

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	The involvement of early stage breast cancer patients during oncology consultations in Italy: a multi-centred, randomized controlled trial of a Question Prompt Sheet versus Question Listing
AUTHORS	Bottacini, Alessandro; Goss, Claudia; Mazzi, Maria Angela; Ghilardi, Alberto; Buizza, Chiara; Molino, Annamaria; Fiorio, Elena; Nortilli, Rolando; Amoroso, Vito; Vassalli, Lucia; Brown, Richard

VERSION 1 - REVIEW

REVIEWER	Kathryn Martinez, PhD, MPH Cleveland Clinic, Center for Value-Based Care Research Cleveland, OH, USA
REVIEW RETURNED	25-Nov-2016

GENERAL COMMENTS	<p>This is an interesting paper describing the results of a study comparing QL and QPS on various communication and patient-centered outcomes in breast oncology.</p> <p>The authors found that patients in the QPS selected 22 questions but asked 13, while the patients in the QL group wrote 2.4 but asked 16. And the people who did the QL overall had higher satisfaction with the questions asked and the oncologist's answers. Yet the authors conclude the two strategies have similar impact on patients' participation of question asking during the consultation. While the overall number of questions is similar between the groups, it seems like the strategies have some differences that need to be explored further before any such conclusion can be reached.</p> <p>One thing the authors need to examine is the concordance between the questions circled/listed and the questions asked in the encounter. Are the questions that patients are a prior identifying as important to them the same questions they wind up asking? This has important implications for how the study was conducted, given that patients were unable to bring their question list sheets in. It is likely far less important to blind the oncologists to the study arm than it is to evaluate the impact of the intervention as it is intended to be administered. This is a key limitation of the study that was not adequately addressed.</p> <p>Below find specific comments: Page 4, lines 21-25: Not sure these statements about family members are necessary. This is not the point of this paper. I would just delete this and go straight from the introductory sentence into the following paragraph about question asking. Page 5, line 14: Could you provide some examples of "outcomes?" were health outcomes improved or psychosocial ones? Page 5, paragraph 2: Belongs in Methods, not Introduction</p>
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	<p>Page 5, line 16: I would not call this a “comparative effectiveness study” given this study is randomized. Comparative effectiveness is generally observational in nature.</p> <p>Page 5, line 41: What was the rationale behind your hypotheses?</p> <p>Page 6, line 31: How was early stage defined? Stage I-III?</p> <p>Page 6, lines 35-36: How were the eligible patients identified? Their oncologists? Had they met with these oncologists previously? It's unclear from your methods what phase of decision making these patients were in? How long had it been, on average, since they were diagnosed?</p> <p>Page 6, line 36: Delete the word “mainly”</p> <p>Page 6, line 40: How was level of cognitive impairment assessed?</p> <p>Page 8-9: Please describe the specific items used to assess satisfaction and decision. Sample items from the STAI-DIFF scale should be presented, and if there is space, a complete description of said measures should appear in a table or figure (or appendix). Did you use the STAI-X1/R or the STAI-X1? Also how is this scored – total score? Sub-scale scores? Please describe further.</p> <p>Did you compare what was circled on the QPS and written on the QL and what was actually asked or just the numbers of questions? How many of the questions that were circled on the QPS were asked, on average?</p> <p>Page 15-16: Isn't it also possible that patients in the QPS felt somewhat constrained by the questions they had to choose from and therefore self-generated fewer questions? This is why it's important to compare the questions they circled with the actual questions they asked to start to determine the mechanism of the prompt sheet in motivating question asking.</p> <p>Study limitations need to be more specifically addressed in a stand-alone paragraph.</p> <p>Page 17, lines 30-34: Conclusions regarding the opportunity to rehearse do not flow logically from this study. This should be a proposal for future research instead.</p> <p>Page 17, final sentence: There is no indication that disseminating patient-centered interventions in oncology care is “easy.” In fact, this is pretty difficult.</p>
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REVIEWER	Aron Goldhirsch European Institute of Oncology Via Ripamonti 435 20141 Milano Italy
REVIEW RETURNED	26-Nov-2016

