

Osteoarthritis and Cartilage



Letter to the Editor

2-Year outcome from two parallel randomized controlled trials. Reporting considerations

To the editor

We read the article by Skou *et al.*¹ with great interest. The authors reported the 2-year outcomes of two parallel trials comparing 1) total knee replacement (TKR) surgery followed by 12-week non-surgical treatment vs 12-week non-surgical treatment alone in patients eligible for TKR, and 2) non-surgical treatment alone vs written advice in patients not eligible for TKR.

The study provides an important contribution to the discussion on preferable knee osteoarthritis (OA) treatment options between patients and healthcare providers. However, we believe that the reporting of these RCTs' results raises some issues and deserves clarification.

First, we notice a discrepancy in the primary outcome reported in the publication compared with the trial registration records ([ClinicalTrials.gov](https://clinicaltrials.gov) numbers NCT01410409 and NCT01535001). In the article, the authors stated that the primary outcome of the study was the between-group difference in change from baseline to 2-year follow up in KOOS₄. However, in the study protocols, trial registrations and subsequent publications of the two parallel trials, the primary outcome was the between-group difference in change from baseline to 12 months in KOOS₄^{2–5}. The expected improvement of 10 points in KOOS₄ at the endpoint of 12 months was previously used to calculate the sample size of 100 patients in each trial^{3,5}.

The second issue relates to the reporting of the results of the two trials that could be misinterpreted as being the results of a single four-arm trial. For example, Figure 3 reported the mean score of KOOS₄ at baseline, 3, 6, 12 and 24 months follow-ups for all four groups from the two randomized controlled trials¹. The figures make it appear as though trial participants had come from the same population. While, the patients in the two trials came from two separate populations and underwent different screening procedures with distinct reasons for exclusion. Similar issues are seen in Figure 1 and Figure 4¹. We believe that more explicit presentations of these figures indicating the difference between the two populations would be helpful in order to avoid unwanted misinterpretation.

Similarly, the abstract conclusion did not clearly highlight the two different populations involved and thus, it could be misinterpreted that the four treatment options were tested on the same population.

Conclusion

We commend the authors for their efforts to compare total knee replacement surgery vs non-surgical treatment in patients with knee osteoarthritis. With this letter, we encourage a more thorough discussion on the reporting of the trial.

Author contributions

VN and CS had substantial contributions to conception and wrote the manuscript. IB contributed to the final version of the manuscript. IB supervised the project.

Conflict of interest

The authors declare no conflicts of interest.

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