Reviewer's report

Title: Diagnostic Randomised Controlled Trials: The Final Frontier

Version: 2 Date: 12 March 2012

Reviewer: Dragan Ilic

Reviewer's report:

The authors present a novel manuscript that argues the point for conducting diagnostic randomised controlled trials. Overall, the article addresses an important issue, is well structured and balanced. The following comments are provided as suggestions for further strengthening the manuscript.

Major Compulsory Revisions

• The authors make the comment that “While randomized trials of non-therapeutic interventions such as surgical procedures and behavioural interventions lag far behind those of drugs, randomized trials of diagnostic procedures are an even rarer species.” Can the authors provide some insight into as to why this is so?

• The authors describe the diagnostic randomised controlled trial (RCT) as a comparison of two diagnostic interventions (one standard and one experimental) with identical therapeutic interventions based on the results of competing diagnostic interventions... Several figures are also provided with the manuscript, however these are not referred to in the manuscript. Please incorporate/refer to Figures 2, 3 and 4 when describing the proposed diagnostic RCT, as these figures would greatly clarify for readers the proposed methodology.

• The paragraphs under the section titled “The value of the diagnostic randomized controlled trial design” lack any references to support the statements. Please include appropriate references to support statements.

Discretionary Revisions

• The authors dedicate a section explaining the value of the diagnostic RCT using their venography and clot tri-corder example. Is it possible to construct a figure that may visually describe some of the concepts discussed within this section? e.g. selection bias etc...

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

Quality of written English: Acceptable

Declaration of competing interests:

I declare that I have no competing interests.