highlighted communication, sources of support and individualisation as important themes to support engagement with prehabilitation.
4. There is little evidence to support prehabilitation.
5. We developed a prehabilitation intervention with clinicians, patients and researchers ready for testing in a randomised controlled trial.

Dissemination, outputs and impacts

We have shared these results with community groups, special interest groups, academic journal publications and conference outputs and in lay summary blogs.

Patient and public involvement

Our PPIE group advised throughout the realist review and intervention development.

Conclusions and future plans

It is unclear if prehabilitation helps people with LSS waiting for surgery. We plan to test the developed programme to understand the benefit for patients and the NHS.

Keywords

Neurosurgery; Preoperative Exercise; spinal stenosis;

Summary of Research Findings:

Background

Degenerative lumbar spinal stenosis (LSS) is an age-related condition that refers to narrowing of the spinal canal due to changes in the facet joints, ligamentum flavum and

discs(1,2). These can lead to symptoms of neurogenic claudication (NC). The estimated prevalence of LSS with NC clinical symptoms and radiological concordance is between 15 and 32% in symptomatic populations(3), and a clinical diagnosis is present in 11% of community dwelling adults(4). In the UK, the aging population is growing at an unprecedented rate: by 2045, the number of those aged 85 and over is expected to almost double from what it was in 2020 (3.1 million from 1.7 million)(5).

NC is the most commonly reported symptom associated with LSS and can describe any combination of the following: altered sensation, proprioception, pain and or weakness in the lower limbs that increases with activities such as standing or walking and is eased by bent positions such as sitting(6). NC can result in a reduction of walking ability due to pain or sensory changes (7), and can result in increased falls(8). Given the growing aging population in the UK, the prevalence of LSS will increase, leading to rising healthcare and societal costs.

Over 35,000 spinal surgical procedures were performed in those over 60 in the year 2021/2 in the UK(9), of which the majority can be attributed to NC due to LSS(10). Surgical treatment for NC may include posterior spinal decompression, with or without stabilisation in the form of fusion. The risks for surgical complications increase with older age, and those over the age of 65 years stay on average 30% longer in hospital(11).

Since the COVID pandemic, many National Health Service (NHS) Trusts have had difficulty meeting the referral to treatment target of 18 weeks for 92% of patients (12). In May 2024, NHS England reported that only 55% of neurosurgical patients and 64% of other surgical services were meeting this target, (13)

The associated effects on health, quality of life and wellbeing in patients with NC due to LSS, including increased co-morbidities, reduced walking distance, greater frailty and worse psychological status, are likely to be significant(8,14–17). In older adults undergoing spinal fusion, frailty and nutritional status are important predictors of surgical outcome and are significantly related to an increased risk of post-operative complications (18,19). Studies investigating nutritional status in older patients with orthopaedic problems report that on average 13% (95% confidence interval (CI) 5-20) were malnourished, and 47% (95%CI 40-54) were at risk of malnutrition, with a significant association between low nutritional status and poor function(18). These factors are independently recognised as risk factors for poor postoperative outcome and are likely to be exacerbated by the long waits for surgery (20–23). Postoperatively these are likely to affect the length of hospital stay, complication and readmission rates, leading to further increased health costs, as well as poorer patient outcomes(21).

Prehabilitation is defined as pre-operative rehabilitation, with the goal of optimising surgical outcome and readiness(24). Patients undergoing LSS decompression have highlighted the value in education and physical therapy in a prehabilitation setting(25). However, there is limited research evaluating the impact of prehabilitation for patients awaiting surgery for NC. Levett and Grimmett(16) called for studies to test a trimodal approach to surgical prehabilitation, suggesting that psychologically informed physical prehabilitation alongside nutritional supplementation provides optimal pre-operative intervention, warranting further investigation. The potential for prehabilitation to improve post-operative outcomes is evident in other surgical areas. Enhanced recovery after surgery (ERAS) is an evidence-based care process for surgical patients that aims to implement the best evidence through use of a multidisciplinary team (26,27). ERAS-informed models of care combine optimised clinical

interventions with improved logistics throughout the prehabilitation and post-discharge stages. There is a strong case for ERAS pathways in hip and knee orthopaedic surgery, where high quality evidence has demonstrated reduced length of stay, significant cost savings and reduced 90-day mortality rate(28–30). ERAS pathways have been shown to be promising for patients undergoing spinal surgery (31). A consensus statement was developed for spinal fusion, but implementation is lacking in the UK (32).

There is inconsistent and conflicting evidence to support prehabilitation for people with NC due to LSS, and a lack of clarity as to what optimal prehabilitation should consist of. Some trials have been conducted in non-UK countries with short waiting periods for surgery which may reduce the opportunity to implement prehabilitation programmes effectively; whilst others have evaluated suboptimal prehabilitation programmes(33,34). The optimal prehabilitation package and the period of the intervention for people undergoing spinal decompression for NC is unclear. During this research programme, we sought to undertake preparatory work to inform the future design, delivery and testing of a prehabilitation intervention package for NHS care.

