Reviewer's report

Title: Comparison of a high and a low intensity smoking cessation intervention in a dentistry setting in Sweden - a randomized trial

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Reviewer: Carl J Lombard

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I have read this manuscript with interest since I have been involved in pragmatic trials which can be used to classify this trial in dentistry setting. The authors will do well to read the publication on reporting of pragmatic trials and the CONSORT statement.


As an example from this paper one wonders about the dental hygienists who delivered the intervention. Are they the standard councillor available in a normal dentistry setting or where they specially trained for this purpose. What is meant by experienced - 5 years of smoking cessation counselling? Obviously they were no blinded to the intervention groups. Where patients randomised to the three counsellors to start with? Did the each counsellors deliver the interventions of both groups to the same number of participants? Did a participants in the LIH group received the follow-up sessions from the same councillor? What was the number of expected sessions completed in both arms?

Reporting of the trials results

Table 1 is NOT suitable for the reporting of the baseline characteristics of the trial since it reports on subgroups (gender) and not on the intervention groups as a whole. The current table is only for secondary analysis purposes.

Table 2

The reporting of the intention to treat analysis is the correct approach. This analysis should be based on the number of subjects randomised (n=300) the six subjects who did not complete the baseline questionnaire cannot be excluded just for that reason. The study team should have done the short questionnaire on them at 12 months to ensure a complete follow-up. The should therefore be part of the non-completers in both arms. No information is provided on their group status. Hopefully it will be balanced across arms.

The current per-protocol results for the main outcomes are very similar to the incomplete ITT results and in my view does not add anything to the understanding of the trial.
Sub group analysis.

Hopefully all the subgroup analyses were specified in the protocol. What is important for the trial is the consistency of the intervention across important subgroups: gender, education, intensity of smoking etc. A formal test for homogeneity of the trial results for the important subgroups should be reported which can be done in the text. The logistic regression models can be modified to do this or a Mantel-Haenszel approach can be used. This is OK for variables measured at baseline or randomisation.

Post-randomisation variables.

Sub-group analysis is not suitable for variables measured post-randomisation such as other support and depression. Both other support and depressive mood fall into this frame. The handling of co-interventions and other states is a difficult issue and any analysis is only for understanding or exploratory. See for instance the paper by Rochan J. Supplementing the intent-to-treat analysis: accounting for covariates observed postrandomization in clinical trials. Journal of the American Statistical Association Vol 90 no 429 (Mar 1995) pp 292-300.

Determinant analysis.

The multiple logistic regression model presented in Table 4 is a secondary analysis and has two post randomisation co-variates as determinants. I am not convinced that this model is OK for this purpose. I would limit the analysis to the baseline covariates only. One approach to understand the role of other support and depression is to model these as secondary trial outcomes in the spirit of the paper of Rochan.

The FULL ITT analysis will be the best unbiased estimate of the intervention effect and for that purpose I would even consider reporting the difference in proportions and confidence intervals as the statistical measure of the trial.

The trial has been conducted in a good pragmatic approach and it was designed to answer a basic question: can smoking cessation work in a dentistry setting. It was not designed to tease out determinants of smoking cessation and thus the focus should be to report the way the trial was done and its results in the best way possible.

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.