GENERAL COMMENTS	<p>The thought of authors was that promoting a higher number of questions asked by patients during a consultation is an indicator of a better involvement of patients.</p> <p>In particular, the working hypothesis was that patients who had the possibility to select their questions while consulting a Question Prompt Sheet, with prepared list of questions provided by researchers ahead of the consultation with their oncologist, would ask a greater number of questions than patients from whom a self-generated list of questions was a requisite to before the consultation. Patients' satisfaction and degree of anxiety were assessed.</p> <p>I think that albeit the topic addressed is of primary interest, the study has at least four main limitations:</p> <p>1) The choice of the primary endpoint selected for the trial was the</p>
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	<p>mean difference in the number of questions asked by each patient included in the two groups during consultation, does not provide a certain measure of the involvement of patients in an oncological consultation. One should probably consider that the consultation itself is a rather complex process, which requires a more differentiated approach evaluating comprehension of disease, detailed prognostic features and responsiveness to treatment, availability of characteristics which enhance coping and hope, social, work and daily life issues, family and living environment issues are only some of the facets of a useful consultation.</p> <p>2) There is no description of how the Question Prompt Sheet (that is the prepared list of questions provided to individuals by random allocation to one of groups) was generated and validated.</p> <p>3) The results of the trial show no difference in the two interventional approaches. A proper control arm could have been a consultation conducted by “free navigation”, in which an inventory of the patient’s problems and concerns are first constructed in order to entirely enhance patient’s participation through his own priorities selected before any question formulation.</p> <p>Moreover, authors assert that one of the strengths of the study was that oncologists were blinded to which experimental approach participants were randomized to, and this allowed the evaluation of the real power of the interventions.</p> <p>However, as patients in one arm selected the questions from a list of only 50 items and each oncologist in this trial did on average 15 consultations, it is likely that blinding was not entirely obtained.</p>
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REVIEWER	Arwen Pieterse Leiden University Medical Center, the Netherlands
REVIEW RETURNED	12-Dec-2016

GENERAL COMMENTS	<p>The manuscript describes a randomized controlled trial of two interventions to promote question asking in women diagnosed with early-stage breast cancer who visit their oncologist. The results do not support the hypothesized superiority of one intervention over the other.</p> <p>Main comments</p> <p>1. The authors aimed to compare two interventions to promote question-asking in patients: distributing a question prompt sheet (QPS) versus asking patients to list questions (Question listing, QL). They further hypothesized that the QPS should be superior to QL in terms of number of questions asked and patient outcomes. The authors do not explain the relevance of comparing these two interventions nor why they expect the QPS to be superior to the QL. Please clarify.</p> <p>2. The two interventions were not carried out as they are intended to be, i.e., the patients could not take a copy of their list of questions to the consultation and it is unclear to what extent the oncologists endorsed the interventions. Also, the patients allocated to the QL intervention were asked to list questions on their own instead of coached by an independent assistant. Thus, the present study did not actually compare the interventions as they were intended and this should be made clear from the outset. Please made this clear, including in the title.</p>
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	<p>3. The primary outcomes are overall number of questions and number of questions per category. The description of how this was coded is too succinct to assess how well this was done. The authors indicate that three coders were involved (see p. 7, line 37). Did all three code all consultations? If so, why three coders? How were final decisions about questions/categories made? If the coders did not all rate all the consultations, how was the work divided between them? And, how was coding reliability determined, and what were the scores? Please describe.</p> <p>4. The authors provide very limited information about their measure of 'satisfaction with information'. Apparently, they designed the items themselves but do not report on how it was developed, how participants responded to the items (e.g., missing items) nor on its psychometric properties (e.g., internal validity). Please provide more details.</p> <p>5. The authors conclude that the two interventions were 'equally important to prepare patients to ask questions" (p. 15, line 19). However, the authors did not compare the intervention to care as usual and thus, cannot draw such a conclusion. Please reword.</p> <p>6. The explanation that the authors offer for their results, which go against their hypothesis, is difficult to follow (see e.g., p. 15, lines 44-48 and p. 16, lines 5-19). Moreover, the authors refer to an observational study in which patients asked more questions without intervention (see p. 15, lines 36-43). Please explain findings more clearly in light of this..</p> <p>Minor comments</p> <p>1. It is unclear whether the QPS used was relevant to patients with early-stage breast cancer. Please discuss.</p> <p>2. Methods: At what point in time did the patients receive the QPS/QL exactly and how much time did they have to go through it? Please provide details.</p> <p>3. Methods, p. 6, lines 17-19: How could treatment allocation be concealed from research assistants and patients? Please explain.</p> <p>4. Methods, p. 7, line 39: Questions were defined as "utterances in interrogative form...". Others have defined questions in a somewhat broader manner, i.e., as a verbal utterance with the presumable goal of eliciting an informative response, even when no actual response follows, see Eggle et al (2011) Patient Educ Couns 82:63-68. This could be seen as a limitation of the study, as relevant questions may have been missed. Please reflect on how questions were defined may have affected the findings.</p> <p>5. Methods, p. 9, lines 10-23: The authors used a version of the STAI that seems unfamiliar, with 20 items prior to the consultation and 10 afterwards. Please explain this difference. Also, why not use the STAI-10 or STAI-6 versions?</p> <p>6. Methods, p. 9, lines 45-52: The description of the analyses is difficult to follow, especially re. the confounders. Please clarify. Also, how were differences between centers checked (p. 10, line 3)?</p> <p>7. Did intervention significantly affect number of questions per category (in particular questions about symptoms) or not? The authors state that this was the case in their Discussion (p. 14, lines</p>
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	<p>51-53) but not in their results (see Table 2). Please explain.</p> <p>8. The authors state that the study increases knowledge of cultural differences on question asking (p. 16, line 56). Please explain. Also, the research would support the aim of improving mutual understanding between countries. Again, please explain.</p> <p>9. The authors relate their study to findings on shared decision making (p. 17, lines 16-21). Please better explain the link between the two.</p> <p>Finally, the manuscript would greatly profit from English proofreading.</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Reviewer Name: Kathryn Martinez, PhD, MPH Institution and Country: Cleveland Clinic, Center for Value-Based Care Research, Cleveland, OH, USA Competing Interests: I have no competing interests to disclose.