Aims and Objectives

The overarching aim of the Programme Development Grant was to undertake preparatory work to inform the future design and testing of a prehabilitation package for NHS care. Our development work package (DWP) aims were to:

1) Define current preoperative intervention practice and waiting times in the UK.
    a. We were unable to estimate waiting times as participants did not want to disclose individual Trust waiting times, and NHS England waiting times appeared to differ from that reported by clinicians. The data from the referral to treatment clocks was harder to interpret than anticipated.
2) Characterise the NC spinal surgery population (demography, co-morbidities, deprivation profiles) in the UK.
3) Assemble a patient advisory group (PAG) representative of those undergoing surgery for NC with respect to demographics, ethnic group and deprivation profiles.
4) Assemble an expert advisory group (EAG) and conduct a meeting to identify areas of uncertainty to guide the realist review.
5) Conduct a realist and systematic review addressing the uncertainties highlighted by the expert advisory and PAG.
6) Conduct a second meeting with the EAG to agree the key prehabilitation components for NC spinal surgery.
    a. We modified the final DWP to develop an intervention as opposed to developing clinical guidance. We did not feel able to make national recommendations without definitively testing a prehabilitation intervention in a randomised controlled trial.

We will now describe the six DWP regarding their methods and key findings.

Developmental Work Package 1: Survey of Current Care

Aim

The aim of this survey was to conduct a national audit of current preoperative rehabilitation and waiting times for NC in spinal services.

Methods

Study Design

We undertook an electronic survey and telephone interviews to determine current pre-operative care. The HRA decision-making tool deemed this activity as not requiring ethics.

Recruitment

We used a convenience sample of complex care spinal centres across the UK (n=25/37) between January and May 2024, and engaged physiotherapists, triage spinal specialists involved in the surgical pathway and surgeons listing for surgery at each of these sites to explore what routine pre-operative treatment, education and support is offered prior to surgery for NC. We also asked regarding routine waiting times to surgery for NC due to LSS.

Data Collection

An electronic survey was developed by the research team using Microsoft Forms. The content of the Form included job description, current preoperative provision, what community services were currently used, plans for preoperative provision, as well as estimated routine waits to undergo surgery for patients with NC. In addition, we explored barriers to offering a prehabilitation programme. This was completed electronically or verbally by the researcher in a telephone interview depending on the respondent's preference.

Data Extraction

All responses were collated and interpreted with descriptive data (number, percentages) of total responses.

Results

The results combined data from 15 trusts (eleven 45-minute semi-structured interviews and four questionnaire responses). All participants were senior physiotherapists involved in the triage of patients for spinal surgery. Ten Trusts did not respond to contact attempts.

Current pre-operative provision

Ten of 15 NHS Specialist Spinal Trusts (67%) provided information leaflets about lumbar spinal surgery to their patients, while written information on optimising surgical outcomes (such as advice on smoking cessation, healthy eating, and exercise) was provided by seven trusts (47%). In addition, some services directed patients to relevant surgical information websites (n=7, 47%) and health-optimisation websites (n=6, 40%). Physiotherapy services were offered by most NHS Specialist Spinal Trusts when patients were identified with poor function or lacking prior conservative treatment (n=10, 67%). One service had access to psychological services prior to surgery (n=1, 7%), and one Trust offered nutritional advice/services preoperatively (n=1, 7%) (see Figure 1).

