PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Internet based support for self-management strategies for people with COPD – protocol for a controlled pragmatic pilot trial of effectiveness and a process evaluation in primary health care
AUTHORS	Nyberg, André; Wadell, Karin; Lindgren, Helena; Tistad, Malin

VERSION 1 - REVIEW

REVIEWER	Marilyn Moy, MD, MSc VA Boston Healthcare System and Harvard Medical School, Boston, MA, USA
REVIEW RETURNED	28-Mar-2017

GENERAL COMMENTS	This is a study protocol of a pilot study assessing an internet based intervention for patients and healthcare professionals for COPD self-management. The intervention would benefit from a conceptual model, and have the parts of the intervention target the components of the pillars of the conceptual model. What are the specific self-management strategies? <u>Specific Comments</u> Title: This is very long. What does evidence based self-management strategies mean? Methods: Inclusion/exclusion criteria seem very limited. Can patients have comorbid disease, like cardiovascular disease or peripheral vascular disease that can confound assessments of dyspnea and physical activity, for examples? An example of a webpage viewed by patients and that viewed by providers would be very informative. More detail on the content would strengthen this paper. How do users interact with COPDweb over 12 months? Is there dynamic content, recurrent content or all new content? A glaring omission is self-management of acute exacerbations-home meds of antibiotics or prednisone, when to call provider etc. This

	needs to be included. What happens to patients in the study if they get hospitalized or have an acute exacerbation? There are a lot of questionnaires. What is the burden on the patient? Is this feasible to administer so many? Seven days of activity monitoring will likely yield 5 days, so a weekend may not be captured. Would recommend at least 10 days of monitoring to capture weekend days too. How will the qualitative interviews be analyzed? Measurement of fidelity of patients and providers needs to be clarified Since this is pragmatic trial, how will the exposure to usual provider encounters and counseling on self-management, outside of the study, be assessed and taken into consideration in the analyses?

REVIEWER	Linda Nici, M.D. Providence Veterans Affairs Medical Center and Brown University, Providence, Rhode Island, USA
REVIEW RETURNED	11-Apr-2017

GENERAL COMMENTS	The manuscript, "Internet-based support for evidence based self-management strategies for people with COPD - a controlled pragmatic pilot trial of effectiveness and a process evaluation in the primary health care", by Nyberg and colleagues, is a pragmatic controlled pilot trial to evaluate the feasibility and effectiveness of an internet-based COPD self-management program from both the patient and the providers perspective. The study is well described and has the potential for real impact in this arena, however, there are some issues that need to be addressed and discussed, which are not clear in the manuscript's present form: 1- Why are patients completing self-assessments at home? The literature supports having these items done in the presence of the staff such that they are clearly the answers of the patient, not the caregivers and that there are no issues with comprehension or completeness. 2- There is no discussion of the criteria for the COPD patient enrollment- i.e. severity of disease, documentation by PFT, some element of matching by disease severity, age, gender, co-morbidities. While I realize this is a pilot study, your outcome measures may be heavily influenced if there is a broad range of disease severity or if underlying respiratory disease is not clear. 3- It is not totally clear to me why the HCP is trained using the web-based program? Is it your intention for them to interact with the patient face-to-face as the study moves forward such that they are actually reinforcing the web-based information? If so, will this be standardized. If some patients see their provider more times than others and material is reinforced, this may bias outcomes from the web based product alone. 4- Is there any plans to videotape the interactions between provider

	and patient for internal consistency?

