Author's response to reviews

Title: Trial protocol: Rapid reduction versus abrupt quitting for smokers who want to stop soon: a randomised controlled non-inferiority trial

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Author's response to reviews: see over
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Dear Sir/Madam

Re: Trial Protocol: Rapid reduction versus abrupt quitting for smokers who want to stop soon: a randomised controlled non-inferiority trial.

I am writing to you to submit my revised research protocol. I have revised the manuscript in response to peer review comments, as outlined below:

Comment 1: “First, there are a great many acronyms and initials used in the paper. In one paragraph alone, I think I counted seven unique ones. Certainly, some of these initials are in common use, but many are not (perhaps particularly for those not in the United Kingdom or in the particular research field). Additionally, in a few cases, either the acronym or initial is not spelled out fully before first use, or it is done at a subsequent use. I would strongly suggest limiting the usage of initials. Most are not used so frequently that they could not be spelled out on each occasion. And, as noted, care should be taken to make sure that all are spelled out on the first usage.”

Response: In some cases acronyms/initials have been spelled out fully on each usage, and in the cases where acronyms and initials are used they have been spelled out fully on the first usage.

Comment 2: “Second, on page 24, the sample size assumes that data will be obtained from essentially all randomized participants. Is that truly likely? How will missing data be handled? Is the primary analysis intention-to-treat?”

Response: The following has been added to the paragraph titled ‘power calculation’ on pg. 24: “Analyses will be carried out on an intention-to-treat basis, according to the Russell Standard, where participants lost to follow up are assumed to be smokers [20].”

Comment 3: “Third, on page 11, the top line of the last paragraph implies that participants who discontinue treatment will be excluded from the trial. I do not think that is the intent, so I would suggest saying that “We will exclude from treatment all those who have had severe adverse reactions . . . .”
Response: The sentence on pg.11, which previously read “Treatment withdrawal: We will exclude from the trial all those who have had severe adverse reactions previously and, given the established safety profile of NRT and the evidence from trials of combination NRT, we do not expect any serious adverse events due to the medication.” has been changed to: “Treatment withdrawal: One of our exclusion criteria is previous adverse reactions to NRT; so given that most smokers have used NRT recently, the established safety profile of NRT and the evidence from trials of combination NRT, we do not expect any serious adverse events due to the medication.” This clarifies that we do not suggest that anyone who discontinues treatment will be excluded, but that we will not recruit individuals who have experienced adverse reactions to NRT in the past, which will hopefully reduce the likelihood of adverse events caused by the NRT.

Comment 4: “Fourth, a few trivial comments: In a few places, there are singular/plural discrepancies (e.g., page 7, line 14 where “data” is used as singular; page 13, third paragraph, top line, “Participant” should probably be plural; page 15, bottom lines “participant” and “their”; page 16, line16, “participant” and “they”). Also, under Competing Interests, “PNA” is “PA under Authors’ Contributions and on the title page.”

Response: All of the minor adjustments suggested have been actioned.

In addition to this I have changed my name slightly on the manuscript from Nicola L Lindson to Nicola Lindson. This is in the interests of continuity as it has come to my attention that another paper I am an author on has been submitted as such.

Please do not hesitate to get in touch if further clarification is needed

Yours Faithfully

Nicola Lindson