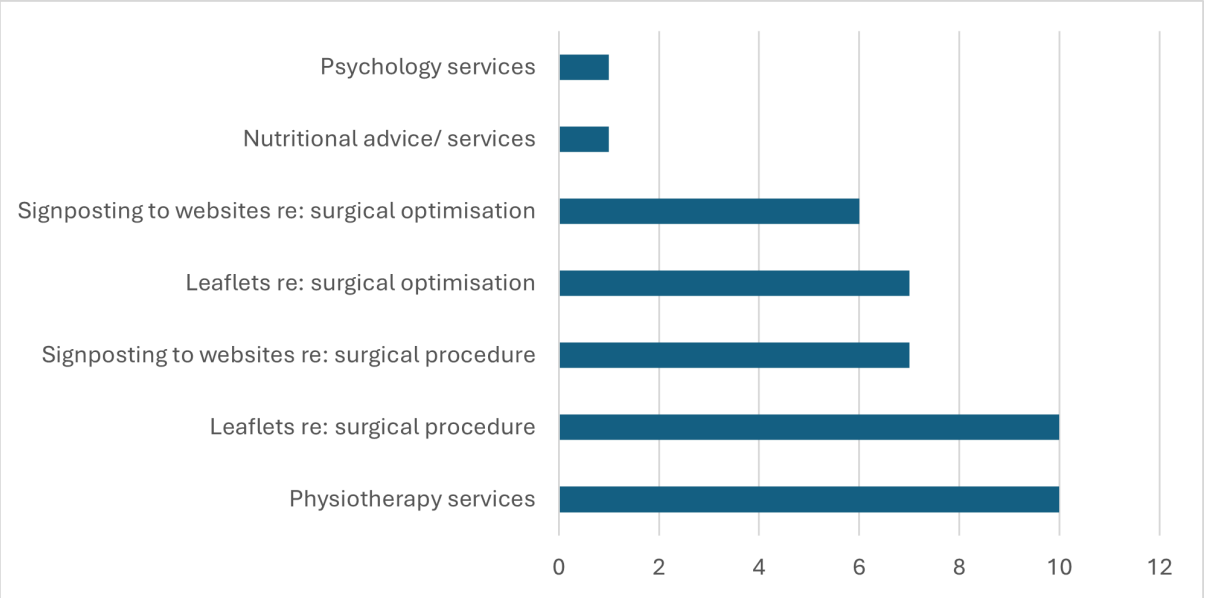

Figure 1: Bar chart showing current provision of prehabilitation by sampled Trusts

Only 2 Trusts offered prehabilitation programmes (13%), one in the form of a generic back class and the other an unclear intervention. Of the remaining 13 (87%) Trusts, none had plans to implement prehabilitation within the next six months. Barriers to Implementation

Two key barriers were identified: a perceived lack of robust evidence supporting the efficacy of prehabilitation interventions (n=10/15, 67%) and uncertainty regarding the optimal content to be delivered (n=9, 60%).

Key Learning Points

- A limitation was that not all identified Trusts had an Advanced Practitioner Triage service as a point of contact so we did not include these Trusts within our sample. Not all eligible Trusts were surveyed due to time constraints and lack of contact points.
- We were unable to identify national waiting times to surgery as the method for documenting this varied and NHS England websites conflicted with clinician reports.

Clinical/ research implications

- Clinicians highlighted a lack of evidence regarding the effectiveness of prehabilitation as a barrier to implementation.
- The results suggested a need to investigate optimal programme components, delivery methods, and timing (e.g., weeks or months pre-surgery).

This DWP answered Objective 1 “Define current preoperative intervention practice”.

Output

The results of this survey are under review in the Annals Journal & Bulletin Journal of the Royal College of Surgeons of England.

Development Work Package 2: Retrospective Analysis of British Spinal Registry Data

Aim

To describe the characteristics of BSR patients undergoing surgery for LSS and to estimate the association between patient characteristics and the proportion of patients achieving the

MCID in Oswestry Disability Index (ODI) at six months post-surgery as an indicator of early success of surgery.

Methods

Study Design

This was a retrospective analysis of a prospective cohort of patients registered with the BSR prior to surgery for LSS.

For more details regarding data collection, extraction and statistical analysis, please see the publication report at https://doi.org/10.1007/s00586-025-09000-x

Results

Of 7,247 BSR registered patients with a diagnosis of LSS between 2012 and 2023, 94% (6,801/7247) were 50 years of age and over and were included in the study. Follow-up PROM data was provided by 77% (3,124/4,045) at 6-weeks and by 62% (2,528/4,045) at 6-months. Older adults and those with higher baseline disability scores were less likely to respond at 6months (respectively, OR 0.98; 95% CI 0.96,0.99; $p<0.001$ and OR 0.99; 95% CI 0.98, 1.00; $p=0.02$).

Objective 1 - To describe the characteristics of patients undergoing surgery for LSS

Patients were on average 70.5 (SD 9.1) years of age and evenly split across genders (female=3452/6794, 51%). Patients were disproportionately represented from higher socioeconomic groups with 64% (3439/5403) of patients from IMD scores of 75 and above. Prior to surgery, on average, patients had moderate leg pain (VAS 7.0, SD 2.4) worse than back pain (VAS 6.3, SD 2.5), and severe back pain related disability (ODI 48.7, SD 17.5).

Objective 2 - To explore the associations of patient and surgical characteristics with those achieving a minimum clinically important difference on the ODI

Only 58% (1160/2008) of patients achieved the minimum clinically important difference (MCID) in ODI at 6-months. This was lower than outcomes reported by other international registries (35).

In the primary analysis (n=1957), we found that more severe baseline back pain reduced the odds of reaching the MCID post-surgery (OR 0.9; 95% CI 0.9, 0.9).

Key Learning Points

- Many patients undergoing surgery for LSS do not achieve clinically important improvement in disability at 6-months post-surgery.
- BSR patients were on average 70.5 years with moderate leg pain severity and severe disability pre-operatively (leg pain 7.0 and ODI 48.6).
- BSR patients had high rates of comorbidity (54%).

This DWP answered Objective 2 “Characterise the NC spinal surgery population (demography, co-morbidities, deprivation profiles) in the UK.”

Clinical/ research implications

Clinicians can support patients by better expectation setting and honest discussions about the likelihood of clinically meaningful improvements after surgery.

Interventions to improve pre-operative pain and disability may improve the likelihood of achieving a meaningful improvement in disability post-operatively.

