Reviewer's report

Title: Improving adherence to web-based cessation programs: a randomized controlled trial study protocol

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Reviewer: John Norrie

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The authors provide a very clear protocol. There are some issues that could usefully be clarified, as follows:

1. The authors describe this as a 2 (NRT, no NRT) * 2 (SN, no SN) factorial design, but this doesn’t seem to reflect the way they are setting up the hypotheses and powering the study – it seems instead it is a straight forward 4-group trial of WEB[1], WEB+NRT[2], WEB+SN[3], and WEB+NRT+SN[4], with the 5 comparisons of interest as 2, 3, or 4 vs 1, and then 2, 3 vs 4. For a standard 2*2 factorial, the main comparisons would be for the main effect of NRT [2+4 vs 1+3] and the main effect of SN [3+4 vs 1+2], and the study would implicitly assume no interaction in the power calculation. Here the authors actually are explicitly including a small interactive effect (since 8% + 6.5% for the individual effects is less than the 16% assumed for the combination), and they have powered the study at a 1% level of significance to adjust for the 5 stated primary comparisons. So I think it will needlessly confuse readers introducing the terminology ‘2*2 factorial’?

2. The description of the ‘social network integrators’ isn’t that clear. How many of these integrators are intended to be recruited? There is a target of 2,000 participants going to be randomised to the two social network arms – how many can an integrator deal with? The description on page 21 talks of the ‘use of dedicated staff’ and ‘full time professionals’ – what is the time commitment expected from these integrators?

3. Also, how long does someone who has successfully quit smoking stay involved in an on-line community devoted to helping people quit smoking? Does there come a point where they consider themselves to be an established non-smoker and of little or no further interest in smoking and its culture and issues?

4. The authors discuss ‘contamination’ (page 21) and sensibly see that the uptake of either NRT in groups not randomised to free NRT for the initial 4 weeks, or the participation in a social network online for those likewise not randomised to this intervention as ‘unavoidable and part of the nature of conducting dissemination work’. However, the authors go on to point out that a very small percentage of participants engage in the community and use pharmacotherapy as directed – so doesn’t this make the influence of any contamination proportionally more rather than less of a worry? That is, if uptake was universal a small amount of contamination wouldn’t matter that much,
5. Also, isn’t there potentially a major issue in that 4 weeks of NRT isn’t perhaps long enough? What was the 4 weeks based on? Cost, or evidence of effectiveness?

6. It would be useful to understand better the ‘website utilisation’ metrics – they seem naively to be based purely on time-based ‘exposure’ measures – not on whether the important content has been received, understood and acted upon. For example, if someone is highly motivated and finds the right information quickly or establishes an important social network quickly, there ‘website utilisation’ might seem very modest (albeit ultra effective) – whereas someone online for a long time might just be reflecting an unsuccessful period of usage? That is, these metrics may be non-linear in their relationship with outcome?

7. The authors clearly indicate that biochemical verification of smoking status isn’t feasible on a national sample enrolled through the internet – that is understood – but the proposed random sample of 10% of self-reported quitters with an established protocol for verification by a significant other still presumably relies on self-report? Was there no possibility of conducting a separate substudy on e.g. 5% using biochemical verification?

8. In terms of the exclusion criteria, are these all solely based on self-report too? Would all potential participants reliably know and report any of these contraindications to NRT?

9. The authors should clarify the nature and rapidity of the feedback and professional guidance that is going to be available – they say the website is open 24/7, but later say that ‘Administrative support is available and all questions are addressed within 2 business days’ – so is this just about technical internet issues, not about quit questions etc?

10. Page 19 – the authors seem to be committing to formal statistical tests of baseline imbalance between the randomised groups. This is considered poor statistical practice – imbalances are to be expected and by definition of randomisation are chance events. It is more appropriate to identify a priori what covariates are known or likely to be strongly associated with the outcomes, and then adjust for them regardless of their distribution in the experiment at hand.