Reviewer's report

**Title:** Use of clustering analysis in randomized controlled trials in orthopaedic surgery

**Version:** 2  **Date:** 12 October 2014

**Reviewer:** Sahul Bharti

**Reviewer's report:**

**Major Compulsory Revisions:**

A justification for using higher level of significance (alpha 10%) in present study is warranted.

A predictor of sample size with odds ratio of 1 does not make any clinical or statistical sense and hence must be ignored from results or discussion section.

In how many studies, there was clear identification of term ‘cluster randomized’ in the title or abstract of the report? This will indirectly give insight about a priori awareness of trial investigators for the role of clustering in analyzing their outcomes?

What were prevalence rates of adjustment for clustering between binary and continuous primary outcomes?

What proportion of included studies accounted for clustering while calculating sample size using either intra-cluster correlation coefficient (ICC) or design effect? To improve the power of study and reduce bias, it is crucial whether or not the sample size calculation (if reported) accounted for clustering. A trial is classified as meeting the sample size requirement if the sample size calculation is presented and clearly accounted for clustering (such as by using the intracluster correlation, coefficient of variation, or design effect).

Nature of analysis used to adjust for clustering was not differentially described by study authors. What percentage of studies carried out cluster level analysis by using summary measures (cluster level analysis), and what proportion of studies used individual level analysis adjusted for clustering. Since type of statistical adjustment for clustering mainly dependent upon number of clusters included in trial, it would be important that authors highlight the distribution of clusters in included RCTs.

**Minor Essential Revisions:**

As per consort guidelines for cluster RCT, it is imperative for any cluster RCT to estimate ICC value for similar future studies. How many studies did indeed report estimation of ICC?

It would be nice if authors could justify whether sample size of their own study
was adjusted for clustering among 5 top orthopedic journals?

Discretionary Revisions:

Did authors use any CONSORT (Consolidated Standards of Reporting Trials) checklist for analyzing the reporting of clustered randomized controlled trials in order to determine how well each trial adhered to the published reporting guidelines?

The extension to CONSORT for cluster randomized trials had indeed resulted in improvements in reporting of cluster RCTs. It is also likely that the extension had a greater impact in journals that actively endorsed (and explicitly enforced) the guideline. Therefore, did authors evaluate or determine whether CONSORT extensions for cluster RCT were endorsed by each participating journal or how they were enforced?

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no competing interests