Reviewer’s report

Title: The EKSPECT Study: The influence of Expectation modification in Knee arthroplasty on Satisfaction of Patients: study protocol for a Randomized Controlled Trial.

Version: 0 Date: 27 Jun 2018

Reviewer: Stephanie Filbay

Reviewer’s report:

There is a great need for research investigating the impact of patient expectation modification on postoperative outcomes. I commend the authors for taking the time to perform a RCT on this topic. Overall, I am satisfied with the trial methodology. I do however, have some comments surrounding the study objective and choice of primary outcomes that I hope the authors will take into consideration.

RE: 112-114: The effect of pre-operative expectation management on post-operative expectation fulfilment and ultimately better post-operative satisfaction after TKA has not yet been studied.

Is expectation fulfilment and satisfaction with surgery the most appropriate and meaningful outcome to be assessing? If a patient expects a poor outcome after surgery, they are much more likely to have this expectation met or exceeded, and be satisfied with the surgical outcome. This however, does not mean they are satisfied with their function, QOL, knee symptoms etc. Considering the positive relationship between expectations and outcome in the literature, reducing one's positive expectations has potential to negatively impact outcome. I would argue that it is very important to evaluate surgical outcome (e.g. activity limitation/function/symptoms/pain) not only surgical satisfaction and fulfilment of expectations.

RE: lines 103-104: These findings suggest that more realistic expectations potentially lead to higher post-operative satisfaction.

Is there evidence to suggest that lowering 'optimistic' patient expectations to align with what is deemed more 'realistic', is likely to improve postoperative outcome? The literature shows that higher patient expectations are associated with better postoperative outcomes than lower expectations, even if those expectations may be deemed unrealistically optimistic. I would argue that this is one of the key reasons why research is needed to determine the impact of altering expectations on post-operative outcomes.

RE: lines 211-226.

You have provided a clear overview of the evidence regarding the relationship between positive expectations and improved outcome, and highlight that 'there are no intervention studies available on the effect of increasing expectations to improve treatment outcome in TKA patients.'
I agree that this research is needed, this evidence reiterates the importance of evaluating surgical outcome. Notably, you are collecting appropriate measures (e.g. KOOS-PS, OKS, EQ-5D and NRS Pain), however, it is not clear how you intend to use these measures? Will you evaluate the relationship between expectation education and one or more of these outcomes?

I support the decision to include LOT-R, PCS, as these may be important mediators of expectation education on outcome.

Line 118-119 RE: realistic expectations for long-term recovery of symptoms, physical functioning and psychological issues (intervention group)

What is considered a realistic expectation? For some, a very high expectation will be realistic. The 'average' outcome of a sample is not a 'realistic' outcome for all patients. Is this reflected in the education given? Lowering a patient’s expectations may negatively impact their outcome, whereas providing information about the distribution of outcome, whilst not dampening ones optimism, (i.e. you may be in the minority who do extremely well after surgery, and the fact that you expect to do so, increases your likelihood of doing so) may be of greater value to the patient.

Line 126-128: RE: Additionally, an explorative analysis will be performed on the effect of the additional education module in subgroups of patients, depending on age, gender, severity of symptoms, symptoms of depression and coping mechanisms.

I suggest performing an exploratory analysis on the effect of modifying high vs. low expectations on outcome

Line 158: RE: Symptomatic and radiographic knee osteoarthritis indicated for a primary TKA How will this be defined?

Line 235. RE: 'Therefore, to the authors' opinion an education module should not result in overly optimistic expectations to be most effective.'

This statement is unclear, please clarify and re-phrase.

RE: Additionally, modifying factors are addressed that predict higher or lower outcome for an individual patient; age, medical co-morbidity, body mass index (BMI), psychosocial factors, pain severity and pre-operative functional status.[33,34]

I think the relationship between positive/optimistic expectations and better outcome should also be included here, explained in lay language that patients can easily understand.

Lines 275-289:

Some of this material is phrased with a negative bias. Example, '..only 43% is reported to return to high-impact sports' instead of '..57% of patients return to high impact sports'. Such phrasing is likely to lower patient expectations, and make patients less likely to engage in such activities or attempt such activities as 'kneeling' or 'walking longer distances.' Since they might, after
receiving this information, expect that they will not be able to perform these activities. This in turn, has potential to negatively impact outcome, further highlighting the importance of evaluating postoperative outcome.

RE: Table 1 column heading: 'Pre-operative, at admission'

Please re-phrase this heading to make it clearer that this is referring to pre-operative, but post education intervention

Lines 269-273: Why was there no patient involvement when developing the expectations education material? This was largely developed by surgeons whose experience of surgery is likely to differ greatly from that of the patient. Why not work with patients who have undergone TKA to inform the design of the materials?

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