Reviewer’s report

Title: Hospital Inpatient versus HOme-based rehabilitation after knee arthroplasty (The HIHO study): A randomised controlled trial protocol

Version: 1 Date: 18 September 2013

Reviewer: Andrew Judge

Reviewer’s report:

- Major Compulsory Revisions (which the author must respond to before a decision on publication can be reached)
  None

- Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

Abstract:
Need to remove the use of abbreviations from the abstract.
In the sample size, would state this as 5% level of significance rather than 95% confidence.
In the sample size include the standard deviation of the difference used in the calculation.

Recruitment and consent:
In the exclusion criteria you do not mention patients admitted for trauma, emergency admissions. Are these patients excluded?
The study will take longer as you are following patients up beyond 6-months follow up.

Randomisation and allocation concealment:
Only a few confounding factors have been included for minimization. Other factors could have been included e.g. baseline level of function prior to surgery, and more detailed strata for the confounders already included such as more age groups.

Baseline and other data:
Demographic data collected on potential confounders is minimal. Given the limited factors included in minimization, and in order to confirm how well balanced the groups are following randomization, maybe other prognostic factors should also be collected such as SF36 Mental health or EQ5D anxiety/depression, and problems in other joints?

Sample size:
For the sample size what is the standard deviation used in the sample size. I assume the SD was 120 as you state a 0.5SD difference? Does this come from existing literature or from you recent RCT. Please provide a reference and rationale why a difference of 60m is clinically meaningful. It is generally accepted that half an SD of the change score approximates an MCID, but needs some data or reference on where the SD was obtained from.

Analyses subsets:
How will you deal with missing data for the ITT analysis?
State you are using Analysis of Covariance rather than regression analysis for the primary outcome.
Have you considered using repeated measures regression to look at change in outcome over the 10, 26 and 52 week end-points? You briefly mention a mixed model analysis.
It is unclear how the data on the observational cohort (the third group) that don’t wish to be randomized will be used, and how it will be analysed, or what the sample size of it will be?

- Discretionary Revisions (which are recommendations for improvement but which the author can choose to ignore)
The time of measurement of primary outcome keeps changing between 26 weeks and 6-months. Maybe be consistent and just state 6 months?

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:

No competing interests related to this manuscript. I have received honorariums, held advisory board positions (which involved receipt of fees), and received consortium research grants, respectively, from: ROCHE, Anthera and Servier.