REVIEWER	Chris Burtin Hasselt University, Belgium
REVIEW RETURNED	12-Apr-2017

GENERAL COMMENTS	Dr Nyberg et al submitted a protocol of a trial which will investigate feasibility, acceptance and effectiveness of a web-based program to support patients with COPD and health professionals in light of self-management processes. This trial will be a controlled pilot trial, exploring numerous quantitative and qualitative outcomes, that will be used to design an adequately powered randomized controlled trial in the future. The methodology appears sound and scientifically correct. I have a few remarks and comment about the manuscript/methodology. The title and introduction suggest that this project concerns self-management strategies (as a comprehensive term), but in the methods section it becomes clear that self-management strategies offered by the COPD-web tool are largely related to physical activity and exercise. As self-management is more comprehensive than physical activity and exercise, I am wondering whether this is the correct term to use in this protocol. It is remarkable that the type of health professionals that will be recruited are not further specified. One would assume that different professions need different approaches in terms to optimize their delivery of self-management strategies to patients. Which kind of health professionals will be included? It will be recorded to what extent health care professionals implement the web-tool in their daily clinical practice. On the other hand, the health care professionals are expected to include the patients. Am I correct that the same individuals are both research subject (as health care provider that will use the platform) and researchers (who will include patients for this trial)? In light of that, will the proportion of the target population (patients) that will receive the intervention adequately reflect clinical reality? Will there be any interaction between health care professionals and patients in light of self-management strategies; in other words will the professional assist the patient in his self-management and/or using the COPD-web tool throughout time or will he/she only introduce the patient to it? The timeline of assessments is a difficult to interpret because time lines of both target groups (patients and health care professionals) are mixed. It might be easier to understand when these are separated. According to the timeline (p8), this trial has already started in 2016.

VERSION 1 – AUTHOR RESPONSE

Reviewer 1
What does evidence based self-management strategies mean?
Authors reply: We have revised the title and removed the word evidence based as this might be ambiguous. The self-management strategies presented at the COPD-web are to most parts evidence based and recommended in national and international guidelines i.e. strategies to promote increased level of PA, strategies during exacerbations, strategies in case of malnutrition, strategies for smoking cessation etc. However, as the COPD-web as a strategy to support the self- management not is evidence based, we believe that removing "evidence based" might be more clear. Further, we have added a figure (Figure 2) which show the content on the website.

Inclusion/exclusion criteria seem very limited. Can patients have comorbid disease, like cardiovascular disease or peripheral vascular disease that can confound assessments of dyspnea and physical activity, for examples?
Authors reply: We have chosen a pragmatic approach which, as suggested by Zwarenstein et al 20081, focus on how the intervention work when used in normal practice. This means that the trial is designed to the needs of those who meet the patients in their daily clinical practice. As comorbidities are very common among persons with COPD, a consequence of the pragmatic approach is that also these persons are included in the study. We have clarified this in the discussion section (p 23). (Zwarenstein M, Treweek S, Gagnier JJ, et al. Improving the reporting of pragmatic trials: an extension of the CONSORT statement. BMJ 2008;337:a2390)

An example of a webpage viewed by patients and that viewed by providers would be very informative.
Authors reply: As the COPD-web is made up of several sub-pages and subsub-pages focusing on different topics such as About COPD (How does the lungs work?, Facts about COPD, How do one get the diagnosis? Excacerbations) Self-care and treatment (Smoking, Physical Activity, Register physical activity, Action plan, Follow the disease, Nutrition, Tips for making everyday life easier, Breathing and coughing techniques, etc) we don't believe that an example of the webpage would contribute with added value. However, in order to provide more information about the content on the COPD-web, we have added a map of the content (Figure 1) referred to on page 8.

More detail on the content would strengthen this paper. How do users interact with COPDweb over 12 months? Is there dynamic content, recurrent content or all new content?
Authors reply: We have added some information about how we continuously add new material to the COPD-web on page 9. Today, we do not have an answer to the question about how the users will interact with the COPD-web over time. However, as a part of the process evaluation, we will collect user data from the web site and carry out qualitative interviews at 3 and 12 months and this data will hopefully contribute with information on this issue.

A glaring omission is self-management of acute exacerbations-home meds of antibiotics or prednisone, when to call provider etc. This needs to be included.
Authors reply: We agree with you and this information is on the COPD-web. This information has been added in the manuscript on page 8-9 and Figure 1.

