PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Future Care Planning for patients approaching end-of-life with advanced heart disease: an interview study with patients, carers and healthcare professionals exploring the content, rationale and design of a randomised clinical trial
AUTHORS	DENVIR, MARTIN; Highet, Gill; Robertson, Shirley; Cudmore, Sarah; Reid, Janet; Ness, Andrea; Hogg, Karen; Weir, Christppher; Murray, Scott; Boyd, Kirtsy

VERSION 1 - REVIEW

REVIEWER	Clare Gardiner University of Auckland, New Zealand
REVIEW RETURNED	20-Mar-2014

GENERAL COMMENTS	This study represents the first phase of a wider trial, designed to establish the effectiveness of a palliative care intervention for heart disease. The research area is an important one and the topic highly relevant given concerns over palliative care provision for patients with non-cancer conditions. The qualitative study design is appropriate for collecting pre-trial data, and the paper is well written and articulate. I did have some concerns around the focus of the study and found myself questioning whether the data presented really addressed the research question. The study aim is to 'explore ways in which a holistic intervention could be tested in a randomised trial setting'. However the majority of data relates to issues such as views of care provision, and appropriateness of the proposed intervention. I appreciate that these are important issues, but I got to the end of the paper not really having been convinced that the findings addressed the central question about trial design. I'd suggest either presenting alternative data that much more clearly addresses the research aim, or broadening the research aim to make it clear that secondary aims were to explore the appropriateness of the intervention and patients views on care provision. The second paragraph on page 5 implies this is a feasibility study, but this is not made very clear in the aims or methods. If this study was not intended on being a full feasibility trial then this sentence should be re-phrased or removed for clarity. Minor points

	The final bullet point under ‘strengths and limitations’ is incomplete The first sentence of the introduction could probably do with referencing or qualifying in some way, given the general readership of this journal. The methods are rather brief and could use some more detail. It would be helpful to include further detail on the rationale for a qualitative design, the sampling and recruitment strategies (particularly for HCP’s), some clarification over whether HCP and PCFG were asked the same questions, and detail on the analysis of the data. It might be helpful to include a list of questions/prompts that were used in the interviews and focus groups, again to help convince the reader that these were relevant to the research question. It’s not clear whether figure one refers to the original trial design or the modified trial design (page 13, final paragraph). If this is the modified design, it would be useful to know what has been changed from the original version. The same goes for any changes to the intervention in figure two, that were made in response to findings from this study.

REVIEWER	Dr James Beattie Department of Cardiology, Heart of England NHS Foundation Trust, Birmingham, UK
REVIEW RETURNED	16-Apr-2014

GENERAL COMMENTS	The authors have undertaken qualitative analysis of the views of patients or informal carers of those with heart failure or other chronic cardiac conditions and a variety of health care professionals (HCPs) to inform the design of an anticipatory care plan. This exercise is required to secure funding for a proposed phase 2 trial examining the impact of this anticipatory care plan which targets patients considered to exhibit a 20% chance of dying 12 months following an acute hospital admission based on previously validated prognostic instruments. Transcripts of the results of the patient / care focus groups and the one-to-one interviews with HCPs have been subject to thematic analysis with robust NVivo software. However only broad themes are discussed in the text and those emerging are not particularly new. While the authors contend that there are 'common concerns' between the patient / carers and HCPs, perhaps linked in accommodating comorbidity, the comments of the former groups seemed more weighted towards healthcare care delivery in poor access to timely, informed, coordinated care. In contrast, the HCPs seemed to be more focussed on the challenges presented by the prognostic ambiguity inherent in the cardiac conditions which might engender a reluctance to engage in difficult conversations with a risk of undermining hope for the future. Presumably the Future Care Plan would comprise elements relevant to such conversations in the early or later interview dependent on the result of randomisation.

	The sample future care plan which formed the basis of the discussions with the patient / carers or HCPs is not incorporating in the paper which might offer some context and perhaps it might be worth including this, even as a link, unless embargoed by the confidentiality of the proposed phase 2 study. The authors suggest that the results of the focus groups discussions and interviews were used to amend the design of the structure of Future Care Plan as the intervention but no specific details are offered on the resultant changes are described. Perhaps it might be worth including some information on this as a measure of the effect of this exercise. I share the authors concerns that the number of participants in both the lay and professional groups are rather small and it is unclear what proportion of the patient / carer group were unaffected by heart failure. Certainly, the extension of palliative and supportive care to all cardiac conditions is to be encouraged and the relatively novel inclusion of ACS patients in this study is to be applauded. However I have a general concern in the use of clinically stable patients or their carers to contribute to the design of an intervention specifically targeting end of life issues in those with acute or subacute instability. I think this needs to be more fully justified in the text. The influence of recent hospitalisation on decision making or advance care planning is well described.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1
Reviewer Name Clare Gardiner
Institution and Country University of Auckland, New Zealand
Please state any competing interests or state 'None declared': None declared

This study represents the first phase of a wider trial, designed to establish the effectiveness of a palliative care intervention for heart disease. The research area is an important one and the topic highly relevant given concerns over palliative care provision for patients with non-cancer conditions. The qualitative study design is appropriate for collecting pre-trial data, and the paper is well written and articulate.
RESPONSE: We thank the reviewer for these comments.

