Improving the understanding and management of back pain in older adults: the BOOST research programme including RCT and OPAL cohort

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Scientific summary

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Scientific summary

Background

Back pain (BP) is a common problem for older people but despite this, many older people either do not consult or general practitioners do not prioritise BP treatment for them due to the perception that nothing can be done. Many clinical trials exclude older people, and little attention has been paid to understanding the presentation of BP in older people and developing effective treatments.

Older adults also experience leg pain referred from the lumbar spine. A common clinical presentation of spinal-related leg pain in older adults is neurogenic claudication (NC). It presents as symptoms radiating from the spine into the buttocks and legs which are provoked by walking or standing and relieved by sitting or lumbar flexion, often accompanied by BP. NC is particularly problematic for older people as it can cause severe pain and discomfort and substantially affect an individual's confidence and ability to walk. Symptoms are thought to arise from pressure on nerves and blood vessels caused by degenerative changes narrowing the volume of the lumbar spinal canal. Narrowing may or may not be evident on imaging but when present, the condition is termed lumbar spinal stenosis. Physiotherapy is recommended prior to surgical intervention, but high-quality evidence to guide conservative care, including primary care management or physiotherapy, was lacking. Thus, we focused on NC to develop and test a physiotherapy intervention.

We aimed to conduct a series of linked studies to increase knowledge and understanding about BP in older people and reduce the burden on older people by developing evidence-based treatment strategies.

Objectives

- To describe the presentation and impact of BP in community-dwelling older adults.
- To refine a physiotherapy intervention for older people with NC and to evaluate the clinical and cost-effectiveness of this intervention in a randomised controlled trial (RCT).
- To understand the trial participants' experiences, including acceptability and impact of the interventions.
- To understand the role of low BP in mobility decline through the development of a prognostic tool to predict when older people are at risk of mobility decline.
- To integrate findings into an implementation package.

Methods

We undertook three studies.

- A large population-based cohort study of community-dwelling older people recruited from primary care practices [the Oxford Pain Activity and Lifestyle (OPAL) cohort study].

We recruited older adults from primary care practices who were identified through electronic record searches and randomly selected eligible participants from two stratified age bands (65–74 and ≥ 75 years). In total, 5409 individuals (42.1% of eligible participants) from 35 general practices agreed to participate and followed up for 2 years by postal questionnaire. Participants provided data including demographics, socioeconomic factors, comorbidities, pain including low BP and its impact, other pain problems, physical activity, mobility, falls, frailty and quality of life. At baseline, we investigated the prevalence of BP and related leg pain within the cohort and estimated the association between different

back and leg pain presentations and age-related adverse health states, including falls, frailty and mobility decline, using regression analyses. At 2 years, we estimated recovery rates. We investigated the role of back and leg pain in mobility decline by developing a prediction model for mobility decline at 2 years' follow-up. Thirty-one candidate self-reported baseline predictors were prespecified. Missing data were imputed. Least Absolute Shrinkage and Selection Operator regression was used to select potential predictors. Model performance was assessed by calculating c-statistic, Brier score and decision-curve analysis. Models were internally validated using bootstrapping.

- The Better Outcomes for Older people with Spinal Trouble (BOOST) RCT of physiotherapy interventions for NC.

We evaluated the clinical and cost-effectiveness of a physical and psychological group intervention (BOOST programme) compared to physiotherapy assessment and tailored advice [best practice advice (BPA)] for older people with NC. Participants were identified from spinal clinics (community and secondary care) and general practice records, and were randomised 2:1 to the BOOST programme or BPA. The primary outcome was the Oswestry Disability Index (ODI) at 12 months. Data were also collected at 6 months. Other outcomes included ODI walking item, 6-minute walk test (6MWT) and falls. The primary analysis was intention-to-treat. Prespecified subgroup analyses were also undertaken based on magnetic resonance imaging (MRI) parameters and other baseline factors including age, sex, frailty and physical capacity. The base-case economic evaluation was an intention-to-treat analysis conducted from a UK NHS and personal social services (PSS) perspective and separately from a societal perspective. Costs (2018–19 prices) were collected prospectively over 12 months. A bivariate regression of costs and quality-adjusted life-years (QALYs), with multiple imputation of missing data, was conducted to estimate the incremental cost per QALY gained and the incremental net monetary benefit (INMB) of the BOOST programme in comparison to BPA.

