Reviewer’s report

**Title:** The Challenge of Recruiting Patients Into a Placebo Controlled Surgical Trial - an observational study

**Version:** 2  **Date:** 31 January 2014

**Reviewer:** Kjetil Soreide

**Reviewer’s report:**

1. Is the question posed by the authors new and well defined?  
   Yes

2. Are the methods appropriate and well described, and are sufficient details provided to replicate the work?  
   Yes

3. Are the data sound and well controlled?  
   Yes

4. Does the manuscript adhere to the relevant standards for reporting and data deposition?  
   Yes

5. Are the discussion and conclusions well balanced and adequately supported by the data?  
   See major comments

6. Do the title and abstract accurately convey what has been found?  
   Yes

7. Is the writing acceptable?  
   Yes

**Major Essential Revisions**

I believe the definition used for NNS negatively inflates the numbers, in my view you should consider only those who have symptoms AND diagnostic findings suggesting the need for surgery as being eligible. Now you have included a large group that may a priori not be willing to forego surgery AT ALL due to limited symptoms etc.

So, from the large group of patients now declining to participate, only those that agreed where sent for MRI bases on a clinically SUSPECTED meniscal tear. I assume that is why your NNS at 12 is higher than other studies. The number needed to screen would then be influenced by the referral policy and the pre-test likelihood for truly having the problem under investigation AT ALL, base don GP referral.
You have discussed this in the Discussion, and I agree that consenting those with suspected meniscal tear would be appropriate if the RCT was for arthroscopy per se (say, compared to MRI first), but if the intervention is meniscal repair or not, it should be based on those with ACTUAL demonstration of a tear (say after MRI). And that is what you have in the inclusion criteria, so in my point of view, the first part of the screening process inflates the numbers and make the NNS look higher than it is.

Also, I think it is crucial to view your results in the light of the recent FIDELITY study published in the N Engl J Med 2013, a Finnish study who elegantly accomplished exactly what you proposed to do here. Is the timing of consent and definition of eligibility the clue to high/low rates?

I think it all may be a matter of timing, that is, when has eligibility truly been confirmed?

When is the patient addressed concerning study inclusion?

As stated, oral information is crucial, and I believe (although not stated here) that the physician/person who informs and includes has a VERY large role in how patients find themselves willing to participate in a trial. Factors such as the physician age, gender, voice (tone and manner of information) and even attitude (does the physician believe there is an equipose between real and sham surgery and is this truly conveyed to the patient?) may all contribute to the patient decision, however I acknowledge that these are factors hard to investigate or disclose in a study. However, from personal experience I know that different persons have a different ability to bring forward information which influence the rate of consenting patients.

Minor Essential Revisions

Consider including the experience from:


Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:
I declare that I have no competing interests