Author's response to reviews

Title: Acceptability and effectiveness of opportunistic referral of smokers to telephone cessation advice from a nurse: a randomised trial in Australian general practice

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Author's response to reviews: see over
Dear Dr Norton

Re: Manuscript 5793457416871579
Acceptability and effectiveness of opportunistic referral of smokers to telephone cessation advice from a nurse: a randomised trial in Australian general practice

Thank you for your email correspondence dated 9 January 2008 in which you invited us to resubmit a revised copy of our manuscript that takes into account comments from two reviewers.

First we note the reviewers’ positive statements about the trial – ‘This is a clear account of a well conducted pragmatic trial addressing an important question’ (Reviewer 1) and ‘.. a clearly written paper outlining a well done study of an important intervention’ (Reviewer 2).

Our point-by-point response to criticisms follows.

Reviewer 1 – Discretionary revisions

1.1 Page 5, para 2 - suggests intervention would be more likely to impact on quit attempts and abstinence rather than relapse prevention per se.

We agree with this reviewer’s assessment of the literature and have amended the paragraph as follows:

‘…interventions known to be especially effective in promoting quit attempts and achieving abstinence could perhaps be delegated to and delivered by a nurse’.

1.2 Page 7, last line para 2. Query about the sensitivity of self-reported smoking being 100% in cited study.
We thank the reviewer for picking up an error which had crept in at some point during the editing of this manuscript. In the study undertaken at our colposcopy clinic, sensitivity of self-reported smoking status was 94% (95% CI 83-99%) using a cut off of 600 nm/L for urinary cotinine levels. Specificity was also 94%. We apologise for this error. The manuscript has been corrected.

‘Previous Australian research has confirmed the accuracy of self-report to be high with sensitivity and specificity of 94%’.27

1.3 Page 8, Para 3, requests more detail about ‘usual care’ and raised the issue that GPs may have provided a different level of smoking cessation advice to patients in the control group.

On the basis of previous observational studies in general practice, we anticipated that ‘usual’ GP advice would be minimal or non-existent. We have modified the paragraph to clarify this. The point that GPs may have given differential advice to patients in the control group is an interesting and important one. We did not attempt tape the consultations as, in a previous trial of a smoking cessation intervention in similar general practices, this was not acceptable to either GPs or patients and we were concerned that this would compromise the feasibility of the present study. We have added a paragraph to the discussion (page 15) to address these issues.

‘Patients in the control group received ‘usual care’ from their GP. Based on previous research that consistently has demonstrated minimal smoking cessation advice from GPs to smokers during routine consultations,8,9 it is probable that control group patients received, at best, a recommendation to stop smoking and the provision of a ‘Quit Kit’ to take home. Unfortunately it was not possible to monitor consultations directly as this study was undertaken in non-academic family practices where a requirement for audiotaping would likely have considerably reduced GPs’ willingness to take part in the trial. If GPs had inadvertently ‘compensated’ for patients being allocated to the control group by providing a greater level of advice to these individuals, this could also go some way towards explaining the lack of apparent benefit of the nursing intervention. However, there was no difference between groups in patients’ recall of smoking cessation advice in subsequent consultations so it does not appear that GPs differentially provided greater follow up about smoking cessation for those in the control group.’

Reviewer 1 - minor essential revisions

1.4 Page 5, para 2, line 6 – typo in the CIs

Corrected
Reviewer 2 – Major compulsory revisions

2.1 Requests a power calculation

Our power calculation has now been included. A small pilot study found that telephone counselling from a nurse was accepted by 95% of smokers attending local general practices. Therefore, we did not factor in uptake of the intervention and were surprised by the low uptake of the nursing telephone service in the present trial. The following paragraph has now been added to page 9.

