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**ARTICLE DETAILS**

<table>
<thead>
<tr>
<th>TITLE (PROVISIONAL)</th>
<th>Evaluation of an alternative care provider clinic for severe disordered breathing: a study protocol for a randomized controlled trial</th>
</tr>
</thead>
<tbody>
<tr>
<td>AUTHORS</td>
<td>Ip-Buting, Ada; Kelly, Jenny; Santana, Maria-Jose; Penz, Erika; Flemons, Ward; Tsai, Willis H.; Fraser, Kristin; Hanly, Patrick; Pendharkar, Sachin</td>
</tr>
</tbody>
</table>

**VERSION 1 - REVIEW**

| REVIEWER            | Susan N. Manganaro, MD  
|                     | Stony Brook University Hospital, Department of Neurology, Stony Brook NY USA |
| REVIEW RETURNED     | 30-Sep-2016 |
| GENERAL COMMENTS    | In method section, clarify patients criteria for offering CPAP; what is the difference between the study with or without supplemental oxygen (first sentence of third paragraph); what criteria are used to determine if study will be done with oxygen.  
In Eligibility criteria section, first sentence: "Patients who are referred to the FMC Sleep Centre with suspected severe SDB..." What makes someone suspect severe SDB?  
In Eligibility criteria section, third paragraph; why are insomnia patients being excluded?  
In statistical analysis section, third paragraph: define HUI and QALY (had to look in supplemental materials to see what that was.  
In secondary outcomes, would clarify that ESS was being done at initial evaluation and at followup and that the difference between the two over time is being compared. |

| REVIEWER            | Max Hirshkowitz  
|                     | Baylor College of Medicine, Houston, TX USA  
|                     | Stanford University, Palo Alto, CA USA |
| REVIEW RETURNED     | 10-Oct-2016 |
| GENERAL COMMENTS    | You are describing a program to facilitate the diagnosis and treatment of sleep apnea and you call it "Fast Track". You have failed to mention, however, that there is already a program with that name that has been published.  
This constitutes either a major oversight of published literature in |
your area or an attempt to take credit for someone else's work. Either way, significant revision of the introduction and discussion are in order before this paper can be even considered as independent work.

VERSION 1 – AUTHOR RESPONSE

Response to Comment 1.1
We have revised this list to focus on methodological strengths and limitations of our project.

Reviewer Comments #1
Comment 1.1
In method section, a) clarify patients criteria for offering CPAP;

Response to Comment 1.1
We have revised paragraph 3 of the Methods section to indicate specific indications for offering treatments for SDB. These include PAP therapy or oral appliance for patients with mild to moderate disease and PAP for all patients with severe SDB. (page 6 para 1)

Comment 1.2
What is the difference between the study with or without supplemental oxygen (first sentence of third paragraph); c) what criteria are used to determine if study will be done with oxygen.

Response to Comment 1
We understand how this section as worded may confuse the reader. Oxygen may be prescribed for patients with severe SDB depending on the results of sleep diagnostic testing and arterial blood gas. As this is a minority of patients we have revised this paragraph and removed the reference to oxygen from the manuscript.

Comment 2
In Eligibility criteria section, first sentence: "Patients who are referred to the FMC Sleep Centre with suspected severe SDB..." What makes someone suspect severe SDB?

Response to Comment 2
Patients who meet at least one of the eligibility criteria are suspected to have severe SDB. The sentence in the “Eligibility Criteria” section is changed to avoid confusion.

Comment 3
In Eligibility criteria section, third paragraph; why are insomnia patients being excluded?

Response to Comment 3
While we appreciate that many patients with SDB may have coexisting insomnia, this initial study was intended to assess the efficacy of alternative provider care for a more homogeneous group of patients with severe SDB. Furthermore, the alternative care providers in our study are respiratory therapists, whose training is focused on respiratory care and ventilation as discussed in the Limitations section. In future studies we will consider including patients with other coexisting sleep disorders.

Comment 4
In statistical analysis section, third paragraph: define HUI and QALY (had to look in supplemental materials to see what that was.

Response to Comment 4
We have corrected the oversight of not defining QALY in the section named “Statistical Analysis”. We
Comment 5
In secondary outcomes, would clarify that ESS was being done at initial evaluation and at followup and that the difference between the two over time is being compared.

Response to Comment 5
We have outlined a comprehensive and multi-faceted evaluation strategy for this clinic, which we were unable to describe in detail due to manuscript length restrictions. Thus, we have presented the timeline for each outcome in Table 1. We have also updated the “Statistical Analysis” section to include the specific comparisons that we are making for the ESS and other secondary outcomes.

Reviewer Comments #2

Comment 1
You are describing a program to facilitate the diagnosis and treatment of sleep apnea and you call it “Fast Track”. You have failed to mention, however, that there is already a program with that name that has been published.

See-

This constitutes either a major oversight of published literature in your area or an attempt to take credit for someone else's work. Either way, significant revision of the introduction and discussion are in order before this paper can be even considered as independent work.

Response to Comment 1
We appreciate the reviewer’s comment that another program called ‘Fast Track’ already exists. This paper was not published when we began this project, and was not included in our original literature searches as the concept of telemedicine is somewhat peripheral to our project on alternative care providers. However, when describing innovations to improve access, it is important to consider other strategies that have been explored. Thus, we have modified our introduction to include a brief discussion of the role of telemedicine in the management of patients with SDB, including a reference to the paper highlighted by the reviewer. We removed the term ‘Fast Track’ from our title and have also replaced the term ‘Fast Track’ with ‘ACP clinic’ throughout our manuscript, as the intent was to describe this novel method for delivering care rather than to publish the specific name of the program. At no time was it our intent to take credit for the work of another investigator.
Evaluation of an alternative care provider clinic for severe sleep-disordered breathing: a study protocol for a randomised controlled trial

Ada Ip-Buting, Jenny Kelly, Maria J Santana, Erika D Penz, W Ward Flemons, Willis H Tsai, Kristin L Fraser, Patrick J Hanly and Sachin R Pendharkar

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