Author's response to reviews

Title: Experiences of patients, family and professional caregivers with Integrated Palliative Care in Europe: protocol for an international, multicenter, prospective, mixed method study

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Author's response to reviews:

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The Biomed Central Editorial Team
Object: MS: 2102038662137212 - Experiences of patients, family and professional caregivers with Integrated Palliative Care in Europe: protocol for an international, multicenter, prospective, mixed method study

Thank you for consideration of our manuscript for publication in your journal.
We have reviewed the above manuscript according to your reviewer’s comments.

Reviewer # 1 (Dr. Franca Warmenhoven)

Major Compulsory Revisions

1. In methods, section ‘selection of IPC initiatives’, the authors propose to recruit different IPC initiatives in the study, three for Belgium and five for other countries. It is unclear whether only three initiatives will be recruited for Belgium compared to five for the other countries. In fact, it is also unclear why you choose for either three or five initiatives in any of the countries. Can you clarify why you have chosen or why you expect to be able to include 3-5 initiatives per country?
   • In each country five IPC initiatives will be recruited, while in Belgium only three initiatives will be recruited. This is indicated in the protocol (line 141, 142). The reason is that for Belgium only part of the country will participate (Flanders)
and therefore the initiatives needed are lower.

- It is a novelty that in palliative care research patients and (family) caregivers’ views will be investigated at this large European scale. As integrated palliative care is an upcoming and under-investigated field, there is no theoretical framework or prevailing standard on which we can base the number and selection of cases (IPC initiatives). We expect that three-five initiatives per country and 23 in total will be enough to generate insight in how current IPC initiatives vary in service provision (e.g. diagnostic group(s), organisational structure, caregivers and settings that are involved, etc.) and what this means for patients’ and caregivers’ perspectives on the (quality of) service provision and its barriers and benefits. Although this number may not be enough to reach full saturation, we had to take into account the reality of inclusion of a rather vulnerable patient group which will demand large efforts in time and resources in the project team.

2. In methods, section patients and family caregivers, the authors aim to achieve a total sample of 138 patients and 138 family caregivers. Even with an attrition rate of 30%, this number of participants seems quite ambitious. I have doubts about the attainability of these numbers. This is related also to the section ‘data collection’, in which the authors report that they expect the entire duration of the study period to be eighteen months, including recruitment, which is a very ambitious planning. Furthermore, I would like clarification whether the authors aim to include six subunits per initiative or whether it will also be an option to include less or more subunits per initiative with a mean of six subunits per initiative.

- The sample of 138 patients and 138 family caregivers will be recruited in five countries in 23 initiatives. This means that we will strive for an inclusion of six patients and six family caregivers per IPC initiative. In principle it is not an option to include less or more subunits per initiative with a mean of six. We expect that this small number is attainable within 18 months as this will be done in a multicenter study across 5 European countries with dedicated researchers per site. Herewith we have also taken into account that the qualitative data analysis is not postponed to the end of data collection, but will already start after the first interviews, as data analysis in qualitative research is an iterative process. This has been clarified (line 190-196).

3. In section methods, data collection, the authors say that bereaved carers may
still be included in the study for the final follow-up. The authors have already referred to the existence of the post-bereavement version of the Canhelp Lite. It would be more clear if the authors would explicitly name the use of this version of the Canhelp Lite in bereaved caregivers. Furthermore, the procedure of data collection when a patient deceases is not clear. A bereaved family member may interpret questions in a different way. Please elaborate on how you will deal with the information gathered from bereaved caregivers. I am also interested in how you will use the patient diary information in the case of a deceased patient.

- Considering the CanHelp Lite we added the version names, and mentioned which versions will be used in this study (line 305-307).
- The procedure of data collection: If a patient dies during the study period, we will contact the family caregiver to offer our condolences and, dependent on the circumstances of the bereaved carer, will ascertain if they wish to have a final interview. If so, we will contact them again make an arrangement at a time of their convenience between 4 and 12 weeks afterwards. We will not administer any questionnaires anymore. The final interview will include a review on the most important problems and needs in the dying phase from the perspective of the bereaved family caregiver, which caregivers were involved in this phase and just after bereavement and how the care provision was experienced by the bereaved family caregiver. This has been clarified now (line 215-219 and 281-284).
- With respect to the diary, we will only analyse the diaries to the extent that these have been completed by the patient himself.

4. In the section methods, professional caregivers, focus group, it is unclear how many professionals will be included in the focus group and what kind of professionals will be included. Also it is not stated what the minimum of participants in the focus group will be, which professionals should be present for the focus group to take place, and what will happen if several professional caregivers in a subunit decline the invitation of the focus group. Indeed the authors broadly suggest the topics that will be discussed in the focus group, but a concept of the topic list or the method by which the topics for the topic list will be defined should be given.

