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Response to Letter to Editor: '2-year outcome from two parallel randomized controlled trials. Reporting considerations'

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Response to Letter to Editor: '2-year outcome from two parallel randomized controlled trials. Reporting considerations'

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1 **Response to Letter to Editor: ‘2-year outcome from two parallel randomized controlled trials.**
2 **Reporting considerations’**

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25 Dear Editor,

26 We thank Nguyen et al.¹ for their interest in our recent publication in Osteoarthritis and Cartilage
27 entitled “Total knee replacement and non-surgical treatment of knee osteoarthritis: 2-year outcome
28 from two parallel randomized controlled trials”².

29 We do agree with the authors that clarity and transparency are crucial when reporting research
30 findings. We believe our report from the two, parallel randomized controlled trials is adequate in
31 terms of the comments given and aligns with best practice.

32 First, in the title, abstract, main text and in the figure legends, we clearly state that we are reporting
33 the results from two parallel randomized controlled trials. Furthermore, both trial registration
34 numbers are stated at the end of the abstract as required by Osteoarthritis and Cartilage and
35 suggested by CONSORT. In the introduction and methods, we provide a thorough and transparent
36 description of similarities and differences between the two trials. Based on our reporting, we find it
37 difficult to believe that a reader would misinterpret this as a single four-arm trial. Second, to
38 highlight that this is an extended follow-up of the two trials we refer to the primary reports^{3,4} in the
39 introduction and the methods. As written by Nguyen et al,¹ we clearly defined the primary outcome
40 in this extended report as the between-group difference in change in Knee Injury and Osteoarthritis
41 Outcome Score subscales, covering pain, symptoms, activities of daily living, and quality of life
42 (KOOS₄) at 24 months while the primary endpoint of the two trials was the mean between-group
43 difference in change in the KOOS₄ at 12 months.

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49 AUTHOR CONTRIBUTIONS

50 **Study conception and design.** Skou, Roos, Laursen, Rathleff, Arendt-Nielsen, Rasmussen,
51 Simonsen

52 **Drafting the letter or revising it critically for important intellectual content.** Skou, Roos,
53 Laursen, Rathleff, Arendt-Nielsen, Rasmussen, Simonsen

54 **Final approval of the letter.** Skou, Roos, Laursen, Rathleff, Arendt-Nielsen, Rasmussen,
55 Simonsen

56 All authors take responsibility for the integrity and accuracy of the content.

57

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66 ROLE OF THE FUNDER/SPONSOR

67 The funders played no role in drafting this letter.

68 CONFLICT OF INTEREST

69 Dr. Roos is deputy editor of Osteoarthritis and Cartilage, the developer of Knee injury and
70 Osteoarthritis Outcome Score (KOOS) and several other freely available patient-reported outcome

71 measures and co-founder of Good Life with Osteoarthritis in Denmark (GLA:D), a not-for profit
72 initiative hosted at University of Southern Denmark aimed at implementing clinical guidelines for
73 osteoarthritis in clinical practice.

74 Dr. Skou is associate editor of Journal of Orthopaedic & Sports Physical Therapy, have received
75 grants from The Lundbeck Foundation, personal fees from Munksgaard, all outside the submitted
76 work. He is co-founder of GLA:D. GLA:D is a not-for profit initiative hosted at University of
77 Southern Denmark aimed at implementing clinical guidelines for osteoarthritis in clinical practice.
78 The authors report no other conflict of interest.

79

80 REFERENCES

- 81 1. Nguyen VT, Superchi C, Boutron I. 2-year outcome from two parallel randomized controlled
82 trials. Reporting 2 considerations. *Osteoarthritis and Cartilage* 2018
83 2. Skou ST, Roos EM, Laursen MB, et al. Total knee replacement and non-surgical treatment of
84 knee osteoarthritis: 2-year outcome from two parallel randomized controlled trials. *Osteoarthritis and*
85 *Cartilage* 2018;26:1170-80. doi: 10.1016/j.joca.2018.04.014
86 3. Skou ST, Rasmussen S, Laursen MB, et al. The efficacy of 12 weeks non-surgical treatment for
87 patients not eligible for total knee replacement: a randomized controlled trial with 1-year follow-up.
88 *Osteoarthritis and cartilage / OARS, Osteoarthritis Research Society* 2015;23:1465-75. doi: S1063-
89 4584(15)01141-3 [pii]
90 4. Skou ST, Roos EM, Laursen MB, et al. A Randomized, Controlled Trial of Total Knee
91 Replacement. *The New England Journal of Medicine* 2015;373:1597-606.

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