**Author's response to reviews**

**Title:** A randomised trial to evaluate the effectiveness of using personal tailored risk information and taster sessions to increase the uptake of smoking cessation services

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**Version:** 2  **Date:** 8 October 2012

**Author's response to reviews:** see over
Dear Editor

Thank you for the invitation to revise this paper and the opportunity to reply to the referee’s comments.

We found the reviewer’s comments useful, and have made some revisions to the paper.

We are, however, a little puzzled as to why this paper was sent out to review. Your author guidelines state that study protocols will usually be published without peer review if the study has received ethics approval and a grant from a major funding body. This study is funded by the NIHR HTA programme and as such underwent thorough peer review prior to funding being granted. It has also received ethical approval. For this reason some of the reviewer’s comments and suggestions are not appropriate. As an ongoing trial approved by the funders and by the ethics committee, the protocol cannot be changed at this stage.

Our full responses to the reviewer’s comment are attached below.

In addition during the 3 months since the paper was submitted, we have received additional funding from the HTA to extend the study. Changes resulting form this funding are documented at the end of the paper under ‘Trial Status’

All changes are tracked in the revised submission. I confirm that the protocol has not been previously published.

Yours sincerely

Hazel Gilbert
Reviewer’s report:
Despite the widespread availability of smoking cessation services, uptake remains suboptimal. The investigators are addressing a clinical important and yet under-studied research question—namely, what are effective strategies for improving recruitment of smokers into smoking cessation treatment services? Generally speaking, the methods are well-described and justified. Methodological strengths include the practical nature of the treatment outreach/recruitment strategies being tested, the large sample size, the clinical capacity of the NHS SSS, novelty of offering introductory sessions, objective validation of NHS SSS session attendance, efforts taken to minimize study condition contamination, efforts to estimate the external validity of the findings by comparing enrollees and non-enrollees and use of intent to treat analyses. The findings are likely to have implications for clinical practice as well as research efforts to improve reach of smoking cessation treatment services.

MAJOR COMULSORY REVISIONS
As currently planned, the experimental condition includes both a personal tailored risk communication letter AND an invitation to attend a “taster” session. Please provide a rationale for not offering the “taster” session to the control group? That would have allowed for the investigators to isolate the effect of these two promising cessation treatment recruitment approaches. (Major compulsory revision)

We appreciate the reviewer’s concerns regarding the design of the study, and agree that it is not possible to break down the components of the intervention to measure the effect of each. In an ideal design, this trial would be a 2*2 factorial design, with one quarter of recruited participants receiving the taster session alone, one quarter receiving a tailored letter alone, one quarter receiving both and one quarter receiving neither. This design was proposed to the funding board, and considered, but was dismissed as the costs would have been prohibitively high. It was ultimately the funder's decision.

The trial is a pragmatic trial evaluating the whole intervention that would be of benefit in primary care and could potentially be rolled out as an aid to recruitment to the services.

MINOR ESSENTIAL REVISIONS
The title would benefit from rewording to achieve greater specificity and clarity regarding the intervention condition. See recommended changes in the paper title. “A randomized trial to evaluate the effectiveness of using a personalized letter with tailored risk information and invitation to attend an introductory session taster sessions to increase the uptake of smoking cessation services.” (Minor essential revision)

The project and this title were approved by the funders and by the ethics committee, and it would not be appropriate or possible to change the title of the trial at this stage.

For greater clarity, I suggest rewording of “taster” session to either “tester” session or “introductory” session or “sample” session. At least from an American English language perspective, the term “taster” invokes more common reference to snacks or a buffet table!

The term ‘taster’ in England is not understood only with reference to food, and is an appropriate term to describe these sessions which give the opportunity to get a ‘taste’ of what the service offers.
As before, this is an ongoing trial, not a proposal for a trial, there is therefore no opportunity to change any part of the Intervention.