Outputs

For more details, please see the peer-reviewed publication:

- Wood L, Hunter R, Williamson E, Salem KM, Sahota O, Phillips BE, Hendrick P, Lamb SE. Characterising patients undergoing surgery for lumbar spinal stenosis associated neurogenic claudication in the UK: what does the British Spinal Registry tell us? European Spine Journal. 4 June 2025. https://doi.org/10.1007/s00586-025-09000-x
- In addition, the results have been presented as a platform presentation at the British Association of Spinal Societies national conference in Manchester, UK (12-14 March 2025) and the International Forum for Back and Neck Pain Research in Davos, Switzerland (24-27 June 2025) as well as to clinical teams in the Royal Devon and Exeter University Hospitals NHS Trust as part of in-service training.

Developmental Work Package 3: Patient Advisory Group (PAG)

Please see the section on Patient and Public Involvement which describes in detail how we assembled our PAG, their role in this research, and the outputs of their contribution.

Developmental Work Package 4: Expert Advisory Group (EAG)

Aim

This DWP aimed to assemble an EAG using a diverse and representative group of clinicians and patients from the PAG to discuss uncertainties regarding prehabilitation in spinal surgery for NC to guide the realist review.

Methods

Study Design

DWP4 assembled an EAG purposely sampled and representative of the diversity of settings in the UK, including speciality centres from deprived or rural settings.

Recruitment

Purposive sampling was used to ensure multidisciplinary and diverse perspectives were represented. This included invitations to spinal surgeons, neurosurgeons and spinal triage practitioners involved in listing patients for surgery, rehabilitation experts such as physical therapists delivering prehabilitation, exercise physiologists and orthogeriatricians who have expertise in sarcopaenia and frailty, and people with lived experience of NC and LSS.

Data Collection/Session Format

The Expert Advisory Group provided specialist clinical, academic, and physiological insights relevant to the development and refinement of the programme theory within DWP5a. Members participated in two stakeholder consultations held on April 24th and September 18th, 2024.

They were invited to attend the Intervention Development Day (DWP6).

The EAG consisted of:

- Consultant Physician in Ortho-Geriatric Medicine
- Consultant Physiotherapist specialising in spinal surgery
- Consultant Physiotherapist specialising in musculoskeletal conditions

- Academic Physiotherapist with expertise in lumbar spinal stenosis and rehabilitation in older adults
- Professor of Translational Physiology
- Clinical Exercise Physiologist

This met Objective 4 “Assemble an expert advisory group (EAG) and conduct a meeting to identify areas of uncertainty to guide the realist review.”

Key Learning Points

- It was very difficult to engage spinal surgeons or anaesthetists in attending the EAGs due to diary restrictions. We were able to consult with them independent of group sessions
- We were able to recruit specialists from known urban centres (e.g. Nottingham, London) but had more difficulty engaging with rural centres due to a lack of existing relationships.

Output

This group contributed to the development and refinement of the final programme theories of DWP5a.

DWP 5a: Realist Review

Aim

The aim of DWP5 was to undertake a systematic and realist review of the literature regarding prehabilitation for NC to address the key uncertainties identified in DWP1-4.

Methods

Study Design

A realist review was undertaken by our team following Pawson's methodological framework (36) and was conducted and reported in accordance with the RAMESES quality and reporting standards(37). The study was registered with PROSPERO (CRD42024564345).

Development of Initial Programme Theories

An initial programme theory was developed through background scoping of full text reports of the research literature (Google Scholar) and expert and patient advisory input. This theory was iteratively refined into context–mechanism–outcome configurations (CMOCs) via further literature searches and stakeholder engagement. The process was iterative and guided by the PAG.

Stakeholder Group

This review was informed by the PAG and EAG. Four consultations were held at key stages to support the credibility and refinement of the CMOCs.

Database Searches

This review benefited from the guidance of an Information Specialist (AB) to ensure the search strategy was inclusive of all potentially relevant evidence(38). A two-phase literature search was conducted to identify, refine, and test CMOCs relevant to prehabilitation in LSS.

Phase 1: Comprehensive Search

In June 2024, a systematic search was carried out across four databases: MEDLINE via PubMed, CINAHL, Scopus, and Web of Science (Science and Social Science Citation Indexes).

Phase 2: Targeted CMOC Testing

To test and refine emerging CMOCs, a targeted search was conducted using two AI-assisted platforms—Scite (v0.4.5) and Undermind (v0.4.7)—in November 2024 (pilot) and February 2025. These tools enabled rapid evidence mapping through citation tracking and snowballing.

Data Selection

Phase 1 Selection

Title and abstract screening was conducted using a bespoke screening tool, scoring relevance on a 1-5 scale. Articles scoring 3 or higher were retained, resulting in 55 papers eligible for fulltext screening (one was unobtainable).

Phase 2 Selection

AI-generated outputs were screened for empirical relevance to each CMOC. Only primary qualitative or quantitative studies were included.

Assessment of rigour

Rigour was assessed at both the document and data levels, guided by recommendations from Dada et al.(39).

Data extraction

Data extraction was conducted by a single researcher (RH).

Analysis and Synthesis

An iterative, theory-driven approach underpinned data synthesis. Using abductive and retroductive reasoning(40), emerging data were coded holistically —reflective annotations capturing broader meanings and connections across studies— were developed to create and test causal explanations.