- A longitudinal qualitative study embedded within the BOOST RCT.

Embedded within the BOOST RCT was a longitudinal qualitative study. Semistructured interviews with participants were undertaken at baseline, 1 month after receiving their intervention and at 12 months. We analysed 30 sets of three interviews. We undertook an inductive thematic analysis and comparatively analysed data from the three time points to explore patients' experiences with the trial interventions, including the impact on symptoms and their experiences of long-term exercise adherence.

Results

Oxford Pain Activity and Lifestyle cohort study

Among OPAL participants, 34% (1786/5304) reported BP. A further 19.5% (1035/5304) reported BP and associated leg pain, with 11.2% (n = 594/5304) reporting symptoms consistent with NC. Participants with BP had worse quality of life compared to those without BP. All BP presentations were significantly associated with adverse health states. Those with NC were most affected. In particular, there was greater relative risk (RR) of low walking confidence [RR 3.11, 95% confidence interval (CI) 2.56 to 3.78], frailty (RR 1.88, 95% CI 1.67 to 2.11) and mobility decline (RR 1.74, 95% CI 1.54 to 1.97) compared to no BP. Of the participants reporting BP at baseline, 2139/2859 (74.8%) returned the 2-year follow-up questionnaire, and 23% of respondents no longer reported back or leg symptoms (489/2100). Recovery was highest among those reporting only BP at baseline (27.4%) and lowest among those reporting NC at baseline (10.9%). Participants reporting NC at baseline were most affected by symptoms at follow-up, reporting BP more frequently, with the highest proportion reporting very or extremely troublesome BP. They reported the highest pain interference ratings at follow-up, with the greatest proportion reporting severe interference with activity (26%).

At baseline, the majority of OPAL participants reported no mobility problems (60.7%; 3146/5184) and 5.4% (280/5184) reported severe mobility problems. Two-year follow-up data were provided by 4115/5184 (79.4%) participants, with 18.6% (n = 765/4115) reporting mobility decline. We examined the univariable relationship between the baseline variables and the 2-year outcome. Nearly all the selected baseline factors had a univariate relationship with the outcome. Among those with mobility decline at 2 years, there were more reports of back and leg pain and greater numbers reporting multisite pain and widespread pain at baseline. The biggest difference in pain presentation was lower limb pain at baseline, which was reported by 68% of participants with mobility decline at follow-up, compared to 56% without. Baseline pain severity was also associated with mobility decline at follow-up. The multivariable analyses found that in addition to mobility status (no problems or mild problems) at baseline, 13 variables were identified as predictors of mobility decline at 2 years in ≥ 80% of the multiple imputed data sets. BP with/without leg pain was not an independent predictor of mobility decline, but lower limb pain and the report of severe pain were independent predictors. Demographic and socioeconomic factors (older age and those who perceived their income as inadequate) were also identified. There were multiple factors related to mobility, including participants who reported a slow usual walking pace, had difficulty maintaining their balance, had low confidence to walk long distances, rated their walking as worse compared to last year and reported sometimes using a walking aid outside, which were associated with a decline in mobility after 2 years. General health-related factors associated with decline in mobility at 2 years were having a higher body mass index, greater number of health conditions, problems in daily life due to physical tiredness, and poor self-reported general health. The multivariable model revealed a median c-statistic of 0.740 (range 0.737–0.743), indicating moderately good discrimination. The median Brier score was 0.136 (range 0.135–0.137). We developed a point scoring system to facilitate use in clinical practice.