'Based on previous research demonstrating that differences in quit rates of over 10% can be achieved with intensive smoking cessation interventions involving individualised behavioural counselling and repeated follow up, we calculated that 214 smokers would be needed in each group in order to detect a 10% difference in quit rates at 12 months, with 80% power and 5% alpha. A pilot study conducted in three general practices found very high acceptance of the intervention among smokers with only 5% declining telephone assistance from a nurse.'

2.2 Requests clarity about whether the providers actually carried out the intervention.

GPs were required only to provide usual care and to obtain consent from patients in the intervention group to be contacted by the nurse. Please see response to 1.3 above about what constitutes ‘usual care’. The GPs’ receptionists were responsible for handing out study packs to all patients (regardless of smoking status) who attended for routine consultations on the data collection days. The provision of packs in consecutive order to patients (to maintain the randomisation schedule) was recorded in study logs and monitored by the study team.

While we agree that there will be differences in intervention effectiveness according to the skill and enthusiasm of the provider, we do not see this as a major issue in our study. In our study, the smoking cessation intervention was provided by a trained nurse in a standardised manner according to a study manual that outlined the timing and content of each call. The nurse maintained a log of all attempted and completed calls for quality assurance purposes. We do not feel that we could have implemented the phone intervention in a more standardised manner. We agree that the amount of smoking cessation advice delivered by GPs to patients in the control group could vary, but previous research has consistently shown that this is usually extremely limited. Furthermore, as noted by Reviewer 1, this is a pragmatic trial that is essentially asking the question of whether a nursing telephone smoking cessation service could improve quit rates among GP patients in the real world, over and above what is happening already. We did monitor whether GPs differentially followed up smokers in the control group, eg by asking them to return for a follow up visit to discuss smoking or by referring
them to other available cessation services. This did not appear to be the case and is the purpose of Table 5.

2.3 Suggests changing the smoking cessation advice section and Table 5.

Table 5 is included to show that GPs did not provide a differential level of smoking cessation advice to intervention or control group patients during the time of the nursing intervention. It is possible that the study could have raised awareness the need to intervene with smokers and we wanted to monitor whether a differential number of smokers in each group received further advice or follow up by the GP. The question in the questionnaire about referral to a telephone clinic or counsellor focussed on other smoking cessation services that are available in the area, not to the intervention nursing service (hence only 5% of smokers in the intervention group replied in the affirmative to this question).

2.4 Requests information about social marketing or other implementation strategies that were used to maintain adequate levels of physician participation in the trial.

We did not attempt to change GPs’ actual behaviour in providing smoking cessation advice in this trial. GPs were involved only in the recruitment and referral of patients. A mutually convenient three-week study period was arranged for patient recruitment at each practice. This was done sequentially, practice by practice, to maintain a regular workload for study staff and the nurse. Study staff visited each practice twice weekly to collect questionnaires, check study processes and logs and to liaise with practice staff and GPs. A sentence about this has now been added to the Methods section.

‘Practices were visited by research staff twice each week during the study period to collect completed questionnaires and study logs and to liaise with practice staff.’

2.5 Suggests omitting Table 2 and Table 4.

We will follow editorial direction on this point. Given the lower than expected uptake of the intervention, we feel it is important to investigate the characteristics of patients who did or did not consent to nurse referral as shown in Table 2. We think that in providing the numerators and denominators for each of the categories of subgroup, Table 4 may help readers understand the subgroup analysis as from our experience, this type of information is difficult to convey fully and clearly in text.

2.6 Requests omitting chi square values from article and tables.

All test statistics and degrees of freedom have now been removed from the article and tables.
2.7 Suggests removing test statistics and p values from Table 3 and reformatting table.

We have removed the column of test statistics and p values. We attempted to reformat the table as suggested by this reviewer but were unable to maintain the portrait orientation (as requested in Instructions to Authors page on the website) and the font size as the table still requires seven columns. We will follow editorial advice on this point and will provide the table in landscape format if preferred.

**Reviewer 2 - Minor essential revisions**

2.8 Requests that all numbers are rounded to the nearest integer to improve clarity.

All numbers have now been rounded to the nearest integer.