Results

Included Studies

Sixty-seven papers were included. All were rated moderately (n=37) or highly relevant (n=30), with moderate (n=17) or high (n=50) rigour.

Context-Mechanism-Outcome configurations

Our findings form a programme theory of 14 CMOCs explaining factors that enhance patient engagement with prehabilitation while awaiting surgery for NC. Structured around three interconnected themes—communication, personalisation, and support—these CMOCs highlight key mechanisms and contextual influences on engagement. The final programme theory is illustrated in Figure 2.

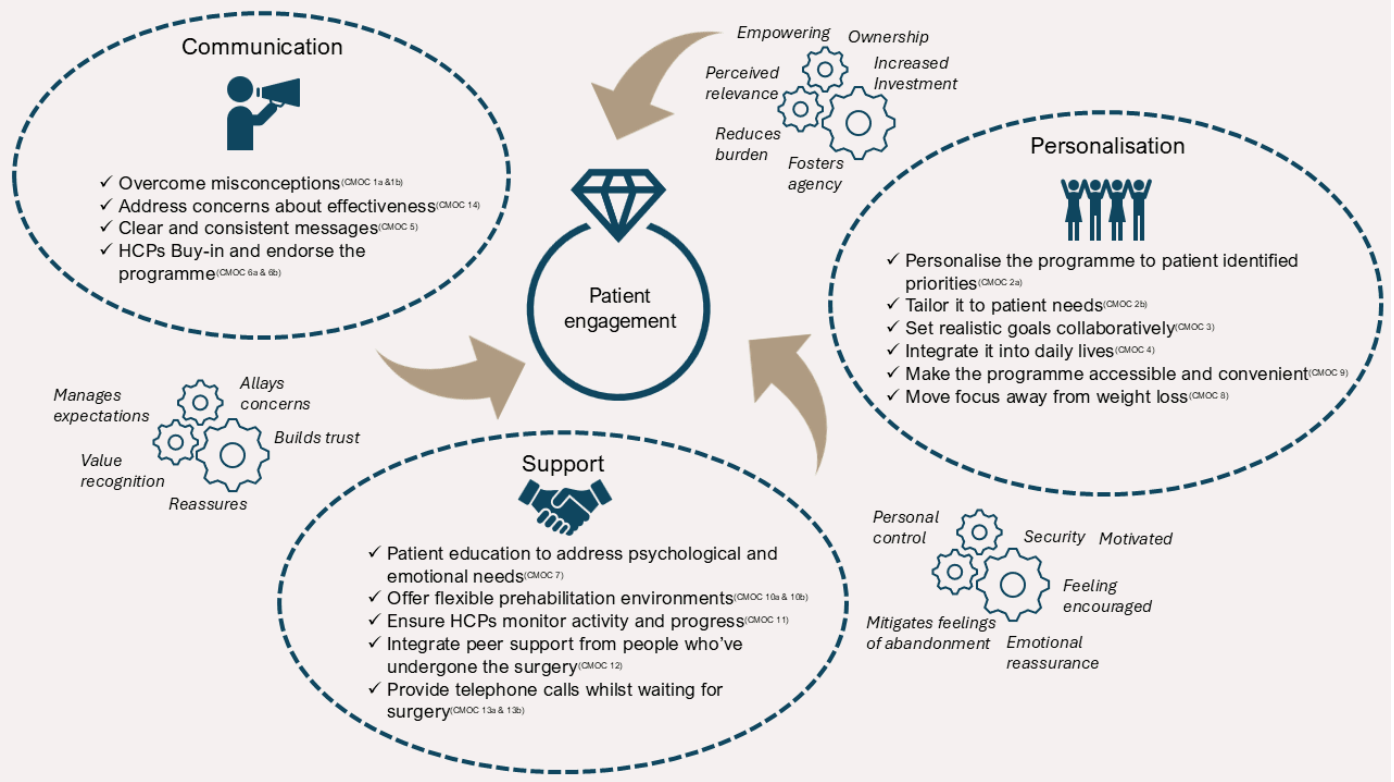

Figure 2: Final programme theory. Thematic divisions are artificial constructs, employed to delineate a cohesive programme theory. Porous boundaries, indicated by dashed circles, acknowledge CMOCs' potential relevance across multiple themes. Similarly, depicted mechanisms represent salient findings, not exhaustive instances, as some were observed in multiple CMOCs. HCP = Healthcare professionals

<u>Key Learning Points</u>

- Personalised prehabilitation programmes, delivered with clear and consistent messaging across the surgical team, with peer and health care support during the preoperative waiting time may help to increase patient engagement with prehabilitation by managing expectations, motivating patients, building trust and reassurance and fostering agency.
- However, an intervention incorporating these theories needs to be evaluated to understand whether the patient -perceived benefits translate into service-level and post-operative benefits.

This met objective 5 "Conduct a realist and systematic review addressing the uncertainties highlighted by the expert advisory and PAG."

<u>Clinical/ Research Implications</u>

This programme theory and the individual CMOCs need to be incorporated into a prehabilitation intervention for further evaluation.

