Author's response to reviews

Title: Do oral corticosteroids provide clinical and cost-effective symptom relief for sore throat: study protocol for a randomized controlled trial.

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Version: 3
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Author's response to reviews: see over
Dear Trials editorial team,

Re: MS: 8262558301152999
Do oral corticosteroids provide clinical and cost-effective symptom relief for sore throat? A multi-centre, double blind, randomized, placebo-controlled trial.

Many thanks for accepting our protocol for publication pending our revisions. We attach our updated Trial Protocol with the following tracked changes.

Response to Referees comments:

My only question concerns the statement (bottom of page 16) that those participants found to be ineligible after randomization will not be included in the intention-to-treat analysis, but the middle of page 27 would suggest at all randomized will be included. True ITT would include even those found to be ineligible

In order to make the method of intention to treat consistent within the protocol we have clarified that it is only eligible participants that will be included within the intention to treat analysis. We have made the following change to the text:

All eligible randomised participants will be included in the analysis, assuming no complete resolution for missing data. (Page 29).

The Trial Status section (page 33) might be updated. Is there an expected date of completion?

We have updated the section on page 34 as follows:

Open and recruiting in all centres and currently on target, Aiming to complete recruitment in December 2014 and patient follow up in February 2015.

Response to Editorial requests:

Please ensure the title conforms to journal style for study protocol articles. The title should follow the format "___________: study protocol for a randomized controlled trial."

We have amended this as follows: Do oral corticosteroids provide clinical and cost-effective symptom relief for sore throat: study protocol for a randomized controlled trial. (Page1)
Please include the date of registration with your trial registration number at the end of your Abstract.

We have included the following information on page 4

Trial Identifier: ISRCTN17435450
Date of ISRCTN assignation: 26/03/2013

Please ensure the abstract is on a separate page, this should follow the title page.

The Abstract is now on a separate page, page 3.

Please mention each author individually in your Authors' Contributions section.

We have amended our Authors Contribution section as follows: (page 36)

GH conceived the study and participated in the designing of the trial, wrote the first draft of the trial protocol and revised this manuscript. CH conceived the study and participated in the designing of the trial and revised this manuscript. MT also conceived the study and participated in the designing of the trial and revised this manuscript. JW commented on and revised trial design and revised this manuscript. AH commented on and revised the trial design. MM commented on and revised the trial design. KH also commented on and revised the trial design. JC participates in implementing the study, wrote the first draft of the trial protocol and wrote this manuscript. JA also participates in implementing the study and revised this manuscript. MV commented on and revised this manuscript. All authors commented on the draft and approved the final manuscript.

Additional changes:

- Minor amendments to the Statistical sections, pages 24, 25 and 28 to reflect the current statistical analysis plan.
- Name change Johanna Maughan to Johanna Cook (Page 1)
- Change of Corresponding Author from Carl Heneghan to Gail Hayward (Page 1)

Best wishes,

Yours Sincerely,

Ms Johanna Cook and Dr Gail Hayward