What happens to patients in the study if they get hospitalized or have an acute exacerbation?
Authors reply: Considering the study, nothing happens. This study will not capture the participants use of health care services, neither the frequency of exacerbations.

There are a lot of questionnaires. What is the burden on the patient? Is this feasible to administer so many?
Authors reply: We realize that there are a lot of questionnaires. However, as this is a pilot study, one of the aims is to evaluate the feasibility (research question: Are the intervention and the study

procedures acceptable and feasible from the perspective of patients with COPD and health professionals?) and we might probably decrease the number of questionnaires in the full study.

Seven days of activity monitoring will likely yield 5 days, so a weekend may not be captured. Would recommend at least 10 days of monitoring to capture weekend days too.
Authors reply: Thank you for your recommendation which we will consider carefully. We have also added a reference (Demeyer 2014) in which at least 4 days is recommended. However, according to our experience from previous studies, the participants have worn the activity monitor during 7 full days and a weekend day has consequently been monitored. Moreover, as this is a pilot study, we will evaluate the feasibility of this method for measuring the participants' physical activity and consider your recommendation of at least 10 days.

How will the qualitative interviews be analyzed?
Authors reply: As stated on page 20, the qualitative interviews will be analyzed using qualitative content analysis. We have elaborated the description slightly in order to clarify which of the process evaluation components that will be analyzed using inductive and deductive qualitative content analysis respectively (ses also below).

Measurement of fidelity of patients and providers needs to be clarified
Authors reply: We will assess the fidelity considering health professionals' delivery of the intervention. The fidelity will be assessed using the qualitative interviews and the observations performed during the health professional –patient encounter when the patient is introduced to the COPD-web. We have elaborated the description of the analyzed of the qualitative data slightly in order to clarify which of the process evaluation components that will be analyzed using inductive and deductive qualitative content analysis respectively (page 20). Thank you for this useful comment.

Since this is pragmatic trial, how will the exposure to usual provider encounters and counseling on self-management, outside of the study, be assessed and taken into consideration in the analyses?
Authors reply: This will to some extent be captured in the qualitative interviews. However, exposure to usual provider encounters will always have a potential influence in clinical studies and since we have a control group we hope to make up for this.

Reviewer 2
1- Why are patients completing self-assessments at home? The literature supports having these items done in the presence of the staff such that they are clearly the answers of the patient, not the caregivers and that there are no issues with comprehension or completeness.
Authors reply: To have the participants to complete the self-assessment tool in the presence of the staff might be an ideal situation. However, due to the situation in the primary care in Sweden today with a shortage of health professionals and a constant time pressure, this would not be possible. As the participants will be recruited at six primary care units, it will neither be possible for us to administer this task. However, the feasibility of this procedure will be evaluated.

2- There is no discussion of the criteria for the COPD patient enrollment- i.e. severity of disease, documentation by PFT, some element of matching by disease severity, age, gender, co-morbidities. While I realize this is a pilot study, your outcome measures may be heavily influenced if there is a broad range of disease severity or if underlying respiratory disease is not clear.
Authors reply: We have chosen a pragmatic approach which, as suggested by Zwarenstein et al 2008, focus on how the intervention work when used in normal practice. This means that the trial is designed to the needs of those who meet the patients in their daily clinical practice. As comorbidities are very common among persons with COPD, a consequence of the pragmatic approach is that also these persons are included in the study. We have clarified this in the discussion section.
(Zwarenstein M, Treweek S, Gagnier JJ, et al. Improving the reporting of pragmatic trials: an

extension of the CONSORT statement. BMJ 2008;337:a2390)

3- It is not totally clear to me why the HCP is trained using the web-based program? Is it your intention for them to interact with the patient face-to-face as the study moves forward such that they are actually reinforcing the web-based information? If so, will this be standardized. If some patients see their provider more times than others and material is reinforced, this may bias outcomes from the web based product alone.
Authors reply: In the present study, the health professionals are the ones that introduce the COPD-web to the patients when they visit the primary care. The introduction follow a standardized routine described in Box 1. In line with the pragmatic approach the intervention should be "applied flexibly as it would be in normal practice" (Zwarenstein 2008). Consequently, in the present study, there might be patients who see their providers more times and have the material reinforced. However, also in the control group, some patients might see their provider more than once.