<u>Output</u>

The realist review and resulting programme theory has been submitted for publication in Age and Ageing. In addition, the novel search strategy using AI search tools has been described and submitted for publication as well.

- R Hunter, A Booth, J Fitch, E Williamson, O Sahota, BE Phillips, P Hendrick, SE Lamb, L

Wood. Prehabilitation for Lumbar Spinal Stenosis: Understanding Mechanisms and Contexts for Enhanced Engagement: A Realist Review. Submitted to Age and Ageing May 2025, under review.

- R. Hunter, A. Booth. L. Wood. Searching Smarter, Not Harder: Leveraging AI to Enhance Realist Review Literature Searches. A methodological case study. Under review
- Oral presentation to the National Spinal Network annual meeting (Manchester, UK; 11 March 2025); and the International Forum for Back and Neck Pain Research (Davos, Switzerland, 24-27 June 2025). Poster Presentation at Chartered Society of Physiotherapy Annual Conference (Newport, UK; 20-22nd November 2025)

DWP 5b: Systematic Review

Aim

The aim of this systematic review was to identify key elements of prehabilitation programmes associated with improved outcomes in people undergoing surgery for LSS.

Methods

Study Design:

The protocol for this review was registered with PROSPERO (CRD42025645253) and it was reported according to the PRISMA guidelines (41).

Study Searches:

We searched for eligible papers published in English between 2011 and 22 January 2025 from PubMed, CINAHL, Scopus and Web of Science.

Data Extraction

The Cochrane Risk of Bias Tool (version 2)(42) was used to assess risk of bias for each of 5 domains and an overall judgement of risk of bias for each study. In addition, we assessed the intervention reporting using TIDieR guidelines.

Data Syntheses

An intervention component analysis (ICA) approach was used to identify intervention components and their association with outcome results. The ICA approach involves a two-step process: 1) identify the individual intervention components from each study intervention; 2) identify which study interventions, and their constituent components, were associated with successful or unsuccessful interventions. “Successful” or “unsuccessful” interventions were defined as those that resulted in a statistically significant (or not) between group difference in favour of prehabilitation or usual care respectively for relevant outcomes.

Results

Included studies

Eight publications providing unique data regarding four trials were included from the 3180 papers identified in the initial searches. Three of the four included trials had an overall risk of bias assessment of ‘Some concerns’ and one had an overall assessment of ‘High’ due to the lack of blinding of the principal investigator. Only one RCT evaluated prehabilitation exclusively in a LSS population, the others included patients with degenerative lumbar disorders including LSS. Most prehabilitation programs were of relatively short duration (mean 6.5 weeks, range 4-9 weeks).

The sample sizes of the included trials were generally small. In particular, Marchand(34) did not recruit to target and was underpowered to detect between group differences. Along with Lindback (43), they reported a high drop-out rate particularly at later follow-up timepoints.

Intervention Components

Forty-seven individual prehabilitation components were identified. Programmes consisted of cognitive behavioural therapy(44), exercise alone(43), or exercise in combination with other components such as manual therapy, protein supplements and/or behavioural approaches(33,34). Two trials provided extra post-operative care for participants in the prehabilitation arm (33,44).

Sixteen of 28 outcomes showed greater improvement following prehabilitation compared to usual care though there were marked differences at each timepoint with most improvement seen at the post-prehabilitation/pre-surgery timepoint. No difference between prehabilitation and control participants was reported for the remaining 12 outcomes.

Mapping of the 47 components across all timepoints (post-prehab/pre-surgery, perioperative, post-surgery) and all 28 outcomes revealed that 15/47 individual components featured in successful interventions (see Figure 3).