- The focus group will consist of 6-10 participants per initiative. In order to maximize an exploration of different perspectives on the initiative as it is experienced in practice, we aim at a convenience sample for the focus group
containing various professional roles and responsibilities within the initiative. As the protocol says, for the focus group professional caregivers who are identified in the patient’s care network and are involved in the IPC initiative will be invited for the focus group. The final invitation list will be made after inclusion of the last patient, with alternatives in case of decline. This has been clarified (line 199-205).

- As stated in line 324-326, the topics of the topic list are as follows: components considered important for high quality integrated care, set-up of the initiative (roles, responsibilities, relationships), expectations and/or future improvements.

5. In the section methods, data management and analysis, the authors describe that researchers from each partner country will jointly develop a preliminary coding schedule with the results of the first two interviews. Will this procedure take place with both baseline and ending interviews?
- Yes, we will use one codebook for both the baseline and final interview as the content of the baseline and ending interview largely overlap. This has been clarified (line 334, 335).

6. In the section methods, data management and analysis, it is unclear how the Focus group data will be managed.
- The procedure used for the interviews will also be used to analyse the focus group data. For the focus groups a separate code book will be developed by the researchers. This has been clarified (line 338, 339).

Minor Essential Revisions
1. The reference of Lukas Radbruch indicates that he works in Leuven and the reference of Johan Menten indicates that he works in Bonn. This should be reversed.
- Done

2. In the methods section, participants (subunits), ICP should be IPC.
- Done

Discretionary Revisions
1. In the conclusion of the abstract the abbreviation IPC is used. Please add ‘(IPC)’ in the abstract ‘background’ where you use the term Integrated Palliative Care for the first time.
- Done
2. In the manuscript ‘Background’ the sentence that refers to the study of Epiphanio (ref.17) is difficult to read. You may want to consider rephrasing this sentence.
• This section has been revised (line 86-89).

3. Research questions: The main research question in this study is very broad in the sense that it includes experiences of patients, family and professional caregivers. However, it is not completely clear whether subsidiary question 2 also includes all of these 3 perspectives (family and professional caregivers).
Furthermore, I wonder whether subsidiary question 3 and 4 will be related to the integrated palliative care pathways, which are the subject of this study.
• ‘Family’ and ‘professional’ have been added to subsidiary question 2, in order to make clear that this question included the perspectives of both, patients, family and professional caregivers.
• This research project has the overall objective of identifying (prerequisites for) best practices of integrated palliative care on the level of treatment pathways, networks and collaborations. The current study relates to this subject by investigating how integration of palliative care in treatment pathways, networks and collaborations works in practice within several IPC initiatives, viewed from the perspectives of patients, and their caregivers. “Integrated palliative care pathways” therefore refers to the overarching subject of the research project “Patient-centred integrated palliative care pathways in advanced cancer and chronic disease”. Subsidiary questions 3 and 4 will then investigate how patients experience their symptoms, quality of life and how family caregiver experience their burden/reward of caregivers and whether the IPC initiative meets the needs of the patients in these domains. It will also investigate what mechanisms in these IPC initiatives constitute successful palliative care integration.

4. The section methods, patients and family caregivers, semi-structured interview, describes how semi-structured interviews will be used to explore views of patients and caregivers. A few questions arise in this section: Who will perform the interviews? Will these interviews be performed with patient and family caregiver together at the same time? How will you deal with the influences that patient and family caregivers have on each other and how will you secure collecting data from both patient and family caregiver instead of collecting most
data from the most dominant partner in the interview?

- The interviews will be conducted by researchers from the project teams in each of the five participating countries (clarified in line 261, 262). They all attended the data collection training.
- In principle the interviews will be conducted separately. For practical reasons the researcher may deviate from this and conduct the interview with both patient and family caregiver at the same time.5
- In order to minimize influences between patients and family caregivers when they are together, we will emphasize before the start of the interview that we are interested in both the personal view of the patient and the family caregiver. Further we will ask either the patient or family caregiver directly for his/her own view, e.g.: “Is this problem you just mentioned also a problem in your own view, or is this a problem in the view of [name of family caregiver]?” Patients in our study are vulnerable and often more comfortable in the surrounding of their partner, so we do not want to be too strict in a separate interview to restrict the burden for the patient as much as possible. This has been clarified now (line 262-272).

5. In the additional file 1: Caregiver network analysis questionnaire. This questionnaire may bring some unclarity (question 2) if ‘the how’ of the contact that the patient has with the caregiver is varying (e.g. Sometimes telephone, sometimes face to face). It may be worthwhile adapting this question so more options are possible.
- If the patient has contact both by telephone and face to face, it is possible to fill in both options. The researchers are present when the patient is filling in the questionnaire, so if s/he has questions about it, it is possible to answer these immediately.
- For practical reasons, we do not want to give too much options as every option will increase the risk of interpretation bias for the respondent

6. In the section methods, questionnaires, the authors indicate that the Palliative care Outcome Scale, is being translated into Hungarian. This information about Hungarian translation/availability misses in the case of the other questionnaires, Caregiver Reaction Assessment and Canhelp Lite. Either mention the state of process in all questionnaires, or restrict this to the general remark that you have already made in the general questionnaires section.
7. Methods, ethical issues. I am surprised that the study does not have to go through a Dutch ethical review committee, but I trust that the same conditions apply to the Dutch participants compared to the participants from other nationalities.