This is an interesting paper describing the results of a study comparing QL and QPS on various communication and patient-centered outcomes in breast oncology.

The authors found that patients in the QPS selected 22 questions but asked 13, while the patients in the QL group wrote 2.4 but asked 16. And the people who did the QL overall had higher satisfaction with the questions asked and the oncologist's answers. Yet the authors conclude the two strategies have similar impact on patients' participation of question asking during the consultation. While the overall number of questions is similar between the groups, it seems like the strategies have some differences that need to be explored further before any such conclusion can be reached.

One thing the authors need to examine is the concordance between the questions circled/listed and the questions asked in the encounter. Are the questions that patients are a prior identifying as important to them the same questions they wind up asking? This has important implications for how the study was conducted, given that patients were unable to bring their question list sheets in. It is likely far less important to blind the oncologists to the study arm than it is to evaluate the impact of the intervention as it is intended to be administered. This is a key limitation of the study that was not adequately addressed.

R: This is indeed an interesting point to examine and we thank the reviewer for noting this. We have added additional details about this in the Results section (see page 13) and have added a point in the Discussion section that hypothesizes a reason for the result obtained (see page 17). We have also future plans to explore this point using qualitative analyses (exploring the information exchange between patient and oncologist). As this work will differ from the main aim of the trial and it requires more thinking we decide to leave it for another paper.

Below find specific comments:

Page 4, lines 21-25: Not sure these statements about family members are necessary. This is not the point of this paper. I would just delete this and go straight from the introductory sentence into the following paragraph about question asking.

R: We thank the reviewer for this helpful comment and in response we have now removed the sentence about family members.

Page 5, line 14: Could you provide some examples of "outcomes?" were health outcomes improved or psychosocial ones?

R: We have now provided examples of outcomes that include: enhanced information recall and reduced level of anxiety during the consultation.

Page 5, paragraph 2: Belongs in Methods, not Introduction Page 5, line 16: I would not call this a “comparative effectiveness study” given this study is randomized. Comparative effectiveness is generally observational in nature.

R: Yes, we agree with the reviewer and in response we have now removed the phrase.

Page 5, line 41: What was the rationale behind your hypotheses?

R: The QPS is a more structured intervention that suggests a reflection on questions belonging to several arguments, thus it can stimulate more questions than a less structured intervention (QL) that focuses on limited and immediate information needs. We have added a sentence on page 5 before our hypotheses that explains the rationale.

Page 6, line 31: How was early stage defined? Stage I-III?

