Reviewer’s report

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

Version: 5 Date: 2 February 2009

Reviewer: Carl J Lombard

Reviewer’s report:

The description of the composition of the intervention activities in both groups are now fine and inform the reader.

The results presented in Table 1(a) also reflect the available data in the two groups. The randomization provided two groups with a balanced profile. Except for age there is no difference between the two groups. Therefor there is no association between these variables and the intervention. This has the implication that they are no confounders (the aim and purpose of randomization). Due to the successful randomisation the need to do an adjusted analysis falls away. The similarity in the estimated OR for HIT vs LIT for the ITT analysis and the adjusted analysis is therefor as expected! The statement about the adjusted estimate in the discussion is therefore needless and a duplication of the main finding. This statement would have been important if the randomization was flawed or the study was observational.

Table 2 with the ITT is now complete and represents the important findings of the trial.

A comment below Table 3 informs the reader that there is homogeneity in the treatment effect across all baseline variables considered. The authors rightly comment in the discussion that the power of the study to evaluate this aspect was low at the start of the study. The sample size consider for the study was planned for the main outcome but not for these interactions.

Table 4. The determinants of abstinence are the main feature of this table. See earlier comments on the adjusted OR for the intervention comparison. Again the study was not designed with this purpose in mind and is thus exploratory.

Major

In the results the smoking intensity at baseline is not associated with the intervention but is associated with the outcome. There is no statistical evidence of a differential association across the treatment groups (no interaction or effect modification). The recommendation that the HIT intervention should be offered to people who smoke more that 20 cigs /day is therefore based only on observational data. The study participants were not stratified on smoking intensity for randomisation at baseline. This statement should be toned down and qualified.
Minor:
Figure 1.
A proper ITT analysis was done but this is not reflected in the figure. The reader does not know in which arms the 6 participants were who dropped out at the start. The 150 randomised in each arm should be broken down by completed study, started by did no complete and never started. This would reflect an ITT trial schema.

Minor

There is no discussion why the point prevalence was not significant between the two groups but the longer term outcome was. It is stated that the overall point prevalence in the LIT was higher. In my view one would expect the point prevalence difference to be bigger than the longer term abstinence. Is this differential also evident in other smoking cessation studies?

**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.

**Declaration of competing interests:**

'I declare that I have no competing interests'