Author's response to reviews

Title: Goal-setting intervention in patients with active asthma: protocol for a pilot cluster randomised controlled trial

Authors:

Gaylor Hoskins (gaylor.hoskins@stir.ac.uk)
Purva Abhyankar (purva.abhyankar@stir.ac.uk)
Anne D Taylor (a.d.taylor@stir.ac.uk)
Edward Duncan (edward.duncan@stir.ac.uk)
Aziz Sheikh (Aziz.Sheikh@ed.ac.uk)
Hilary Pinnock (Hilary.Pinnock@ed.ac.uk)
Marjon van der Pol (m.vanderpol@abdn.ac.uk)
Peter T Donnan (p.t.donnan@dundee.ac.uk)
Brian Williams (brian.williams@stir.ac.uk)

Version: 3 Date: 13 August 2013

Author's response to reviews: see over
Mr Barry Davis  
Editorial Office  
Trials Journal  

Dear Mr Davis  

Study protocol MS: 1547988811998694  
Goal-setting intervention in patients with active asthma: protocol for a pilot cluster randomised controlled trial.  
Gaylors Hoskins, Purva Abhyankar, Anne D Taylor, Edward Duncan, Aziz Sheikh, Hilary Pinnock, Marjon van der Pol, Peter T Donnan and Brian Williams  

Thank you for giving us the opportunity to revise the above manuscript and resubmit for consideration of publication in the Trials Journal. The helpful and encouraging comments from the editor and the reviewer have been considered in detail and the manuscript revised to reflect them. We now have pleasure in submitting our revised manuscript. For your convenience we reproduce the comments verbatim before detailing our response to each of the points made.  

I look forward to hearing from you in the near future.  

Kind regards  
Yours faithfully  
Dr Gaylor Hoskins
Goal-setting intervention in patients with active asthma: protocol for a pilot cluster randomised controlled trial.
Gaylor Hoskins, Purva Abhyankar, Anne D Taylor, Edward Duncan, Aziz Sheikh, Hilary Pinnock, Marjon van der Pol, Peter T Donnan and Brian Williams

Trials

Thank you for your helpful and encouraging comments which have been considered in detail and the manuscript revised to reflect them. Any changes made in line with the comments are highlighted in track changes. For ease of reading we have reproduced the editor and reviewer comments verbatim before detailing our response to each of the points made.

Editorial comment

Please mention each author individually in your Authors’ Contribution section. We suggest the following format (please use initials to refer to each author’s contribution): AB carried out the molecular genetic studies, participated in the sequence alignment and drafted the manuscript. JY carried out the immunoassays. MT participated in the sequence alignment. ES participated in the design of the study and performed the statistical analysis. FG conceived of the study, and participated in its design and coordination and helped to draft the manuscript. All authors read and approved the final manuscript.

Response:

Additional information on each author’s contribution to the study and manuscript has been added. The text now reads:

Authors’ contribution

All authors have contributed to the design of the study and the preparation of the draft manuscript. GH, as chief investigator, co-conceived the study, wrote the study protocol, designed the study materials, applied for ethics and NHS R&D approvals, and drafted the manuscript; PA and AT have co-managed the study, collected the patient outcomes, conducted the patient and health professional interviews, and contributed to the manuscript. ED, a grant holder, contributed to the design and co-ordination of the study particularly the conceptualisation of the theory upon which the intervention is based, and commented on the draft manuscript. AS and HP contributed to designing the study, are grant-holders, and commented on the draft manuscript. MP, a grant holder, provided health economics input for both the study protocol and the draft manuscript. PD, a grant holder, provided the statistical analysis framework for the study and commented on the draft manuscript. BW co-conceived the study, participated in its design and co-ordination, and commented on the draft manuscript. All authors read, commented on and approved the final manuscript. (Page 26).
Reviewer Comments

Comment 1
Why have the authors chosen to randomise the primary care practices before patient recruitment? Patients were aware of the study procedure before they gave their consent and this could have led to different types of patients participating in the intervention and in the usual care group (for example patients in the intervention group could have uncontrolled asthma and hope to achieve more asthma control by participating, whereas in the usual care group patients already felt their asthma was controlled and would like to continue as usual).

Response:
Randomisation was at practice level – a condition specified by the funding body. The intervention had two components – one aimed at nurses and one aimed at patients. The nurse(s) (and hence the practice they came from as not all practices had more than one nurse) had to be part of the randomisation. If we had randomised the patients then in some practices the same nurse would have had to do the intervention review consultations as well as the control review consultations. This would have introduced bias due to a potential cross-over effect of intervention on the reviews of control patients.