R: In response to the reviewer’s request for greater specificity we have added a few words, to the text on page 6, to note that we considered early stage to be from stage 0 (Tis) to stage III. We also included subgroups (e.g. IIIA, IIIB).

Page 6, lines 35-36: How were the eligible patients identified? Their oncologists? Had they met with these oncologists previously? It’s unclear from your methods what phase of decision making these patients were in? How long had it been, on average, since they were diagnosed?

R: In response to the reviewers helpful comments regarding our identification and recruitment methods we have altered the paragraph on Page 6, It now reads as follows:

“Eligible patients, scheduled for their first visit to the oncologist to discuss treatment options and who were previously determined to have early stage disease were contacted in the clinic waiting room by the oncology nurse. The nurse described the study goals and interested patients were accompanied to a dedicated room and were given by the research assistant further detailed information.”

In the results section on page 10, we have noted that the average time since diagnosis was two months.

Page 6, line 36: Delete the word “mainly”

R: This has been deleted.

Page 6, line 40: How was level of cognitive impairment assessed?

R: We did not conduct a formal assessment of cognitive impairment for the purpose of this study. We planned to exclude patients who had a clinical diagnosis, available through their patient notes, of a severe psychiatric or neurological disorder. No patients presented with this type of diagnosis.

Page 8-9: Please describe the specific items used to assess satisfaction and decision.

R: The Satisfaction With Decision scale and the three questions used to assess satisfaction with the information received were added within the Appendix.

Sample items from the STAI-DIFF scale should be presented, and if there is space, a complete description of said measures should appear in a table or figure (or appendix).

R: In response to the reviewer’s comment we have added specificity about this point in the text. The STAI-DIFF is not a scale but a value. It is the mathematical difference between the STAI-X1 scale, administered before the consultation, and the STAI-X1/R scale, administered after the consultation (on 10 items used in both scales). We have included the items for both scales in the Appendix.

Did you use the STAI-X1/R or the STAI-X1? Also how is this scored – total score? Sub-scale scores? Please describe further.

R: We used the STAI-X1 scale to assess the state anxiety level before the consultation and, the STAI-X1/R (R stands for “Reduced form”, which is composed by 10 out of the 20 items of the STAI-X1 scale) to assess the state anxiety level after the consultation. The STAI-X1/R was built using the items 1, 3, 5, 6, 8, 9, 12, 13, 17, 20 of the STAI-X1 and the total score was calculated in the same way, (items number 3, 6, 9, 12, 13, 17 are direct-worded, while items 1, 5, 8 and 20 are reverse-worded).

A more detailed explanation has been added within the text.

Did you compare what was circled on the QPS and written on the QL and what was actually asked or just the numbers of questions? How many of the questions that were circled on the QPS were asked, on average?

R: We agree with the reviewer that this is a critical aspect of the study to explore. Given the constraints of this paper we plan to present detailed data in a future paper. In response to the reviewer’s comment we have added some preliminary data in the result section to indicate that patients who received the QPS selected a total of 3392 questions. They asked their physicians a total of 259 questions previously selected. 3133 questions were selected and not asked. Patients who received the QL wrote a total of 293 questions and asked a total of 133 of their questions. 160 questions were written and not asked. We expect that this may be due to the oncologist having already provided information about these questions.

Page 15-16: Isn’t it also possible that patients in the QPS felt somewhat constrained by the questions they had to choose from and therefore self-generated fewer questions? This is why it’s important to compare the questions they circled with the actual questions they asked to start to determine the mechanism of the prompt sheet in motivating question asking.

R: Yes, it is possible that the QPS forced patients to select needs that were not a priority. As noted above we are working on the full analysis of these data. We have added a sentence to the Discussion section to address this interpretation.

Study limitations need to be more specifically addressed in a stand-alone paragraph.

R: The discussion section has been modified according the reviewer’s suggestion. Limitations are now explained in a stand-alone paragraph.

Page 17, lines 30-34: Conclusions regarding the opportunity to rehearse do not flow logically from this study. This should be a proposal for future research instead.

R: We thank the reviewer for this suggestion and the sentence has been reworded to be responsive.

Page 17, final sentence: There is no indication that disseminating patient-centered interventions in oncology care is “easy.” In fact, this is pretty difficult.

R: We agree that disseminating patient-centered interventions is not easy. Using the adjective “easy” we meant that this is a relatively simple and inexpensive intervention that could be disseminated into routine care with limited disruption to clinic flow. We have altered the sentence to make this assertion more precise.

