Author’s response to reviews

Title: An individualized patient-reported outcome measure (PROM) based patient decision aid and surgeon report for patients considering total knee arthroplasty: protocol for a pragmatic randomized controlled trial

Authors:

Nick Bansback (nick.bansback@ubc.ca)
Logan Trenaman (trenaman@alumni.ubc.ca)
Karen MacDonald (karenv.macdonald@ucalgary.ca)
Gillian Hawker (g.hawker@utoronto.ca)
Jeffrey Johnson (jeff.johnson@ualberta.ca)
Dawn Stacey (dstacey@uottawa.ca)
Deborah Marshall (damarsha@ucalgary.ca)

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Author’s response to reviews:

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Dear Deepa Nath and Sondos Majeed,

We would like to thank you on behalf of all the authors for the thoughtful comments on the manuscript. We have provided a detailed response to each author comment.

If you have any questions or comments, please be in touch. We look forward to receiving your feedback.

Sincerely,
Reviewer comment: Overall I thought this was a well constructed RCT and I have very few criticisms. My major question is about pain and how it influences PROMS data. In my experience much of the PROMS data is influenced by pain eg if you ask a patient why their knee is stiff they will often say it is because of pain. So pain plays a major role in completing ADLs and some how the authors need to remove pain from these assessments by asking whether the "functional" deficit was due to pain, or whether the poor outcome was pain related. This would improve the validity of their results significantly.

Author response: This is a good point. We recognize that pain is a primary concern for those with knee osteoarthritis, and that it undoubtedly impacts an individuals’ assessment of other aspects of quality of life, such as their ability to undertake other activities of daily living. However, given that the measures we are using are standardized (e.g., EQ-5D, WOMAC) we need to collect them as designed. However, there is an opportunity to address these concerns through analysis. For example, we can explore the relationship between items from these instruments to understand the relationship. This includes the ‘pain/discomfort’ dimension of the EQ-5D, which will undoubtedly be highly correlated with the ‘usual activities’ dimension. By exploring the bivariate relationship between the two at the analysis stage, we hope to be able to understand the independent relationship with our outcome of interest. One planned analysis
includes seeing how baseline responses to the dimensions of the EQ-5D impact long-term outcomes.

We have also highlighted in the introduction that pain is an important outcome for patients. The passage now reads “Notably, previously developed decision aids are not individualised for each patient, instead relying on average risk information. In addition, they tend to provide information on a narrow set of clinically focussed outcomes (e.g., operative mortality) but not on how treatment will influence outcomes such as pain, which is a clear priority for patients, in addition to mobility, ability to self-care, and ability to participate in activities of daily living.”

Reviewer 2: Jörg Lützner

Reviewer comment: L58 It would be helpful for the reader if the criteria would be named here.

Author response: We have added in additional criteria. This passage now reads:

“Six criteria have been endorsed to assess TKA appropriateness.[4] While the surgeon is the best judge for several of these criteria (i.e., the patient has evidence of arthritis on examination; the patient has had an adequate trial of nonsurgical arthritis treatment; the patient is physically and mentally ready to have surgery), two require the elicitation of the patient’s knowledge and preferences.”

Reviewer comment: L123 It would be completely clear if you add that only patients which completed the questionnaire online can be included

Author response: We have clarified that those who do not complete the questionnaire online before their consult will not be eligible to participate. This passage now reads:

“Participants will be excluded if they have not completed the Routine Questionnaire 1 online prior to the surgical consultation.”
Reviewer comment: L126 Please explain how many of the surgeons which do perform TKA are participating surgeons.

Author response: We have clarified that 18 out of 23 surgeons at the clinic are participating.

Reviewer comment: L248 Do you think that the final follow-up 3 month after surgery is adequate to assess PROM after TKA. It takes longer to achieve the final result after TKA than THA. It is generally agreed that one year is sufficient to evaluate outcome after TKA, although some journals require a minimum of 2 years after surgery.

Author response: We agree with the reviewer that full recovery from TKA takes longer than the 3-month follow-up of the trial. The primary outcome of this trial is decision quality, and we will be able to assess this outcome once the decision to either have (or forego) surgery is made. While health outcomes are a secondary outcome, we are extremely interested in see if the intervention impacts the patients outcomes (either for better or worse). While we are only collecting data up to 3-months post-op, we are fortunate that the trial is embedded in a health system with routine data collection. Currently, patient outcomes are assessed at one-year follow-up as well, and we will have access to this data when available. This will allow us to look at the long-term impact.