Reviewer’s report

Title: Outcomes in Trials for Management of Caries Lesions (OuTMaC): Protocol

Version: 3  Date: 18 August 2015

Reviewer: Sonja Derman

Reviewer’s report:

The manuscript describes the process to develop a central outcome set (COS) for trials on prevention and management of carious lesions by reviewing the existing evidence and extracting the COS via an e-Delphi process. This is interesting and innovative, even if a French group published a COS for pulp treatments of primary teeth in 2013 (http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3536772/). For their e-Delphi process, they used experts (authors of trials, pediatric dentistry teachers) only. Including patients in this process is unique and consistent regarding an evidence-based, patient-centered dentistry. Moreover, the development of COS needs to be distributed in dentistry and this paper could solve as a guide for future projects.

The authors managed to describe this complex development process in a plain way. I have no recommendations to improve this manuscript with regards to content and language.

There is only one question left: Are primary and permanent teeth included? I think primary teeth are excluded, but it would be helpful if this information would be given.

Regarding the PRISMA checklist, I mentioned a number of points as “not reported”. In my opinion these point do not need to be addressed in reporting a kind of review protocol but in the final publication.

PRISMA #5: Trial can be found on website (www.comet-initiative.org), but no registration number is provided there.

Please update reference style (remove bold and italic parts) according to TRIALS output style.

Figure 1 (Study flow) gives an overview of the COS development. The paper is written in a very clear and structured way. For my opinion, it is not necessary to include.

I highly recommend this manuscript for publication. Please find the PRISMA checklist attached.

Minor essential revisions:

1. There is only one question left: Are primary and permanent teeth included? I think primary teeth are excluded, but it would be helpful if this information would be given.
2. Please update reference style (remove bold and italic parts) according to TRIALS output style.

Discretionary revisions:

1. Figure 1 (Study flow) gives an overview of the COS development. The paper is written in a very clear and structured way. For my opinion, it is not necessary to include.

**Level of interest:** An article of outstanding merit and interest in its field

**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 interest’s below.