Reviewer's report

Title: Functional outcome of total knee replacement: a study protocol for a prospective, doubleblinded, parallel-group randomized, clinical controlled trial of novel, personalized and conventional implants

Version: 1 Date: 28 May 2019

Reviewer: Andrew Beswick

Reviewer's report:

This is a well written protocol for an important RCT. It is good to see appropriate outcomes and long-term follow up.

Reading the title and abstract and paper, I don't know what the interventions are. If they are all cruciate retaining, cemented, fixed bearings, why is one "novel". There must be a way of describing the key features of each implant. I know that protocols/ articles are published comparing Product A with Product B, but many readers would like to know the features that differ between the them.

Title: "novel and conventional implants" does not provide enough information on the implants. If I was researching a particular group of implants, I would expect this to be identified in the title and abstract.

Similarly, in the abstract, it would be good to briefly describe the implants beyond the product name.

BACKGROUND

There is no need to mention hip replacement - the cited articles include hip replacement but report outcomes separately for knee replacement.

"Functional outcome after total knee replacement is, however, considered to be the least favorable measure of these two." I do not think this is necessary but if it stays, a reference is needed.

Line 18. The hip replacement figures are unnecessary

Page 4 Paragraph 2. It would be good to have a brief description of the implants being evaluated. "new" "improved" "new generation" "redesigned" are not enough.

Study objective. Again, it would be good to have the implant described. The product name could be in brackets

METHODS

Line 25. 28 is the wrong reference. Should be 33?
Throughout, check product names are consistent

Reference for 15D

As elsewhere describe the implants

Patient recruitment

It would be good to have some information on methods of informed consent

There is no information on the methods of the cost-effectiveness analysis - what perspective will be used?

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Yes

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

Unable to assess

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

Not relevant to this manuscript

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Please indicate the quality of language in the manuscript:

Acceptable

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