PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	A randomised controlled trial to improve general practitioners' role in cancer rehabilitation: Effect on patients' satisfaction with the general practitioner.
AUTHORS	Bergholdt, Stinne; Hansen, Dorte; Larsen, Pia; Kragstrup, Jakob; Søndergaard, Jens

VERSION 1 - REVIEW

REVIEWER	A/Prof Peter Baade Senior Research Fellow Cancer Council Queensland Australia I have no competing interests
REVIEW RETURNED	21-Feb-2013

THE STUDY	It is very likely that the concept of satisfaction for General practitioners is very different to those of cancer patients. In particular, general practitioners face the competing demands of patient care alongside often increasing time constraints for the care they can provide each of their patients. Also, how should the patients interpret the phrase "sufficient support"? To what extent could negative responses reflect unrealistic expectations regarding waiting times, disease progression and treatment options. A patient might be discouraged at having to wait for two weeks to see the GP, whereas the GP might have bent over backwards to fit the patient in earlier than usual. So the comparison of patient's satisfaction with the support they have obtained from their general practitioner with the general practitioner's view of their own contribution seems inherently problematic. The description of the sample size calculations needs further expansion. There seems no justification provided for the 144 patients in each group, nor is there any description of what effect sizes or differences that this sample size would be able to detect. Based on the results in table 3 for example, some of the Odds ratios are sizeable (eg OR=1.57) but the confidence intervals are extremely wide (0.61-4.05). So this raises the question whether the study was sufficiently powered to detect a clinically relevant association. Was any information obtained regarding the stage of the cancer diagnosed? It is likely that the cancer management process would vary depending on the extent of disease at diagnosis. It would be useful to put the response rate in the abstract. Given that the patients were selected from Vejie Hospital, it would

	be useful to give some information about the representativeness of these patients compared to the total cancer population of Denmark.
RESULTS & CONCLUSIONS	the apparent lack of statistical power have have influenced the null result from this study.
REPORTING & ETHICS	While the study was approved by the Danish Data Protection Agency, it seemed strange that further ethics approval was not required, given that this study involved direct patient contact, and relied only on verbal consent to enable contact with the patient's doctor(s)

REVIEWER	Knut Holtedahl Professor University of Tromsø Norway I declare I have no conflicts of interest
REVIEW RETURNED	22-Apr-2013

THE STUDY	The Consort checklist is ok
GENERAL COMMENTS	I previously reviewed the 2012 BMJ Open article from this large study, with results relating to quality of life. The main question now is whether it is interesting enough to know that patients' satisfaction was not affected when we already know that their QOL was not. I agree with the authors that these outcomes differ and will recommend that the article is published. The description of methods and results and the discussion are satisfactory.

REVIEWER	Dolapo Ayansina Research Fellow in Medical Statistics Division of Applied Health Science University of Aberdeen United Kingdom I have no known competing interest
REVIEW RETURNED	25-Apr-2013

THE STUDY	The statistical methods used are not very clear. Page 12, line 11 - 16 states that logistic regression with random effects was used accounting for possible cluster effects... It is not clear how clustering was accounted for in the analysis. The results section and results tables provide no evidence that clustering was actually taken into account (only age and sex were adjusted for in the models). A mixed methods/multilevel model approach would have been appropriate here.
RESULTS & CONCLUSIONS	For the reasons stated above (the authors fail to account for clustering), what looks like a standard logistic regression may not be the most appropriate way to answer the research question. Although a multilevel approach may not affect the conclusions drawn as the standard errors are likely to be larger), it is still in my opinion the most appropriate approach. It is important to account for clustering as there is likely to be a higher correlation in response from GPs and patients within the same practice than those from different practices (this is amplified further if it is a single doctor practice).

REVIEWER	Smitaa Patel Medical Statistician University of Birmingham Clinical Trials Unit United Kingdom I have no conflicts of interest
REVIEW RETURNED	26-Apr-2013

GENERAL COMMENTS	This is a very clear and concise report of the study undertaken and is very important for both patients and GP's.

VERSION 1 – AUTHOR RESPONSE

Reviewer: A/Prof Peter Baade

Senior Research Fellow

Cancer Council Queensland

Australia

I have no competing interests

3) It is very likely that the concept of satisfaction for General practitioners is very different to those of cancer patients. In particular, general practitioners face the competing demands of patient care alongside often increasing time constraints for the care they can provide each of their patients. Also, how should the patients interpret the phrase “sufficient support”?

To what extent could negative responses reflect unrealistic expectations regarding waiting times, disease progression and treatment options.

A patient might be discouraged at having to wait for two weeks to see the GP, whereas the GP might have bent over backwards to fit the patient in earlier than usual. So the comparison of patient’s satisfaction with the support they have obtained from their general practitioner with the general practitioner’s view of their own contribution seems inherently problematic.

Answer:

The primary focus of this paper was not to evaluate the degree of agreement between patients’ and GPs’ assessments of satisfaction but to compare differences between randomisation groups.

However, we agree with the reviewer that the assessments of satisfaction by the patients and GPs are subjective and have added the following to the discussion section on p. 18: “The subjective assessment of satisfaction with the support provided may vary between patients and GPs and may be influenced by many external factors within each group but also by specific characteristics or experiences of each individual.”

4) The description of the sample size calculations needs further expansion. There seems no justification provided for the 144 patients in each group, nor is there any description of what effect sizes or differences that this sample size would be able to detect. Based on the results in table 3 for example, some of the Odds ratios are sizeable (eg OR=1.57) but the confidence intervals are extremely wide (0.61-4.05). So this raises the question whether the study was sufficiently powered to detect a clinically relevant association.

