OP0225 KNEE BRACING PLUS ADVICE, WRITTEN INFORMATION AND EXERCISE INSTRUCTION VERSUS ADVICE, WRITTEN INFORMATION AND EXERCISE INSTRUCTION ALONE IN ADULTS WITH KNEE OSTEOARTHRITIS: THE PROP OA PARALLEL-GROUP, SUPERIORITY, RANDOMISED CONTROLLED TRIAL [abstract only]

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Abstract

Background:

International clinical guidelines offer contradictory recommendations about knee bracing as an adjunct to core recommended treatment for people with knee

osteoarthritis (OA). There is a paucity of high-quality evidence on the benefits, harms, and costs of knee braces from large, publicly-funded, pragmatic, clinical trials.

Objectives:

To determine the clinical- and cost-effectiveness of adding knee bracing (matched to participants' clinical and radiographic presentation, with adherence support) to advice, written information and exercise instruction (AIE+B) compared with advice, written information and exercise instruction alone (AIE) among people with knee OA.

Methods:

PROP OA (ISRCTN28555470) was a multi-centre, parallel-group, superiority, randomised, controlled trial, with embedded patient and public involvement. Adults 45 years and over with clinically diagnosed symptomatic knee OA reporting moderate-severe knee pain on weight-bearing activity (≥4 on 0-10 numerical rating scale) were recruited from general practices and community advertisements around four regions in England. Participants were randomly assigned (1:1; stratified; block; centralised web-based) to either AIE or AIE+B. The trial statistician was masked to treatment allocation; participants and intervention deliverers were unmasked. AIE was delivered within a single, in-person consultation by a trained physiotherapist. Participants randomised to AIE+B were additionally fitted with either a patellofemoral, tibiofemoral unloading, or neutral stabilising knee brace, according to their predominant compartmental distribution of knee OA. They attended a follow-up consultation with the physiotherapist at two weeks. Brief motivational interviewing and motivational text messages were used to support adherence to brace use. The primary outcome was the composite patient-reported Knee Osteoarthritis Outcomes Score (KOOS-5) (0-100) at 6 months post randomisation. Key secondary outcomes included KOOS-5 at 3 and 12 months, and KOOS subscale scores and knee pain on weight-bearing activity at 3, 6 and 12 months. Primary analysis was estimated using linear mixed models (treatment policy approach). A within-trial economic evaluation was conducted from a United Kingdom National Health Service perspective via a cost-utility analysis (cost per quality-adjusted life year (QALY) gained).

Results:

Between November 2019 and September 2022, 466 participants (mean (SD) age: 64 (9) years; 213 (46%) female; 449 (97%) self-reported White ethnicity; 195 (42%) higher education; 193 (42%) employed) were randomised, with 86%, 85% and 79% returning analysable data at 3, 6, and 12 months respectively. Both groups reported improvements in KOOS-5 at 6 months, with greater improvement in AIE+B compared to AIE (AIE: adjusted between group mean difference 3·39, 95% CI 0·96 to 5·82). Key secondary

outcomes generally followed a similar pattern with greatest benefits on pain and activities of daily living (Table 1). Irritation/redness of skin was more common in AIE+B vs AIE (16% vs 5%); increased swelling, and temporary increased soreness were less common in AIE+B (10% vs 27% and 18% vs 28% respectively) at 6-months. No related serious adverse events were observed. AIE+B had an incremental cost-effectiveness ratio of £10,456 per QALY with an 84% probability of being cost-effective compared to AIE at the £20,000 per QALY threshold.

Conclusion:

Adding knee bracing (matched to participants' clinical and radiographic presentation and with adherence support) to advice, written information and exercise instruction produces small additional benefits on patient-reported outcomes for people with knee OA compared to advice, written information and exercise instruction alone. This safe and cost-effective intervention provides a treatment option for managing this common condition.

REFERENCES:

NIL.

Table 1. Primary and key secondary outcome measures: treatment effects estimates using longitudinal mixed models

Outcome measures	**3-months N = 401**	**6-months N=394**	**12-months N=370**
Primary outcome measure			
KOOS-5: (0-100)			
AIE: Mean (SD)	50.4 (15.1)	52.3 (17.3)	53.3 (18.6)
AIE+B: Mean (SD)	54.1 (15.8)	55.3 (17.0)	56.6 (17.4)
AIE vs AIE+B: Adj‡,§ mean diff (95% CI)	3.67 (1.47, 5.87)	3.39 (0.96, 5.82)	2.67 (-0.24, 5.57)
Key secondary outcomes			
AIE vs AIE+B: Adj‡,§ mean diff (95% CI)			
KOOS: pain (0-100)	4.30 (1.71, 6.89)	6.13 (3.36, 8.91)	4.76 (1.48, 8.04)
KOOS: symptoms (0-100)	2.97 (0.95, 4.98)	2.15 (-0.08, 4.39)	2.01 (-0.19, 4.20)
KOOS: ADL (0-100)	4.12 (1.55, 6.69)	5.24 (2.47, 8.02)	3.60 (0.30, 6.89)
KOOS: Sport/recreation (0-100)	3.32 (-0.75, 7.38)	1.09 (-3.34, 5.53)	0.30 (-4.70, 5.29)

Outcome measures	3-months N = 401	6-months N=394	12-months N=370
KOOS: Knee related QOL (0-100)	3.86 (1.19, 6.53)	3.16 (0.22, 6.11)	2.61 (-0.97, 6.19)
Knee pain during activity (0-10 NRS)	-0.97 (-1.30, -0.63)	-0.80 (-1.15, -0.44)	-0.72 (-1.15, -0.29)

95%CI 95 percent confidence interval; **ADL** Activities of Daily Living; **AIE** Advice, written information, exercise instruction; **+B** plus knee bracing; **KOOS** Knee injury and Osteoarthritis Outcome Score (0-100, with 0 indicating extreme knee problems and 100 representing no knee problems); **NRS** Numerical rating scale; **QOL** Quality of Life

‡§Adjusted mean difference, fitted using linear mixed models, and adjusting for PROP-OA clinic site, predominant compartmental distribution, presence/absence of instability (buckling), age, sex, baseline anxiety, baseline depression, and baseline in the outcome of interest

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Disclosure of Interests:

None declared.

References (0)

Cited by (0)

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