

# A slim-fit knee brace for young adults at risk of post-traumatic knee osteoarthritis: a feasibility study

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## Summary

This six-week randomised controlled trial (RCT) investigated the feasibility and potential for worthwhile treatment effects of a slim-fit knee brace in individuals at risk of post-traumatic osteoarthritis (OA). Of 48 screened volunteers, 50% were deemed eligible and 21 (88%) enrolled in the trial. We found improvements in symptoms (KOOS<sub>4</sub>) and physical performance (hop for distance and vertical hop) in both groups, favouring the brace group for physical performance. A full-scale RCT appears to be feasible to explore the clinical potential of slim-fit knee braces for individuals at risk of post-traumatic OA.

## Introduction

Knee OA is four to six times more likely to develop in those with a history of traumatic knee injury compared to non-injured controls [1]. Slim-fit knee braces, while inconsistently recommended for older adults with insidious-onset OA, may offer a low-cost and easily accessible option to improve symptoms, confidence, and physical performance in younger adults following traumatic knee injuries who are therefore at risk of post-traumatic OA. Our primary aim was to determine the feasibility of a slim-fit knee brace for individuals at risk of post-traumatic OA. Our secondary aims were to explore the potential for worthwhile treatment effects for knee symptoms and physical performance.

## Methods

This six-week feasibility RCT was prospectively registered (ACTRN12623001027606). Eligibility criteria included: i) 1-8 years post-anterior cruciate ligament reconstruction (ACLR); ii) age 18-45 years; and iii) ongoing symptoms (mean score <80/100 from four Knee injury and OA Outcome Score subscales (KOOS<sub>4</sub>)). Participants were randomised (2:1) to the intervention (brace) or control group (no brace). Brace group participants were fitted with a slim-fit knee brace (GenuTrain, Bauerfeind, Germany) and advised to wear it ≥1 hour daily and during aggravating activities. Control group participants were advised to continue their normal activities and received the same brace at follow-up. Feasibility was assessed through eligibility rate, enrolment rate, recruitment rate, dropout rate, adverse events, adherence (using an undisclosed temperature sensor embedded within the brace (Orthotimer, Balingen, Germany)), and acceptability of the brace intervention (through semi-structured interviews). For secondary outcomes, the proportion of participants in each group who achieved at least the minimal important change (MIC) for symptoms (KOOS<sub>4</sub>) and the minimal detectable

change (MDC) for physical performance (hop for distance and vertical hop).

## Results and Discussion

Forty-eight volunteers were screened, of which 50% were deemed eligible. Of the 24 eligible volunteers, 21 (88%) enrolled in the trial (52% male, age 31±6 years, body mass index 27±4 kg/m<sup>2</sup>, time post-ACLR 5±1 years) at a recruitment rate of four participants per month. Fourteen participants were randomised to the BRACE group, and seven to the control group. One control group participant was lost to follow-up (95% retention rate). In the BRACE group, there were two serious and three minor adverse events unrelated to the brace, and six minor adverse events related to a skin response from the brace (e.g., itchiness, redness). Two minor adverse events occurred in the control group. BRACE group adherence averaged ≥1 hour per day on 43% of days over the intervention period (individual participant range 0-78%). Semi-structured interviews indicated that participants found the brace acceptable and were satisfied with it, citing improved confidence during activities. However, some noted challenges remembering to wear it, and it could become uncomfortable during extended use or in warm weather.

For secondary outcomes, 6 (43%) participants in the BRACE group and 3 (50%) in the control group reported improvements in KOOS<sub>4</sub> of at least the MIC (i.e., >8-10 points). For physical performance, 6 (46%) participants in the BRACE group and 1 (17%) participant in the control group demonstrated improvements in hop distance exceeding the MDC (13-14cm). For vertical hop height, 5 (38%) and 3 (50%) participants in the BRACE and control group respectively demonstrated improvements greater than the MDC (1cm).

## Conclusions

A full-scale RCT appears to be feasible to investigate a slim-fit knee brace in young adults at risk of post-traumatic OA. Slim-fit knee braces may have a worthwhile treatment effect for improving knee symptoms and physical performance, but this should be confirmed in an adequately powered study. Future studies should consider exploring more sensitive outcome measures for knee symptoms and physical activity that better reflect the individualised use of slim-fit knee braces (e.g., capturing specific self-nominated activities where the brace may be used for symptom management).

## References

- [1] Poulsen E et al. (2019). *BJSM*, **53**: 1454-63