Further discussion is also warranted regarding the selection of the control group. Did the investigators consider comparison with “usual care”. Presumably GPs provide personalized quitting advice and refer smokers to the NHS SSS. What is routinely done with
smokers seen at these practices? What is the typical uptake for this approach? (minor essential revision)

There is no standard ‘usual care’ in England regarding referral to services. The amount of advice provided by GPs and the number of referrals varies between GPs and GP practices. There are no figures or evidence for the typical number of referrals or of the typical uptake. In addition, the type of standard mail out received by the control group is used intermittently by Some Stop Smoking Services. Therefore it was necessary to introduce a standardized communication and procedure in the control group, and it was more appropriate to assess the relative effectiveness of the intervention over a standard generic letter advertising the service.

What is the rationale for inclusion of only those smokers “motivated to quit”. Presumably this intervention might have an even stronger effect among individuals with less quitting readiness or less motivation to quit. What are the implications of restricting the sample to those motivated to quit? Please add to Discussion. (Minor essential revision)

It is possible that this intervention might have an effect with less motivated quitters. However, the NHS SSS have strict criteria for inclusion. Traditionally smokers must have an intention to quit within the next 2 weeks. While we adapted this to take account of evidence that less ready smokers can be persuaded to take part, and extended these criteria, it was not appropriate to extend the criteria further to include all smokers regardless of their readiness. This is issue is fully discussed and reasons given on p. 8.

P 8. I question the statement that “smokers from the more disadvantaged areas are more interested in receiving help than smokers from areas of low deprivation. Please provide further justification or reword this statement to reflect greater need.

The greater need of this group is not in question here. It is the fact that they are interested that is relevant, and this is fully referenced.

P 24 The estimated response rate (7%) seems very low if the sample is restricted to those motivated to quit. Please explain.

It is because the sample is restricted that we estimated the 7% response rate. Based on our previous studies (Gilbert et al, 2012) including all smokers regardless of readiness to quit would result in a higher response rate of 11-12%.

It is recommended that a sample of the generic letter also be included as supplemental material.

This has been included

DISCRETIONARY REVISIONS
P 3 Delete “prompt more quit attempts” from Discussion as it appears to go beyond the scope of the intervention strategy. (Discretionary revision)

We do not think that prompting quitting activity goes beyond the scope of the intervention strategy. We regard all quitting activity as relevant and seen as positive action. Quit attempts is also a secondary outcome of the study.

Do you plan to stratify the results reporting by occupation or socioeconomic level?
We will explore for trends in specific groups of smokers such as those of lower socio-economic status. However, we are aware that the study will be inadequately powered to do any detailed subgroup analyses.

Several minor wording suggestions:
P 7, … in the UK manual labor ….

The correct terminology is used here.
P 7, … as part of this strategy, the delivery of cessation …

The word ‘cessation’ has been inserted.
P 8, … include those who express a longer period of intent to quit. Please review this sentence and possibly reword

This sentence has been reworded for clarity.
P 9, … the relative effectiveness of two invitation outreach (or recruitment) methods…

The word ‘invitation’ has been changed to ‘recruitment’.
P 10, … Ultimately, this study aims to …

‘Ultimately’ has been inserted.
P 10, … help change their smoking behavior…

‘smoking’ has been inserted.
P 11, … A Freepost stamped, self-addressed envelope….

Freepost is a service offered by Royal Mail and does not involve a stamped addressed envelope

P 12 and p 16, … standard generic letter from the surgery (do you mean GP practice?).

Surgery is a standard way of referring to a GP practice in England. However, this has been changed to GP practice.
P 20, …. three to coincide with the process visits (please clarify the purpose of these visits)

This has been changed to ‘visits to process responses’.
P 20, … Please review and reword description of baseline measures. This citation for the baseline measurement of quitting readiness does not appear to be correct.

We have reviewed the description and can confirm that the reference for the baseline measurement of quitting readiness is correct.
P 27 Consider exploratory analysis of whether findings differ by motivation to quit.

Several exploratory analyses are planned, and analysis by motivation will almost certainly be explored post hoc. However, as stated on p 27, the study is inadequately powered to do any
detailed subgroup analyses on specific groups of smoker such as those of lower socio-economic status and hence we will merely explore for trends.

P 29 What minor revisions were made following completion of the pilot phase?

Changes have been made to clarify the minor revisions.

Reference