Answer: The sample size was estimated to 144 patients in each group based on the primary outcome of the RCT, health related quality of life. This was assessed by use of the global health status items of the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Core 30.

The study was subject to clustering because the unit of randomisation was at the level of the GP, whereas the primary outcome measure was at the level of the patient. A strong effect on outcome of the individual practice was expected, but no data supported estimation of the cluster effect prior to the trial. To allow maximum clustering it was attempted to include patients to each group from a minimum of 144 practices. However, we observed a very low ICC (95% CI 0.000 to 0.103, reference (22)), and thus believe that allowing for maximum clustering was a very conservative approach. We have no reason to expect that the effect of clustering would be stronger in relation to the DanPEP questions and therefore believe that the 565 respondents were sufficient for our analyses.

To clarify, the following has been added to the section about sample size on p. 10: “Allowing for maximum clustering concerning HRQOL turned out to be very conservative (95% ICC: 0.000 to 0.103)(22). It is plausible that the cluster effect is similarly low concerning the outcomes of this study.”

5) Was any information obtained regarding the stage of the cancer diagnosed? It is likely that the cancer management process would vary depending on the extent of disease at diagnosis.

Answer: We agree with the reviewer. Please find the answer to this comment addressed in Answer 1

6) It would be useful to put the response rate in the abstract.

Answer: We agree with the reviewer that this is useful information. However, due to prioritisation of content of the abstract due to strict word limitations, we find ourselves compelled to leave out this information from the abstract. Instead, the reader is referred to Figure 1 for information about overall response rates and to the result section for details regarding completion rates of each specific item.

7) Given that the patients were selected from Vejle Hospital, it would be useful to give some information about the representativeness of these patients compared to the total cancer population of Denmark.

Answer: We agree with the reviewer and the following has been added to the Results section on p. 13: “Due to a large capacity for treating breast cancer at Vejle Hospital, this group is overrepresented, while the group of prostate cancer patients is underrepresented compared to the general distribution of cancer types in the Danish population in 2008, where breast cancer accounted for 13.6 % of the incidents, prostate cancer for 12.8% and lung cancer for 12.0%, as the three largest cancer types. The distribution of cancer types at Vejle Hospital naturally implies an overrepresentation of female cancer patients (an almost even number of men and women were diagnosed with cancer in 2008 at a national level).” A new reference (34) is inserted: Engholm G, Ferlay J, Christensen N, Johannesen TB, Klint Å, Køtlum JE, Milter MC, Ólafsdóttir E, Pukkala E, Storm HH. NORDCAN: Cancer Incidence, Mortality, Prevalence and Survival in the Nordic Countries, Version 5.3 (25.04.2013). Association of the Nordic Cancer Registries. Danish Cancer Society. Available from http://www.ancr.nu, accessed on 11/05/2013.

8) While the study was approved by the Danish Data Protection Agency, it seemed strange that further ethics approval was not required, given that this study involved direct patient contact, and relied only on verbal consent to enable contact with the patient's doctor(s)

Answer: Part of the Ethics section on p. 12 has been rephrased to: “The Regional Committee on Biomedical Research Ethics, which considered our study for approval, stated that the intervention only involved behavioral elements affecting quality assurance of the process of care and was therefore not subject to Danish law regarding approval of medical research projects from the Danish National Committee on Biomedical Research Ethics. (Project-ID: S-20082000-7).”

Reviewer: Knut Holtedahl

Professor

University of Tromsø

Norway

I declare I have no conflicts of interest

10) I previously reviewed the 2012 BMJ Open article from this large study, with results relating to quality of life. The main question now is whether it is interesting enough to know that patients’ satisfaction was not affected when we already know that their QOL was not. I agree with the authors that these outcomes differ and will recommend that the article is published. The description of methods and results and the discussion are satisfactory.

Answer: We thank the reviewers’ for this positive comment.

Reviewer: Dolapo Ayansina

Research Fellow in Medical Statistics

Division of Applied Health Science

University of Aberdeen

United Kingdom

I have no known competing interest

11) The statistical methods used are not very clear. Page 12, line 11 - 16 states that logistic regression with random effects was used accounting for possible cluster effects... It is not clear how clustering was accounted for in the analysis. The results section and results tables provide no evidence that clustering was actually taken into account (only age and sex were adjusted for in the models). A mixed methods/multilevel model approach would have been appropriate here.

For the reasons stated above (the authors fail to account for clustering), what looks like a standard logistic regression may not be the most appropriate way to answer the research question. Although a multilevel approach may not affect the conclusions drawn as the standard errors are likely to be larger), it is still in my opinion the most appropriate approach.

It is important to account for clustering as there is likely to be a higher correlation in response from GPs and patients within the same practice than those from different practices (this is amplified further if it is a single doctor practice).

Answer: We agree with the reviewer that cluster effects within the same practice unit are likely.

We accounted for the practice clusters using a mixed model, that is, including a random effect corresponding to the general practices in the logistic regression model. To clarify, we have rephrased the section of statistical analyses on p. 12 to:

“To analyse the effect of the intervention on patient satisfaction, i.e. group differences of the proportion of top-evaluations of each of the five DanPEP dimensions, we used mixed effect logistic regression accounting for possible cluster effects caused by the cluster randomisation.”

Reviewer: Smitaa Patel

Medical Statistician

University of Birmingham Clinical Trials Unit

United Kingdom

I have no conflicts of interest

13) This is a very clear and concise report of the study undertaken and is very important for both patients and GP's.

Answer: We are very grateful for the reviewer’s statement regarding as well the importance as the reporting of our study.