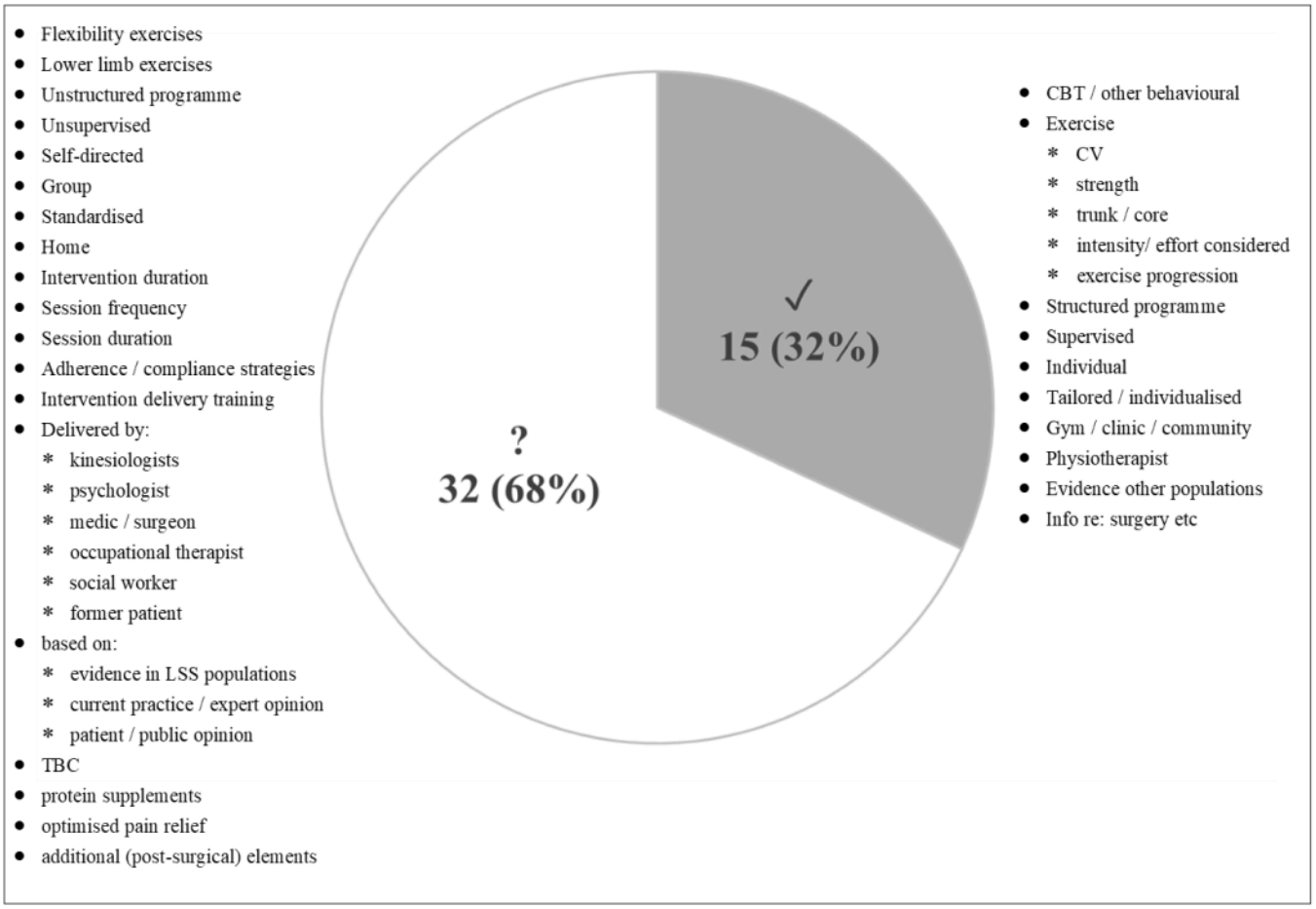

Figure 3: Intervention components featuring in >50% (✓) and ≤50%(?) of successful trial interventions (overall analysis with all outcomes at all timepoints)

Only 3 outcomes were measured by >2 studies at any one timepoint which limited the number of valid syntheses to be performed.

Key findings

- The included trials involved prehabilitation interventions of relatively short duration (4-9 weeks) which may not be long enough to demonstrate any effect. In comparison to the time potentially spent waiting for surgery in the UK, this is a particularly short period of time.
- Most prehabilitation is delivered in the period immediately prior to surgery which could result in people on the waiting list for a considerable time before they access any treatment.

This met objective 5 “Conduct a realist and systematic review addressing the uncertainties highlighted by the expert advisory and PAG.”

Clinical/ Research Implications

- Structured, supervised, individualised sessions delivering exercise with a CBT component appear to be associated with successful interventions but more research is needed to confirm these findings
- There are few high-quality RCTs of prehabilitation delivered in contexts similar to the UK or with components matching the theories underpinned by the realist review.

Output

The results of this systematic review have been submitted for peer reviewed publication.

DWP 6: Intervention Development Day

Aim

The aim of this intervention development day was to present the findings of DWP 1-5 to the EAG and PAG, and gain consensus on the components to be included in a prehabilitation programme that could be evaluated within the NHS.

Methods

Meeting Attendees

All members of the steering committee, EAG, PAG were invited. In addition, we invited clinicians with expertise in managing people with LSS on the surgical pathway, and nutritional experts.

Meeting Agenda

The results of all work packages were summarised and presented at the meeting, alongside a short presentation on the TIDIER guidelines(45) to support attendees in considering evaluating interventions in randomised controlled trials.

Results

One dietician, 8 physiotherapists working in rehabilitation or on the surgical triage pathway, 1 academic physiotherapist, 1 exercise physiologist and 2 patients attended the Intervention Development Day from London, the South West and Birmingham. In addition, 2 spinal surgeons discussed the proposed intervention after the meeting individually.

The proposed intervention combines multidisciplinary education about prehabilitation, with individualised assessment, screening for tailored health interventions and optimised exercise prescription. Peer support and group exercise sessions will be delivered regularly with the option for online or in-person participation. Regular check-ups with the physiotherapists will help to monitor patients while waiting for the surgery.

This answers Objective 6 “Conduct a second meeting with the expert group to review the evidence from DWP5 and develop a prehabilitation intervention for further testing.”

Key Learning Points

- Engaging surgical team members such as Surgeons, Anaesthetists and Nurse specialists has been challenging and is an area for further engagement.
- Regional variation across rural and urban areas may impact the intervention delivery with patient preference.