Yes, the same study procedures will be applied to all of the countries under investigation.

Level of interest: An article of importance in its field
Quality of written English: Acceptable
Statistical review: No, the manuscript does not need to be seen by a statistician
Declaration of competing interests: I do not have any financial or non-financial competing interests relating to this manuscript. I have worked as a researcher at the University Medical Centre Radboud Nijmegen, department of Anaesthesiology, Pain and Palliative Medicine until 2011 but have no current position there at the moment. My current work is at the K.U. Leuven, Academic Centre for General Practice.

Reviewer #1 (Dr. Gunn Grande)

Minor Essential Revisions
This is a well written paper on an interesting multi-centre study. I have some minor comments which it would be helpful if the authors could address.

Page 4, line 80 onwards conflates the IPC approach itself and the study method used to evaluate its effectiveness, and could do with some tidying.

• This section was revised (line 79-89).

Page 7, line 143: local initiatives in the five countries will be ‘identified’ rather than collected? Furthermore, the selection criteria could do with a separate heading or box.
• ‘collected’ has been replaced by ‘identified’ as indicated by the reviewer.
• A heading has been added for the selection criteria for IPC initiatives.

It could be clarified a bit better how the subsidiary questions tie together to inform the main research question. They seem a bit ‘sprawling’ at present.
In order to enable an investigation of ‘experiences’ with (palliative) care provision it is necessary to gain insight in what kind of care patients receive during their final disease trajectories, which caregivers are involved, and how these caregivers work together to provide patient-centred and continuous care. Therefore the first question will examine the organisation of the palliative patient’s care network and how this network develops over 3 months. The second question focuses on the patient’s view on relationships between patient - family caregiver and professional caregivers, collaboration between professional caregivers, the quality of palliative care provided, and whether the care provided meets the need and problems of the patient. The third subsidiary question focuses on the symptoms and quality of life of the patient in order to gain insight in the most important problems and needs. As the family caregiver is often an essential figure in the patient’s (care) network, the perspective of the family caregiver is important to consider in this study about experiences of service users as well. Therefore, the fourth question focuses on family caregivers’ perceived burden and reward in caring for the patient.

Please explain on what basis a sample size of 138 was decided. 7

- The number of 138 patients and 138 family caregivers will be recruited from 23 IPC initiatives in five European countries. This means that we aim to include 6 patients and 6 family caregivers at a minimum per initiative. This number is based on the exploratory nature of this study in an under-investigated field of integrated palliative care.

Will the recruitment procedure enable to participants to be recruited at a ‘similar’ time point (in their disease trajectory or contact with the IPC) to make comparison more meaningful?

- Instead of recruiting participants at a ‘similar’ time point, we aim for a purposive sample of patients who are at different time points in their disease trajectories. This will enable us to capture the various experiences patients can have with care provision at different time points in their disease trajectories. This has been clarified in the protocol (line 187-189). By registering the death date of patients who have died, it will be possible to find out afterwards in which time point they were in their disease trajectory (follow back approach) as a secondary analysis.
Data collection: I know this is outlined in Table 2, but it would help if the text briefly draws the reader’s attention to the fact that different data are collected at different times (for instance semi-structured interviews are not conducted at all time points).

• This part under ‘Data collection’ has been revised and clarified (lines 207-214). Please clarify further whether patients and carers will be interviewed together or separately. How will this work with telephone interviews?

• In principle the interviews will be conducted separately. For practical reasons the researcher may deviate from this and conduct the interview with both patient and family caregiver at the same time. This might not be entirely clear from the protocol, but the interviews which are at baseline and at month 3 will be only face-to-face. The questionnaires and/or diary can be completed by telephone, in case the participant is not able to complete this on his/her own. This has been clarified now (line 262-264).

A bit more explanation of the social network approach would help. For instance, are the data for this collected solely through the questionnaire?

• First of all the data of the social network approach will be collected using the caregiver network analysis questionnaire and the patient diary. In the interviews we will also apply a social network approach to obtain more in depth insight in the relationships between patients/caregivers and between caregivers. This has been clarified now (line 238-240).

It would be good if the analysis gave more indication of how the cases and models are likely to be compared.

• In general, the analysis will focus on the similarities and differences between the IPC initiatives (e.g. the diagnostic group(s), organisational structure, the caregivers and settings that are involved in the care provision) and what these mean for the views of patients, family caregivers and professional caregivers on the care provision. This was clarified in the data analysis section (line 340-343).

Some of the ethics section may be condensed, as the audience here is a palliative care readership, rather than a general funding body, therefore may need less convincing about the ethics.

• The ethics section has been condensed.

Level of interest: An article of importance in its field

Quality of written English: Acceptable
Statistical review: No, the manuscript does not need to be seen by a statistician.
Declaration of competing interests: None