Reviewer’s report

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

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Reviewer: Pieter Honkoop

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The proposed intervention in this study-protocol addresses individualised goal setting for asthma patients, an important issue in self-management. By performing this pilot study the authors hope to assess the feasibility to perform a large cluster randomised trial and determine sample size, utility of the intervention and difficulties in recruitment.

The study is well designed and should be able to address the aims of the study. The study procedures are described very thoroughly and can easily be replicated. To assess the differences between usual care and the intervention a multiple regression analysis is appropriate and adjusting for clustering and baseline necessary. Overall the protocol is well written.

Discretionary Revisions:

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).

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?

3. The authors also mention recording all consultations, which will be subsequently be 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.

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.

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?

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.

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I have no competing interests to declare