

PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

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| TITLE (PROVISIONAL) | Paediatric asthma control under a community management model in China: a protocol for a prospective multicentre cohort study |
| AUTHORS | Xu, Juan; Yin, Yong; Zhang, Hao; Zhong, Wen; Zhang, Lei; Zhang, Jing; Yuan, Shu; Zhang, Fen; Zhao, Li |

VERSION 1 - REVIEW

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| REVIEWER | Scott Montgomery Örebro University Hospital, Sweden |
| REVIEW RETURNED | 26-Apr-2017 |

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| GENERAL COMMENTS | <p>The paper by Xu and colleagues describes a study to investigate asthma control status and adherence of paediatric asthma patients.</p> <ol style="list-style-type: none">1. The methods section of the abstract refers to comparing two patient groups but does not clarify the difference between them.2. It would be helpful if the introduction clarified the study design, beyond just saying it would “explore a new management model...”. The groups to be compared and study design should be defined at least briefly.3. Participants are eligible for participation if they were diagnosed as (having) asthma according to guidelines. Does this depend on an earlier diagnosis (if so, how assessed) or will children with suspected (rather than confirmed) asthma be assessed at the point of possible recruitment?4. The description of how patients are allocated to each arm of the study does not seem to be present in the methods section and the differences in treatment is inadequately described. Is there randomisation or if purely observational, are there issues of equivalence that must be tackled in different ways and what are they? It is essential that these details are included in the text of the methods section.5. It would be useful to see the assumptions underlying the power calculations in terms of estimated percentages in each arm.6. An English language review would be helpful (I understand the difficulties of writing in a second language). |
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VERSION 1 – AUTHOR RESPONSE

Dear professor Scott Montgomery:

Thank you very much for reviewing our manuscript “Paediatric asthma control under a community management model in China: a protocol for a prospective multicenter cohort study”. We have substantially revised the manuscript according to your comments.

Answers to the reviewer’s comments:

1. The methods section of the abstract refers to comparing two patient groups but does not clarify the difference between them.

Answer: Thank you very much for your comments.

We have added “Participants were divided into two groups: tertiary care hospital (Shanghai Children’s Medical Center) follow-up group and community hospital follow-up group” in the methods section of the abstract. The difference between the two groups is just the kind of hospital where they are followed up.

2. It would be helpful if the introduction clarified the study design, beyond just saying it would “explore a new management model....”. The groups to be compared and study design should be defined at least briefly.

Answer: Thank you very much for your comments.

We have revised that “We will undergo a 3.0-year prospective multicenter cohort study to determine whether there is a difference in asthma control rates between asthmatic children who are followed up at Shanghai Children’s Medical Center and those followed up at the community hospitals” at the end of the introduction to clarify the study design.

3. Participants are eligible for participation if they were diagnosed as (having) asthma according to guidelines. Does this depend on an earlier diagnosis (if so, how assessed) or will children with suspected (rather than confirmed) asthma be assessed at the point of possible recruitment?

Answer: Thank you very much for your comments.

We have explained that “All patients will be reassessed as to whether they can be diagnosed as asthma according to asthma guidelines. Children suspected of having asthma will be given diagnostic treatment but not included in the study until the asthma is confirmed” in the methods section.

4. The description of how patients are allocated to each arm of the study does not seem to be present in the methods section and the differences in treatment is inadequately described. Is there randomisation or if purely observational, are there issues of equivalence that must be tackled in different ways and what are they? It is essential that these details are included in the text of the methods section.

Answer: Thank you very much for your comments.

Firstly, it is a purely observational study.

Secondly, it is up to the parents of asthmatic children to follow up at a community hospital or the Shanghai Children’s Medical Center. Participants will be divided into two groups as follows: a tertiary care hospital (Shanghai Children’s Medical Center) follow-up group and a community hospital follow-up group.

Thirdly, we explained the study as follows:

- 1) pulmonary physicians of Shanghai Children’s Medical Center will go to the community hospital clinics to help handling asthma cases once every 3.0 months;
- 2) all community healthcare providers involved in this clinical study will have received systemic training and all will have the qualifications to diagnose and treat asthma;
- 3) the treatments of each child with asthma will be based on the guidelines⁸ for treating children with asthma;
- 4) the 14 community hospitals have the same asthma medication and treatment facilities as Shanghai Children’s Medical Center;
- 5) the distance to the community hospitals is shorter, registration fees are not required, and the proportion of medical compensation is higher.

There is no difference in the treatment guideline between the two groups. The aim of this study is to determine whether there is a difference in asthma control rates between asthmatic children who are followed up at Shanghai Children's Medical Center and those followed up at the community hospitals.

5. It would be useful to see the assumptions underlying the power calculations in terms of estimated percentages in each arm.

Answer: Thank you very much for your comments.

Our hypothesis is that there is a significant difference in asthma control rates between asthmatic children who are followed up at the tertiary care hospital and those followed up at the community hospitals.

6. An English language review would be helpful (I understand the difficulties of writing in a second language).

Answer: Thank you very much for your comments.

The manuscript has been polished by a professional editing company. And we can provide the proof.

VERSION 2 – REVIEW

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| REVIEWER | Scott Montgomery Örebro University Hospital, Sweden. |
| REVIEW RETURNED | 07-Jun-2017 |

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| GENERAL COMMENTS | I am happy with the majority of the authors' responses to my points. The only exception is for point number six, a small point where perhaps my question was unclear. I asked for more information about the assumptions underlying the power calculation. I was looking for details of how the power was calculated in simple terms in the text rather than a mathematical formula. For example, it might be presented as: in group one it is assumed that the rate of asthma control is X%, thus there would be sufficient power to detect an increased rate of at least Y% in group two, using the planned sample size (the actual figures used for the calculation should be substituted for X and Y). Although the original manuscript stated there would be sufficient power to detect a 10% difference this, in |
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| | <p>part, depends on the absolute rate the outcome.</p> <p>I note that for some reason spelling has been changed to American rather than UK English, and I assume this is because the language reviewer did not realise the paper is for a British journal.</p> |
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VERSION 2 – AUTHOR RESPONSE

Dear professor Scott Montgomery:

Thank you very much for reviewing our manuscript “Paediatric asthma control under a community management model in China: a protocol for a prospective multicentre cohort study”. We have substantially revised the manuscript according to your comments.

Answers to the reviewer’s comments:

1. I am happy with the majority of the authors’ responses to my points. The only exception is for point number six, a small point where perhaps my question was unclear. I asked for more information about the assumptions underlying the power calculation. I was looking for details of how the power was calculated in simple terms in the text rather than a mathematical formula. For example, it might be presented as: in group one it is assumed that the rate of asthma control is X%, thus there would be sufficient power to detect an increased rate of at least Y% in group two, using the planned sample size (the actual figures used for the calculation should be substituted for X and Y). Although the original manuscript stated there would be sufficient power to detect a 10% difference this, in part, depends on the absolute rate the outcome.

Answer: Thank you very much for your comments. I am very sorry that we did not clarify this question precisely. We have added “In community hospital follow-up group, it is assumed that the rate of asthma control is 25.7%, thus there would be sufficient power to detect an increased rate of at least 10% in tertiary care hospital (Shanghai Children’s Medical Center) follow-up group, using the planned sample size” in the sample size calculation section.

2. I note that for some reason spelling has been changed to American rather than UK English, and I assume this is because the language reviewer did not realise the paper is for a British journal.

Answer: Thank you very much for your comments and kindly reminder. The manuscript has been edited for UK English.