The proposed intervention will be further refined within the Programme Grant for Applied Research but provides a holistic, multidisciplinary prehabilitation intervention that may be feasible to deliver within the NHS.

Conclusions

What this study adds

This mixed-methods study has undertaken preparatory work to support the rationale, justification and intervention development of a prehabilitation intervention for those undergoing surgery for NC.

We have demonstrated that:

- Few NHS Trusts are providing any prehabilitation care targeting surgical optimisation
- UK patients undergoing surgical decompression have moderate pain and severe disability scores with high comorbidity burdens.
- A prehabilitation programme consisting of clear and consistent messaging from all members in the surgical team, personalised to their individual needs and abilities, with support from health care professionals, peers and adjunctive education to prepare them for surgery may help to improve engagement with prehabilitation.
- Only 4 trials have tested heterogeneous prehabilitation programmes in this patient population.
- A prehabilitation intervention has been co-developed by our team with expert clinicians, patients and carers, and members of the public. This requires evaluation within the NHS to assess its potential impact and effectiveness.

Patient and Public Involvement (PPI)

Aim of PPI

The aim of PPI in this study was twofold: 1) to inform the programme theories developed, refined and tested in the realist review; and 2) to support the development of a prehabilitation intervention fit for evaluation within the NHS.

Methods

Recruitment:

We aimed to recruit a representative sample of PPI within our Patient Advisory Group (PAG) in DWP3. We aimed to ensure the PAG were representative of the characteristics of the patient sample found within the British Spinal Registry. We used a variety of formats to advertise to potential people with lived experience of surgery for lumbar spinal stenosis, including advertising through NHS waiting rooms and clinical teams, social media, Clinical Research Networks and through special interest group platforms such as the National Spinal Network. However, despite this, we had very slow and small response rates.

Eighteen people responded to our advertisements of which 5 responded anonymously so were uncontactable. From the 18, we assembled a group of eight people. They were invited to four meetings over the course of the year and attended as they were able.

Meetings

Meetings were all held online, apart from the final intervention day wherein we held a hybrid event day to celebrate the outputs of the project and discuss the potential prehabilitation intervention.

Representation

The British Spinal Registry study demonstrated that patients undergoing surgery for LSS in the UK were on average 70.5 (SD 9.1) years, 51% (3452/6794) were female, and most were from higher socioeconomic areas (mean Index of Multiple Deprivation rank 84.3, SD 38.8).

Of our group of eight, one participant was aged 50-60, one 60-70, three 70-80 and two 80-90. There were 3 males and 5 females, all White origin (7/8 White British) with most having higher professional or university education (1/8 had secondary school only).

Realist Review Contribution

Seven PPI contributors met on 2 occasions to explore the initial programme theories. This was done in a discursive focus group, exploring different theories that may have limited evidence underpinning them or conflicting sources within the literature. The patient group were able to refine the focus of the realist review to prioritise “engagement” with prehabilitation as the most important outcome. They felt that all the programme theories naturally aligned to supporting patient engagement with the prehabilitation intervention, with the underlying assumption that the intervention was beneficial to their surgical procedure and recovery. Literature regarding dietary advice focussed on nutrition and weight loss prior to surgery but, in contrast, our PPIE group wanted advice on healthy eating and education around why diet would help their surgical outcomes. Our patient co-applicant read our realist review paper and contributed to our steering group meetings and programme theory development.

Prehabilitation Intervention

The PPI group met on two further occasions to discuss in more detail the delivery, components and structure of the proposed prehabilitation intervention. PPI advisers shared that once they were on the waiting list for surgery, they had very little interaction with health care professionals. They felt that having regular contact would provide reassurance, alleviate the worry about being forgotten, and provide emotional and psychological support. Despite almost all group members having been provided with written information pre-operatively, most felt that they had little understanding of what to expect, possible outcomes or consequences of surgery. They all felt that videos, or educational information that was accessible to them at their own pace, would be helpful.

Discussion and Conclusions

The realist review was a co-development project with constant re-iteration from the PPI group to refine and shape the focus of the individual CMOCs and overall programme theory. Their input helped to focus the key outcome of the review (“engagement”).

Patients have played a key role in helping to shape and determine how the intervention may be delivered within the clinical trial. They have helped to provide insight on their multiple and varied experiences and perspectives having been through surgery and the preoperative journey.

Reflective/ Critical Perspective
This study benefited from eight PPI participants. Despite actively seeking out those from underserved communities, we found it very difficult to recruit participants who were not middleclass White British. In addition, most participants were recruited from the south of England, where there may be greater affluence. We will seek to expand our PPI group for the next stage of this research.

Data sharing agreement
The dataset obtained for the analysis in DWP 2 is available by request from the BSR. The anonymised survey data, realist and systematic review datasets are available on reasonable request from the lead author. The NIHR strongly supports the sharing of data in the most appropriate way, to help deliver research that maximises benefits to patients and the wider public, the health and care system and which contributes to economic growth in the UK. All requests for data should be directed to LW and will be managed by LW.

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Appendix 1:

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