2.9 Requests clarification of Page 7, para 3, sentence 3.

The confusing clause has been removed. The impact of the requirement for cotinine validation on participants’ willingness to take part in a study is covered in the discussion (Page 16, last line).

2.10 Requests inclusion of information about the number of patients who received the wrong intervention.

Five patients in the control group received the nursing intervention by mistake. These patients were analysed as controls according to intention to treat principles. This information has been added to the Results section (Page 11, last para).

2.11 Suggests further discussion about differences in intervention uptake by provider.

Unfortunately, the small sample size precluded meaningful comparison of rates of uptake of the intervention by smokers allocated to the intervention group at each of the 30 practices.

2.12 Page 11, para 3, sentence 2, requests omission of ‘Wilcoxon rank sum test’.

This has been removed.

2.13 Page 12, para 1, last sentence requests amendment of the sentence about interpretation of the odds ratios.

The sentence has been amended to read: ‘Smokers who, at baseline, were in ‘contemplation’ had a three-fold increase in the odds (OR 2.6, 95% CI: 0.8-8.1) and those in ‘preparation’ had a nine-fold increase in the odds (OR 8.6, 95% CI: 1.7-44.4) of completing all four calls of the intervention compared with those in ‘pre-contemplation’.'
2.15 Requests clarification of page 12, para 4, second sentence.

This sentence has been clarified. Due to editing of manuscript, the sentence is now in the first para of page 13.

‘Likewise, the intervention was equally ineffective for smokers who were in ‘pre-contemplation’, ‘contemplation’ or ‘preparation’ stages of change for smoking cessation at the time of recruitment to the study (Table 4).’

2.16 Requests text ‘Did not complete questionnaires’ to be moved up in the follow up boxes in the figure.

This has been done and in addition the brackets around numbers have been removed from this figure to improve clarity.

**Reviewer 2 - Discretionary revisions**

2.17 Suggests mentioning that patients having to purchase their own NRT is a barrier to receiving treatment and might result in a lower population quit rate for both groups, thereby making it harder to detect a difference.

NRT products are available in Australia by over the counter purchase from pharmacies. As our study aimed to find out whether telephone cessation advice from a nurse improved quit rates among patients attending for routine consultations in general practice, we did not provide any other resource for patients in either group that would not be generally available outside of the trial. Had we provided free NRT for the nurse to distribute to patients in the intervention group, we would not have been able to distinguish between the effect of the nurse and the effect of the NRT unless we undertook a larger study with a more complex design. If we had provided free NRT for GPs to distribute to all patients (intervention and control group) at the time of enrolment to the study, this may have prompted GPs to change their usual practice and provide a greater level of cessation advice to patients. We therefore would not have been able to answer our primary research question about the impact of the nursing telephone support service over and above GPs’ usual care. We feel that a discussion of whether NRT should be provided free of charge to all smokers, or only to certain subgroups of more motivated smokers as has been suggested in the literature, is beyond the scope of the present article.

2.18 Page 11, para 3 suggests changing ‘patient flows’ to the singular.

This has been changed.

2.19 Suggests grouping the 6-month and 12-month outcome data together.

The Results section has been modified to read:
‘There were no significant differences in study outcomes between groups at either six or 12 months (Table 3).’

In addition, we have added the following paragraph stating each author’s contribution to the study:

**Authors’ contributions**

*JY and JW conceived the study and designed the protocol. JY performed the statistical analyses and drafted the manuscript. SG recruited the GPs, managed the study and contributed to data analysis. TB developed the nursing intervention and co-ordinated the data collection, MH provided the nursing intervention. All authors have read and contributed to this article and approved the final manuscript.*

We have checked that the manuscript is formatted in the journal’s preferred style and have changed the reference format in keeping with the instructions for authors. Please let us know should you require any further amendments to the article.

Thank you for your assistance with this manuscript.

Yours sincerely

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