Reviewer’s report

**Title:** Randomised controlled trial protocol (GRIP study): Examining the effect of involvement of a general practitioner and home care oncology nurse after a cancer diagnosis on patient reported outcomes and healthcare utilization.

**Version:** 1  **Date:** 26 Jul 2017

**Reviewer:** Larissa Nekhlyudov

**Reviewer’s report:**

This is an important study that uses a RCT approach to assess the effect of primary care/oncology nurse intervention on patient oriented outcomes and health care utilization among newly diagnosed cancer patients. The concept is timely and much needed. The study is well designed, has the potential to answer important questions. The paper is mostly well written. The main concern with the study is that while the authors state that they are assessing the role of primary care, the intervention will also include an oncology nurse home visit. Would suggest that the background review the prior literature for both the role of primary care AND home nurse visits, and that more effort is made to address how the authors will be able to tease out the effect of the PCP VERSUS nurse, or if the goal is to indeed evaluate PCP AND nurse, or if some outcomes will be improved by the PCP and others by the nurse intervention?

The paper would also be strengthened by addressing the following concerns, some are minor (but included in the respective sections).

1. **Title** - seems a bit wordy, and does not include that the study will also include an oncology nurse intervention. Perhaps "GRIP Trial: Examining the effect of a general practitioner and oncology nurse involvement at time of diagnosis on patient-oriented outcomes and healthcare utilization"...

2. **Abstract** -
   a. as in the main point above, would include that the study will "assess the effects of primary care and oncology nursing care... on satisfaction..."
   b. would also state that the study will address satisfaction, health care utilization and other patient-oriented outcomes
   c. "possible" inclusion before the....- seems that the goal is to specifically include those who are newly diagnosed and before treatment initiation
   d. typo - should be "Trial"registration

3. **Background**
a. Would include a more thorough review of the literature, beyond the Netherlands, drawing in papers about the role of PCP/GP in cancer care (ie. Klabunde JGIM2009; Rubin Lancet Oncology 2016; Wallner JCO 2016- as examples). Would then propose/hypothesize based on the literature, how PCP involvement may affect satisfaction, health care utilization, and other outcomes.

b. As above, would include literature review about home nurse visits as this is a major piece of the intervention being studied. What outcomes do the authors hypothesize the nurse visits affect?

c. Include reference(s) for statements line 51-54.

d. Line 64, would change "To our knowledge," and .... have not been published (rather than studied).

4. Methods

a. Specify - newly diagnosed and followed for up to 52 weeks

b. line 76, add in the Netherlands

c. inclusion criteria - would be more specific, for example - define newly diagnosed here, how about stage I-III?, GP agrees to participate. also need to have working Dutch language (as stated elsewhere) and also need to have email (based on the fact that email will be used as the means of communication)

d. exclusion criteria - how will these be assessed - patient chart? MD evaluation?

e. Recruitment - is there a specific program that will be used for randomization- more than just a "website"?

f. Time out consultation - how much time will it take for the researcher to describe the appt with the GP? Will the GP know how to respond to specific treatment option questions that the patients may have?

g. Follow up care - how much extra time per patient is estimated for the PCP/patient participating in the GRIP study (in other words, what is the additional burden on the PCP?)

h. intervention training - would actually be helpful to create a table or figure outlining the expectations for the GP/expectations of patients/expectations of oncology nurses in the intervention

i. outcomes - be consistent in the order of outcomes in all sections of the paper
j. primary outcome - please elaborate on the health care utilization items - what is included - are you looking to reduce health care utilization? make it more appropriate? less inappropriate?

k. secondary outcomes - a table with all measures (primary and secondary) may be helpful. There are lots of outcomes, how long will the entire questionnaire take the patient to complete? Will they complete this/be fatigued especially during treatment?

l. At line 238, would add new section - Data collection

m. statistical analyses - more details on the regression model - and how covariates will be categorized, etc. Also, how about patient drop out due to disease progression? (I.e. will patients whose disease progress be excluded?)

5. Discussion

a. As above, please elaborate on how the GP/nurse visit interventions on outcomes will be teased out (other than the satisfaction survey measure), or if will be evaluated together.

b. What are the implications for the study if the intervention is successful? Will this be continued/disseminated?

c. Generalizability outside of the Netherlands?

d. Do the authors have any ideas (or preliminary data) about what types of patients will be enrolled (i.e. mostly breast? early stage? other ideas) Please elaborate on the fact that with the diverse population potentially included, may have disparate results, and perhaps insufficient power to stratify.

6. Figures

a. Probably do not need Figure 1 as the process is also included in Figure 2

b. Should an outline of the CONSORT flow diagram for patient enrollment be included? - will leave at the journal discretion

7. Few typos/formatting of the references to be corrected.

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.
Yes

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

Yes

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I am able to assess the statistics

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