Reviewer: 2

Reviewer Name: Aron Goldhirsch

Institution and Country: European Institute of Oncology, Via Ripamonti 435, Italy Competing Interests: None

The thought of authors was that promoting a higher number of questions asked by patients during a consultation is an indicator of a better involvement of patients.

In particular, the working hypothesis was that patients who had the possibility to select their questions while consulting a Question Prompt Sheet, with prepared list of questions provided by researchers ahead of the consultation with their oncologist, would ask a greater number of questions than patients

from whom a self-generated list of questions was a requisite to before the consultation. Patients' satisfaction and degree of anxiety were assessed.

I think that albeit the topic addressed is of primary interest, the study has at least four main limitations:

1) The choice of the primary endpoint selected for the trial was the mean difference in the number of questions asked by each patient included in the two groups during consultation, does not provide a certain measure of the involvement of patients in an oncological consultation. One should probably consider that the consultation itself is a rather complex process, which requires a more differentiated approach evaluating comprehension of disease, detailed prognostic features and responsiveness to treatment, availability of characteristics which enhance coping and hope, social, work and daily life issues, family and living environment issues are only some of the facets of a useful consultation.

R: We agree that information exchange during a medical consultation is a complex process. The number of questions patients want to ask, and asked, is only a part of the process. Qualitative approaches as for example the conversational analysis may add interesting information that can help to describe the complexity of the doctor-patient communication. This however was not the aim of our study. We selected the number of questions according to the literature (e.g., Siminoff et al., 2000), stating that the number of questions asked could be considered an expression of the most immediate information needs and a first indicator of active participation in the consultation visit with a healthcare provider. We were also consistent with the literature that used this measure to evaluate intervention to improve patient participation.

2) There is no description of how the Question Prompt Sheet (that is the prepared list of questions provided to individuals by random allocation to one of groups) was generated and validated.

R: The Question Prompt-Sheet used for this study was the one largely used in the Australian oncology setting, where it was properly developed (see Butow et al., 1994, 2002, 2004; Brown et al. 1999, 2001; and Clayton et al. 2007) and is now part of routine clinical practice. We translated it into Italian.

3) The results of the trial show no difference in the two interventional approaches. A proper control arm could have been a consultation conducted by "free navigation", in which an inventory of the patient's problems and concerns are first constructed in order to entirely enhance patient's participation through his own priorities selected before any question formulation.

R: We completely agree with the reviewer and certainly considered options to add a third, control arm. One of our concerns was that QPS and QL have been shown to increase question asking and can have subsequent benefits to patient outcomes. Thus we were concerned that a standard of care control arm or a free navigation arm may have undermined the ethical imperative of equipoise. Thus, we conducted an observational phase prior to trial start up to assess the naturalistic phenomenon suggested by the reviewer.

Secondly we decided not to proceed with this design as the sample size calculation suggested that adding a third arm would have been outside the scope of the resources and funding available.

Moreover, authors assert that one of the strengths of the study was that oncologists were blinded to which experimental approach participants were randomized to, and this allowed the evaluation of the real power of the interventions.

However, as patients in one arm selected the questions from a list of only 50 items and each oncologist in this trial did on average 15 consultations, it is likely that blinding was not entirely obtained.

R: We acknowledge the reviewer's concerns however, in our initial analysis we noted considerable overlap between the QPS questions and the self generated QL questions. Thus we were speculated that the ability of the oncologists to guess the intervention arm could be linked to their clinical experience rather than the number of consultation made. That possibility was checked during our preliminary analysis and no between group differences in questions were observed based on years of

experience between centers.

Reviewer: 3

Reviewer Name: Arwen Pieterse

Institution and Country: Leiden University Medical Center, the Netherlands Competing Interests: None declared

The manuscript describes a randomized controlled trial of two interventions to promote question asking in women diagnosed with early-stage breast cancer who visit their oncologist. The results do not support the hypothesized superiority of one intervention over the other.

Main comments

1. The authors aimed to compare two interventions to promote question-asking in patients: distributing a question prompt sheet (QPS) versus asking patients to list questions (Question listing, QL). They further hypothesized that the QPS should be superior to QL in terms of number of questions asked and patient outcomes. The authors do not explain the relevance of comparing these two interventions nor why they expect the QPS to be superior to the QL. Please clarify.

