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: 17 Jun 2018

Reviewer: Dan Riddle

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Trials-D-18-00373

The manuscript is a protocol for a randomized clinical trial designed to align patient expectations with expected total knee replacement outcomes (using an educational intervention) with an outcome of a greater rate of satisfaction in the experimental arm relative to the control arm. Secondary aims relate to whether the intervention modifies preoperative and postoperative achievement of expectations. Finally, additional analyses will determine if the effect of the experimental intervention varies based on participant age, gender, severity of symptoms, symptoms of depression and coping mechanisms. The concept for the trial seems sound and the idea is novel and potentially important. However, I found several credibility issues that appear to need attention and these are identified below.

Page 4, Trial Objectives: It is not clear to me how potential participants can be naïve to the purpose of the study. A standard part of any human subjects consent form is the purpose of the trial and a description of the different arms. How can patients consent to something in which they are not made aware of the interventions?

Page 5, Study population (sample): The inclusion and exclusion criteria do not specify whether unicompartmental arthroplasty will be excluded. Also not mentioned is whether bilateral or staged knee arthroplasty will be included and whether potential participants planning a future hip or knee arthroplasty in the upcoming year will be excluded. It is likely that near future arthroplasty of the knee or hip could influence satisfaction with the index knee.

Page 7, Experimental Intervention: I would encourage the investigators to provide an appendix with the written materials provided to the participants. This is really the only way to judge the content of the intervention and the readers should be able to see the content of the material you are using in the trial.

Page 7: The investigators suggest that expectations are strongly linked to placebo effects and in my view this extrapolation should be deleted. Evidence for this association in knee arthroplasty does not exist, in my opinion, and extrapolation from other literature to knee arthroplasty is far too premature.

Reliance on the HSS expectation survey to guide module development seems quite risky because the data used to inform the HSS expectation survey is approximately 20 or more years old.
Please address this concern. There is an abundance of much more recent evidence to inform prognostic estimates of outcome. Reliance on expert opinion to inform the educational module is discouraged. This approach is not defensible. To be grounded in science (not experience), evidence-based guidance should be the sole source for informing the module.

Page 8: I see on page 8 that a variety of sources of evidence are used to inform the module which is appropriate but this seems inconsistent with other parts of the text as mentioned above.

Page 11: A major concern is the use of the numeric rating scale for satisfaction. There is no reference provided, the wording of the question is not provided and the cutoff of 8 or greater to create a dichotomous judgement is arbitrary and reduces utility of what would otherwise be a continuous scale.

Page 11: the secondary outcome measures are mislabeled. Age and sex, for example are not outcomes.

Page 12: Of note, the factorial validity of the HSS expectation scale is unknown so one cannot be sure that this is actually a unidimensional scale with a single summary score and there are likely multiple dimensions captured with the scale. Secondly, the modifications made by Tilbury et al have not been validated and this needs to be made clear.

Reasons for using the EQ5D are not made clear and seem to be overlapping with other measures. Why are you using this scale? The reader should be informed of the rationale for choosing each scale.

Page 13: A 12 month anchor type question carries substantial bias and error. Patients are greatly influenced by current status when trying to recall baseline state. It is unclear why you are using this problematic scale. I am unclear on why this scale is used in the study.

Power analysis: Power was based on a very small sample study of 44 persons and the likert type scale that asked a very broad-based question "How satisfied are you with the results of the surgery?" I am unaware of the validity of this scale and with the very small sample from approximately a decade ago, this seems like a very crude method for estimating power in your study, particularly since you are not measuring satisfaction with the same scale and you are only dichotomizing your scale. Please explain and clarify. I would strongly encourage more contemporary and more impactful data using an appropriate satisfaction scale and not the one you are currently proposing.

Statistical analysis: The approach is dated and does not handle missing data. A more contemporary approach to the analyses is encouraged. In addition, missing data estimates should be provided and methods for handling missing data should be reported.

Safety: I found no mention of adverse event monitoring and while this appears to be a low risk study, adverse events should be monitored and reported.

**Level of interest**
Please indicate how interesting you found the manuscript:

An article whose findings are important to those with closely related research interests

**Quality of written English**

Please indicate the quality of language in the manuscript:

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**Statistical review**

Is it essential that this manuscript is seen by an expert statistician? If so, please give your reasons in your report.

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