Reviewer’s report

Title: Is a combination of varenicline and nicotine patch more effective in helping smokers quit than varenicline alone? A randomised controlled trial.

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Reviewer: Karl Fagerstrom

Reviewer’s report:

It was a pleasure to read this paper. First it deals with a very obvious question for most therapists, whether combining the most efficacious treatment - varenicline - with the second most effective - nicotine patch - increases smoking cessation rates. Secondly it was clear succinct and easy to read. The need for a study of this kind was very strong and here it is, and done with the standard methodology used for this type of work. Apart from the standard outcomes I was happy to see that the authors also had looked specifically at those who were "non-reactors" to varenicline.

I do not have any major points that needs to be addressed but some minor ones that can improve the paper further.

1. INTRO, second para. Authors say that "the two medications appear alike". Seems to me that they are only thinking about the agonist effects but varenicline also has an antagonistic effect that deserves mentioning here.

2. third para. "Nicotine from NRT acts on all nAChRs..." I would rather say that nicotine from NRT is not specific to alpha4 beta2 or authors should provide a reference where it comes clear that NRT acts on all nAChRs.

3. RESULTS, bottom page11. It seems as the weight increase was contrary to what could be expected, more increase with active patch. Although not significant when the outlyer was taken out I think it could be of interest if the authors could comment that finding a bit.

4. Table 1. In the top of the table is written for Placebo patch (N=53-59) and for Nicotine patch (56-58). It is not clear to me what is ment with 53-59 and 56-58. Did the nume of patients taht had given data to the variables below vary between those numbers? Please clarify.

Further down on Cig consumption the standard deviation was 10.5 for Placebo patch but much bigger 26.3 for Nicotine patch. Was there some extreme outlyer?

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:
I am receiving consulting fees from the manufacturers of both nicotine patches and varenicline.