Reviewer’s report

Title: Reporting of sex and gender in randomized controlled trials in Canada: a cross-sectional methods study

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Reviewer: Sabine Oertelt-Prigione

Reviewer's report:

In the present manuscript, Welch and colleagues address the incorporation of sex and gender specific analysis into Canadian randomized controlled trials. A MEDLINE search provided a large number of Canadian led or funded trials, of which the first 100 were selected for analysis.

Overall, the authors detected little to no incorporation of sex and gender specific analysis in the sample publications, although the Canadian research environment is actively promoting the incorporation of this kind of investigation into biomedical and clinical research.

The paper addresses a very important issue in times where the incorporation of sex and gender specific analysis is being increasingly mandated by funding bodies and journals. The translation of these requirements into practice is of relevance to the research community well beyond the field of sex and gender specific medicine, since all researchers might eventually have to apply these requirements.

The main issue that should be addressed further is the heterogeneity of the publications retrieved through this kind of approach. Selecting the first 100 Canadian RCTs led to a very diverse group of studies and research topics, making it difficult to compare the quality of the performed analysis among these publications. I can understand the approach, yet I feel it needs some more data and specifics. The number of participants ranges from 3 to 3843 males and 1 to 1712 females with medians around 50 in both groups. This leads me to believe that most of the trials were small - and most likely underpowered for any sort of subgroup analysis. Would it be possible to add a table detailing the number of participants within these 100 RCTs? Furthermore, since the criticism many scholars in the field of sex and gender specific medicine have to face is the raise in costs due to the need of inclusion of more individuals in order to perform sex-specific analysis, the question of statistical power becomes essential (and frequently controversial). This should be discussed. Were the studies powered to detect any kind of subgroup difference? Were the sex-specific analyses (if performed) done rigorously? What does it mean for the researchers to perform this kind of analysis? What needs to be considered? The discussion should probably refer to this point as well.

My second point is linked to the first one. Were any specific aspects/commonalities identifiable in the publications that performed some sort of sex and gender specific analysis? Were the trials
larger? Did the type of funding matter? Did authorship matter? Did the publishing journals have some sort of requirement to include this type of analysis? Although not statistically significant, it would be interesting to know whether any trends appear in these manuscripts.

Finally, the authors point to a forthcoming publication about comprehensive sex and gender specific reporting in RCTs, yet it would be desirable to have at least some short recommendations in this manuscript as well. Based on these results, what would the essentials for reporting be?

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- An article of importance in its field

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