4- Is there any plans to videotape the interactions between provider and patient for internal consistency?
Authors reply: No, there are no such plans. Videotaping the interaction would be very interesting for several reason. Unfortunately, to date we do not presently have the resources to videotape or to analyse such data. This will be considered for future studies.

The title and introduction suggest that this project concerns self-management strategies (as a comprehensive term), but in the methods section it becomes clear that self-management strategies offered by the COPD-web tool are largely related to physical activity and exercise. As self-management is more comprehensive than physical activity and exercise, I am wondering whether this is the correct term to use in this protocol.
Authors reply: Thank you for your important comment. We realize that we have focused too much on physical activity and physical training in the description of the COPD-web. We have now elaborated the description of the content of the COPD-web and also added a map of the content of the patient section of the COPD-web (page 8-9 and Figure 1).

It is remarkable that the type of health professionals that will be recruited are not further specified. One would assume that different professions need different approaches in terms to optimize their delivery of self-management strategies to patients. Which kind of health professionals will be included?
Authors reply: The COPD-web is not designed for any particular profession but is thought to be used by the person (could be a nurse, doctor, physiotherapist, etc) meeting a person with COPD in clinical practice. In line with the pragmatic approach in the present study, the intervention i.e. the COPD-web, is applied flexible in order to increase the applicability in ordinary clinical practice.

It will be recorded to what extent health care professionals implement the web-tool in their daily clinical practice. On the other hand, the health care professionals are expected to include the patients. Am I correct that the same individuals are both research subject (as health care provider that will use the platform) and researchers (who will include patients for this trial)? In light of that, will the proportion of the target population (patients) that will receive the intervention adequately reflect clinical reality?
Authors reply: The health care professionals included in the study will be informed to include (ask for participation) all patients with COPD attending the clinic during the study period i.e. they will not be informed to contact patients especially for this study. As the patients will be recruited during an ordinary visit to their clinic, the target population cannot more reflect clinical reality. For example, in Sweden patients with COPD in the primary care have annual visits to their primary care clinic to perform a follow-up of their COPD. If this annual visit occurs during the intervention period, the patient will be asked to participate. However, the reason for the visit could be something completely else. As

long as the reason for the visit is due to their COPD and that they visit their primary care clinic during the intervention period, they will be asked to participate.

Will there be any interaction between health care professionals and patients in light of self-management strategies; in other words will the professional assist the patient in his self-management and/or using the COPD-web tool throughout time or will he/she only introduce the patient to it?
Authors reply: In line with the pragmatic approach in the present study, the intervention i.e. the COPD-web, is applied flexible i.e. the health professional is allowed to use the COPD-web as he/she consider suitable as long as the routine for introduction is carried out. This has been elaborated in the manuscript (page 10).

The timeline of assessments is a difficult to interpret because time lines of both target groups (patients and health care professionals) are mixed. It might be easier to understand when these are separated.
Authors reply: Separating the timeline would mean that several parts of the data collection would be described in two different tables, which might be even more difficult to interpret. We have tried to ease the understanding of the time line by adding information about the source of data collection on each row. We hope that this will facilitate the interpretation.

According to the timeline (p8), this trial has already started in 2016.
Authors reply: Yes, this is correct

VERSION 2 – REVIEW

REVIEWER	Chris Burtin Hasselt University, Belgium
REVIEW RETURNED	05-Jun-2017

GENERAL COMMENTS	I have no further comments