R: Literature showed the efficacy of both interventions. We were interested in assess whether there were differences between the two type of intervention. Is the QPS that promote patient participation or any intervention that lets space for the patients to focus on their own information needs? But, the QPS is a more structured intervention that suggests a reflection on questions belonging to several arguments, thus it can stimulate more questions than a less structured intervention (QL), which focuses on limited and immediate information needs.

The point has been clarified in the text under the Introduction section.

2. The two interventions were not carried out as they are intended to be, i.e., the patients could not take a copy of their list of questions to the consultation and it is unclear to what extent the oncologists endorsed the interventions. Also, the patients allocated to the QL intervention were asked to list questions on their own instead of coached by an independent assistant. Thus, the present study did not actually compare the interventions as they were intended and this should be made clear from the outset. Please make this clear, including in the title.

R: We add some more clarifications in the Introduction section and in the abstract as well. We think it is quite difficult incorporating this aspect in the title.

3. The primary outcomes are overall number of questions and number of questions per category. The description of how this was coded is too succinct to assess how well this was done. The authors indicate that three coders were involved (see p. 7, line 37). Did all three code all consultations? If so, why three coders? How were final decisions about questions/categories made? If the coders did not all rate all the consultations, how was the work divided between them? And, how was coding reliability determined, and what were the scores? Please describe.

R: A codebook and coding procedures for the questions classification by topic was developed to provide definitions, examples and decision rules. Then an Inter-rater reliability among the three coders was calculated on ten consultations, revealing an average percentage agreement of 62.9% and a Cohen's kappa of 0.49, which are acceptable according to Landis and Koch (1977).

Subsequently, all interviews were equally distributed among the three coders who listened to the audiotapes, identified all direct patients' questions, transcribed them verbatim and categorized them using the categories previously identified.

Coders were three because three were the researchers involved in the recruitment and data-coding procedures.

We provide these information only to the reviewer, as we think that they could be redundant within the text, but of course if the reviewer prefer we could add them also in the paper.

4. The authors provide very limited information about their measure of 'satisfaction with information'.

Apparently, they designed the items themselves but do not report on how it was developed, how participants responded to the items (e.g., missing items) nor on its psychometric properties (e.g., internal validity). Please provide more details.

R: The three questions used to assess the patient's satisfaction with information were added in the Appendix A.

They are not a scale but three simple questions. We grouped them under the title "satisfaction with information" for convenience. For more clearness we replaced the term "scale" with "questionnaire".

5. The authors conclude that the two interventions were 'equally important to prepare patients to ask questions' (p. 15, line 19). However, the authors did not compare the intervention to care as usual and thus, cannot draw such a conclusion. Please reword.

R: The sentence has been reworded.

6. The explanation that the authors offer for their results, which go against their hypothesis, is difficult to follow (see e.g., p. 15, lines 44-48 and p. 16, lines 5-19). Moreover, the authors refer to an observational study in which patients asked more questions without intervention (see p. 15, lines 36-43). Please explain findings more clearly in light of this.

R: The hypothesis we made was that the two interventions (administered in this way) could have had reduced the number of questions instead of the usually increasing effect. Maybe, the reason lies in the fact that thinking about their needs before the consultation, helps patients not just to ask more questions, but to focus better on which are their most important needs. The result could be a more focused and precise questions asked during the visit.

Minor comments

1. It is unclear whether the QPS used was relevant to patients with early-stage breast cancer. Please discuss.

R: The use of a QPS is proved to be powerful on early-stage breast cancer patients according to previous literature.

It has been used to prompt questions concerning information needs of patients close to the diagnosis and with no previous visits. Patients, at further stages may have other type of needs, maybe more emotional or concerning end-of-life issues.

2. Methods: At what point in time did the patients receive the QPS/QL exactly and how much time did they have to go through it? Please provide details.

R: Patients received the QPS or the QL after they have completed pre-consultation questionnaires (socio-demographic and anxiety), just before being called by the oncologist. They had no time limit to complete the QPS/QL.

A sentence has been added in the Methods section.

3. Methods, p. 6, lines 17-19: How could treatment allocation be concealed from research assistants and patients? Please explain.