Better Outcomes for Older people with Spinal Trouble randomised controlled trial

We analysed data from 435 trial participants with an average age of 74.9 years [standard deviation (SD) 6.0 years], and 57% (246/435) were female. At baseline, participants reported moderate disability levels [mean ODI 33 (SD 13.9)]. Their walking was markedly reduced [mean 6MWT 255 m (SD 99.1 m)] compared to healthy older adults. The primary outcome was obtained for 88.0% (383/435) and 87.4% (380/435) of participants at 6 months and 12 months, respectively, with 93.0% (403/435) contributing data to the primary analysis. There was no significant difference in ODI scores between treatment groups at 12 months [adjusted mean difference (MD) −1.4, 95% CI −4.03 to 1.17)], but at 6 months, ODI scores favoured the BOOST programme (adjusted MD −3.7, 95% CI −6.27 to −1.06). At 12 months, the BOOST programme resulted in greater improvements in walking capacity (6MWT MD 21.7 m, 95% CI 5.96 to 37.38 m) and ODI walking item (MD −0.2, 95% CI −0.45 to −0.01) and reduced falls risk (odds ratio 0.6, 95% CI 0.40 to 0.98) compared to BPA. No serious adverse events were related to either treatment. The economic analyses showed that the mean NHS and PSS costs over 12 months were £19,752 [standard error (SE) £118] in the BOOST arm versus £1827 (SE £169) in the BPA arm (p = 0.474). Mean (SE) QALY estimates were 0.620 (0.009) versus 0.599 (0.006), respectively (p = 0.093). The probability that the BOOST programme is cost-effective ranged between 67% and 83% (NHS and PSS perspective) and between 79% and 89% (societal perspective) across cost-effectiveness thresholds. INMBs ranged between £145 and £464 at cost-effectiveness thresholds between £15,000 and £30,000 per QALY.

The Better Outcomes for Older people with Spinal Trouble qualitative study

Interviews from 16 men and 14 women were included in this analysis. Fourteen participants were allocated to BPA and 16 were allocated to the BOOST programme. The symptoms of NC manifested both physically and psychologically, limiting participants' ability to perform everyday activities as well their wider participation in social, leisure and recreational activities. Participants adopted coping strategies to minimise the impact of NC.

Participants in the BOOST programme appeared more satisfied with their treatment compared to those allocated to BPA. Dissatisfaction among BPA participants seemed to arise from lack of feedback and

follow-up. BOOST participants benefited from peer support and discussions. Most participants felt the exercises were appropriate and helpful, although this did not necessarily translate to improvements in pain. Dissatisfaction with the BOOST programme was mostly related to lack of pain relief. Pain remained a substantial problem for some participants. BOOST programme participants also talked about other improvements from the exercises, including improved posture, strength and confidence, highlighting the broader benefits of the BOOST programme. These types of changes were less evident in the narratives of BPA participants. BOOST participants reported benefit from the cognitive–behavioural component, including helping them to find their own solutions, manage flare-ups and understand the importance of long-term exercise. Reasons for stopping the home exercises were similar between treatment arms. These included competing priorities, lack of motivation and aggravation of pain. Adaptations allowed some BOOST participants to continue at least some of the exercises even when they were difficult. Participant narratives provided insight into ways to optimise the BOOST programme to improve long-term exercise adherence, including additional support to provide motivation for ongoing exercises (by the physiotherapist or by linking to exercise opportunities in the community), provide greater guidance on how to adapt exercises if they are painful, and to help plan integration into everyday life or transition to activities they enjoy.

We have developed a package of implementation for the BOOST programme. Feedback from interview participants, patient and public involvement representatives and clinicians who delivered the BOOST programme and ongoing analyses of BOOST data will inform further refinement of the programme to better target pain-related disability.

Conclusions

Back pain is a substantial and persistent problem for older people, associated with reduced quality of life and age-related adverse health states. The impact is greatest on those with NC, but other presentations should not be ignored due to the high proportion of participants who reported ongoing symptoms. We developed a programme that successfully improved mobility and reduced falls among older people with NC, and future iterations of the programme will aim to reduce long-term pain-related disability. As it stands, the BOOST programme has a high probability of being cost-effective. There is a need to develop other interventions for the large number of older adults affected by BP, especially for those with more severe symptoms. Back and leg pain were not independent predictors of mobility decline, but severe pain was a predictor. This highlights a broader need to manage pain better in older people regardless of the type or presentation of pain. The developed prognostic tool has the potential to help clinicians, older people and their families to identify when an older person is at risk of declining mobility and to take preventative actions. We developed a scoring system so that it could be easily implemented in clinical practice, and future research will focus on external validation of this tool.

Study registration

This trial is registered as BOOST trial ISRCTN12698674.

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