A minimum of 8 practices, 4 in each region (2 large and 2 small) were required. Randomisation was carried out when enough practices fitting this configuration were recruited. Recruitment of patients could not begin until the nurses in the recruited practices were trained and comfortable with the study protocol and procedures. Nurses in the intervention arm had additional training relevant to the intervention and therefore had to be told which arm they were in before attending the training. The decision to randomise the practices before recruitment of patients had begun was therefore a pragmatic and organizational one directly related to the need to train the nurses on their role within the study.

A potential limitation of the study is the fact that the template for the covering letter practices were invited to use to introduce the study to their patients also included information on the arm of the study the practice had been allocated to. Although some practices chose not to use this template, preferring to create their own letter, this information was unnecessarily given and we accept the reviewer’s comment that it may potentially affect study recruitment. The authors acknowledge this and will look closely at the patient characteristics in both arms of the study during analysis. We will also ensure that, for any future trial, this information is not revealed prior to patient recruitment. I attach the patient information leaflet as accepted by the REC for your information. You will see from this that patients are not told they will be given any indication of the practice allocation prior to agreeing to participate. For clarity I added a sentence to the text.

The text now reads:
“A template of a covering letter - stating the study arm to which the practice has been allocated - has been provided for this purpose although practices can opt to create/use their own letter. Patients being aware of the study procedure before consenting to take part could lead to a difference in the type of patients participating in the intervention and in the usual care group. Any differences will be identified and controlled for in the final analysis.” (Page 11, Paragraph 1)
Comment 2
In the intervention group participants can state the wish for a follow-up visit to address their progress with implementing the action plan. If patients additionally visit the NP to address their individual goals and how the achieve them, this does not pose a problem. However, bias could be introduced if the NP addresses issues such as inhaler technique or adjusts treatment when patients are uncontrolled. In that case differences in outcomes between the intervention and usual care could be the result of more extensive monitoring rather than the intervention itself. How do the authors prepare to prevent this from happening? Or is a more extensive monitoring part of the intervention?

Response:
This is a complex intervention and we will seek to describe the processes through which any effects are achieved, including possible differences in follow-up rates between arms. Better communication and monitoring of the patient is an important element of the study. Achievement of identified goals may be related to asthma control and therefore it may be necessary, as part of the intervention, to more closely monitor medication usage and trigger control etc. Rather than introduce bias we see this as a positive move towards more holistic management particularly as the norm in the UK now is for an annual review. Hence, the more extensive monitoring is envisaged to be a part of the intervention. A related issue however is whether there is likely to be extensive monitoring for controlled group patients whose asthma is not well controlled, which may in turn minimise the differences in outcomes between control and intervention groups. The data on health service resource use (HSRU), which indicate the number of outpatient visits, hospital admissions, emergency care visits and medication use, are a reflection of asthma control and these data will be collected for all patients in both arms of the study pre and post intervention. Patients’ asthma control prior to the intervention will thus be used as a covariate in the statistical analyses examining group differences in outcome measures. This information will reflect clinical factors.

Comment 3
The authors also mention recording all consultations, which will be subsequently listened to for consultation variation. This procedure is not further explicated. A consultation is highly dependent on the style of performing a consultation of the nurse practitioner. In this study the participating primary care practices, and therefore the nurse practitioners involved, are different for the intervention and the usual care groups. Therefore checking the fidelity of the intervention process by listening to the consultation variation of approximately four different nurse practitioners per group seems difficult to achieve.

Response:
Current asthma guidelines are clear on the elements that need to be included within a quality asthma review. [Reference: British Thoracic Society & the Scottish Intercollegiate Guidelines Network, British Guideline on the Management of Asthma. Guideline No. 101 http://www.sign.ac.uk, 2012.] The authors accept that consultation style is very individual but what we are listening for within the consultation is whether the review has been carried out according to guidelines and how much goal related discussion has been incorporated in to the consultation as a result of the intervention. We accept that, without prior knowledge of consultation style, we have no way of knowing whether the nurse normally talks about goals as part of
her consultation but we feel that as the nurses in both arms are experienced practice nurses with an asthma diploma we will be able to discern whether the review has been carried out as per instructions and whether the intervention has introduced a more holistic approach to the discussion. This was a fidelity check on the whole review process and not meant to be measured as an outcome. As a result, and to avoid confusion, we have removed the last sentence in the section entitled ‘Comparison between treatment arms’ on page 18/19 which read:

“To aid this process all consultations whether in the intervention or control arm, will be recorded and independently listened to for consultation variation.”(Page 20, Paragraph 1)

To further clarify the situation the sentence under the section headed ‘Recordings of asthma reviews’ on Page 24 has been altered slightly and now reads as:

“All consultations whether in the intervention or control arm, will be recorded and independently listened to. This will allow us to check the fidelity of the review process.”(Page 24, Paragraph 2)


Comment 4
The study timeline should probably be adjusted. According to the current study status mentioned right after the study timeline, patients are still being recruited. Therefore most of the proposed time targets seem not attainable.

Response:
The authors accept the reviewer’s comments and have amended the text as follows:

**Study timeline**
Trial Start: 1 October 2012
Baseline data collection: From January 2013 until all patients recruited
Interventions in general practice: January 2013 (training); January 2013 onwards (patient recruitment), February 2013 onwards (patient review appointments PNs)
End of interventions and follow-up in general practice: November 2013
Qualitative interviews: July to November 2013
Start of data analysis: November 2013
Planned study end date: end December 2013
Duration: 15 months

This reflects the changes to the original recruitment process. (Page 25, Paragraph 1)

Comment 5
In the background you mention existing current asthma action plans already being used and that they focus mainly on management strategies in the presence of (deteriorating) symptoms. In the example of the proposed GOAL action plan in appendix 3 the focus is entirely on personalised goals and it doesn’t contain a section with the before mentioned
more traditional approach of an action plan. Do you plan to entirely leave the current concept of action points in action plans? Or will patients in the intervention strategy who already have an asthma action plan essentially have two action plans (i.e. yours and the ‘normal action plan’)? And what about practice nurses that are already used to working with Asthma Action Plans, can they continue to start with these as well, or just the new one?

Response:
The GOAL action plan and the traditional asthma action plan are two completely distinct entities, conceptually and in practice, and are therefore independent of each other. Each addresses a different issue – whereas the asthma action plan is oriented towards symptom-management, the GOAL action plan is oriented towards specific goals which may or may not be asthma related. The GOAL action plan will only be used when patients have goals to achieve or issues to address, laying out what specific action(s) need to be taken to achieve the identified goal. Depending on the agreed steps for achieving an identified goal the plan may refer to the asthma action plan, however it is not a replacement for it.

The text now reads:

“The written record of the personalised GOAL action plan will be given to the patient. This plan will be in addition to any symptom related asthma action plan provided by the practice.” (Page 14, Paragraph 3)

Comment 6
Just as a minor issue, the lines in the example in the bottom of the table of part 1 of appendix 2 are not at the same height or missing between the different cells, which is a bit confusing.

Response:
The alignment within this section of the table has been amended as below:

<table>
<thead>
<tr>
<th>Example</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>I want to be able to work</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I want to lose weight</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I want to be able to sleep well</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I want to get back to being an active mum/dad</td>
<td>Not sure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I want to be able to go out with friends</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Authors' information

“GH is a clinical researcher with a background in primary care respiratory management and asthma research. BW is a social scientist with an extensive portfolio in qualitative research in public health and primary care who has conducted a number of asthma related projects and has experience of general practice behaviour and guideline interpretation and implementation; PD is a biostatistician with experience of asthma related research and randomised control trial techniques; MvdP is a health economist with an extensive portfolio of research into the cost benefits of health interventions; AS is an epidemiologist and professor of general practice with expertise in the design and implementation of cluster and parallel groups RCTs; HP is a general practitioner with expertise in asthma who sits on the BTS/SIGN asthma guideline steering group and has experience in development and evaluation of complex interventions; ED is an occupational therapist and Senior Research Fellow in the NMAHP-RU with a portfolio of work which includes goal related issues. PA is a psychologist with experience in conducting and analysing qualitative research, AT is a nurse and clinical research fellow. The principal investigator (GH) has been a recipient of the CSO Primary Care Research Award and currently holds a clinical research fellowship with the CSO funded NMAHP Research Unit at the University of Stirling. HP is currently a recipient of the CSO Primary Care Research Award. BW is the director and ED a senior researcher with the Nursing, Midwifery & Allied Health Professional (NMAHP) Research Unit.”  (Page 27, Paragraph 2).