R: Research assistants received the QPS/QL concealed in numbered envelopes before going to the hospital (randomized and enveloped by the research statistician). Patients were given the consecutive envelope at the end of the questionnaires completion. The envelope number was reported next to the patient's identification number on a sheet of paper. The patient did not know the contents of the envelope until it has been opened. As the patient has completed the QPS/QL alone and has reinserted the leaflet into the envelope before attending the consultation, the research assistant did not know whether the patient completed the QPS or the QL.

We have added a sentence on page 6, under the Methods section to better explain the blindness.

4. Methods, p. 7, line 39: Questions were defined as "utterances in interrogative form...". Others have

defined questions in a somewhat broader manner, i.e., as a verbal utterance with the presumable goal of eliciting an informative response, even when no actual response follows, see Eggly et al (2011) *Patient Educ Couns* 82:63-68. This could be seen as a limitation of the study, as relevant questions may have been missed. Please reflect on how questions were defined may have affected the findings.

R: We chose to use this definition to lower the risk of overestimating the request of information, a risk that is more frequent in the Italian language respect to German or English. This is due to two main reasons: one is linked properly to the language and how questions are made. It regards the intonation of the Italian interrogative form that is the only thing characterizing direct questions. The second one is related to a cultural difference. Italians are known to be talkative persons and, according to this, each patient's intervention using a broad definition such as verbal utterance with the presumable goal of eliciting an informative response was likely to be coded as a request for information. We therefore decided to use the Street et al. (2007) definition to allow also a more precise comparison to what patients circled in the QPS or state in QL and what they had really asked during the consultation.

5. Methods, p. 9, lines 10-23: The authors used a version of the STAI that seems unfamiliar, with 20 items prior to the consultation and 10 afterwards. Please explain this difference. Also, why not use the STAI-10 or STAI-6 versions?

R: We add more detail and clarification in the text. They are two different version of the STAI-X1. These are included in the CBA (Cognitive Behavioral Assessment), a package developed in Italy for clinical assessment that has the STAI-X1 administered at the beginning and the STAI-X1/R administered at the end. The scores are compared to see the anxiety fluctuation during the assessment (STAI-DIFF).

6. Methods, p. 9, lines 45-52: The description of the analyses is difficult to follow, especially re. the confounders. Please clarify. Also, how were differences between centers checked (p. 10, line 3)?

R: We know that the description of the analyses is not easy but this is due to the complexity of the analysis procedure. We try to express the sentence in a more clear way within the Sample size calculation and statistical analysis section.

Regarding the differences between centers, in order to investigate the presence of socio-demographic differences as potential confounders among patients in the three centers, chi-squared test and one-way ANOVA were performed for categorical and continuous variables respectively.

7. Did intervention significantly affect number of questions per category (in particular questions about symptoms) or not? The authors state that this was the case in their Discussion (p. 14, lines 51-53) but not in their results (see Table 2). Please explain.

R: The sentence in the discussion section has been reworded.

8. The authors state that the study increases knowledge of cultural differences on question asking (p. 16, line 56). Please explain. Also, the research would support the aim of improving mutual understanding between countries. Again, please explain.

R: European studies on question asking are really few and to our knowledge this is the first study conducted in Italy. The Italian setting are not enough explored and this study wants to say something about question asking of Italian patients in the oncology setting.

Re-reading this part for us is quite clear. We meant that European studies on question asking are really few and to our knowledge this is the first study conducted in Italy. Moreover as it is known southern Europe is different from northern Europe (e.g., more talkative, less willing to be involved...). Studies show that there are different patterns of doctor-patient communication related to national culture (Meeuwesen et al., 2009; van den Brink-Muinen et al., 2008) and differences in patients' information needs (Harding et al., 2013). Based on Meeuwesen et al. (2009) results, in Italy we might expect more fixed roles of doctors and patients, less biomedical information exchange, and less patient question asking.

9. The authors relate their study to findings on shared decision making (p. 17, lines 16-21). Please better explain the link between the two.

R: Previous findings in shared decision-making showed that oncologists have limited skills in involving patients during the consultation. There is the need to improve such skills but we need to know the differences between countries to generate a powerful and focused training program. Oncologists and patients communicate differently across countries and our study opens a window on the Italian setting.

Finally, the manuscript would greatly profit from English proofreading.

R: Dr. Brown, who is one of the authors, has proof read and revised the draft. We hope it is more clear now.