I did have some concerns around the focus of the study and found myself questioning whether the data presented really addressed the research question.
RESPONSE:Thank you for raising this issue. The aim of the study was indeed to seek the views of patient and carers and of healthcare professionals on the design and delivery of a randomised controlled trial of end of life care in patents with advanced heart disease. We feel we have addressed this by using a qualitative approach. However, it was also important during this phase to explore the patient's experiences of healthcare interactions and their relation to the provision of high quality holistic care, a hallmark of good end of life care. The lack of good care, as described by the patients and their carers, is directly relevant since it justified the need for the trial itself. We chose to report these findings in addition to their views on the design of the trial.

The study aim is to 'explore ways in which a holistic intervention could be tested in a randomised trial setting'. However the majority of data relates to issues such as views of care provision, and appropriateness of the proposed intervention.
RESPONSE:These issues are directly related to the design and implementation of a trial of this nature since current models of care within the UK are widely accepted as inadequate and unable to provide end of life care for non-cancer related illnesses. Therefore exploring patent's experiences and views as a baseline task during the focus groups allowed us to ensure that our design and

intervention specifically addressed the shortfalls in care provision highlighted by our PCFG.

I appreciate that these are important issues, but I got to the end of the paper not really having been convinced that the findings addressed the central question about trial design.
RESPONSE:Thanks for these comments. The central theme of the work was to seek the views of patients, carers and healthcare professionals on the design of a trial. However, we have also included their views on various aspects of end of life care since these issues are highly relevant to the central theme of the manuscript. We have added and altered text in the results and discussion sections to clarify this issue.

I'd suggest either presenting alternative data that much more clearly addresses the research aim, or broadening the research aim to make it clear that secondary aims were to explore the appropriateness of the intervention and patients views on care provision.
RESPONSE:Many thanks for these suggestions, we have added text in the introduction, methods and discussion to broaden the aims of the study and to explain why these broader aims remain pertinent to the trial design itself.

The second paragraph on page 5 implies this is a feasibility study, but this is not made very clear in the aims or methods. If this study was not intended on being a full feasibility trial then this sentence should be re-phrased or removed for clarity.
RESPONSE:Thanks for this point, we have removed reference to a feasibility study.

Minor points

The final bullet point under 'strengths and limitations' is incomplete
Thanks for pointing this out. RESPONSE:This has been amended.

The first sentence of the introduction could probably do with referencing or qualifying in some way, given the general readership of this journal.
RESPONSE:We have included a reference for this statement.

The methods are rather brief and could use some more detail. It would be helpful to include further detail on the rationale for a qualitative design, the sampling and recruitment strategies (particularly for HCP's), some clarification over whether HCP and PCFG were asked the same questions, and detail on the analysis of the data.
RESPONSE:We have added further details about methods and we have added appendices for the questions used to structure the PCFG (appendix 1A) and the HCP interviews (appendix 1B)

It might be helpful to include a list of questions/prompts that were used in the interviews and focus groups, again to help convince the reader that these were relevant to the research question.
RESPONSE:These have been added as appendices as described in the point above.

It's not clear whether figure one refers to the original trial design or the modified trial design (page 13, final paragraph). If this is the modified design, it would be useful to know what has been changed from the original version. The same goes for any changes to the intervention in figure two, that were made in response to findings from this study.
RESPONSE:We have not changed these figures but we have added text in the methods and discussion explaining how the basic design of the study changed as a result of the consultation process.

Reviewer: 2

Reviewer Name Dr James Beattie
Institution and Country Department of Cardiology,
Heart of England NHS Foundation Trust,
Birmingham, UK
Please state any competing interests or state ‘None declared’: None declared

The authors have undertaken qualitative analysis of the views of patients or informal carers of those with heart failure or other chronic cardiac conditions and a variety of health care professionals (HCPs) to inform the design of an anticipatory care plan. This exercise is required to secure funding for a proposed phase 2 trial examining the impact of this anticipatory care plan which targets patients considered to exhibit a 20% chance of dying 12 months following an acute hospital admission based on previously validated prognostic instruments.
Transcripts of the results of the patient / care focus groups and the one-to-one interviews with HCPs have been subject to thematic analysis with robust NVivo software. However only broad themes are discussed in the text and those emerging are not particularly new.

RESPONSE:We agree that some of the themes which emerged in these interviews have been reported previously by other workers in the field. We have mentioned this in the discussion and referenced additional work in this regard (refs 18,19). We would also point out, however, that the rationale for the study is novel in that we sought the views of patients, carers and healthcare professionals on the content and design of a trial of end of life care. We had to discuss the current shortfalls in this type of care at the start of all of the interviews and focus groups to justify the need for a trial to the participants. Reporting these findings within the manuscript is therefore relevant and important.

While the authors contend that there are 'common concerns' between the patient / carers and HCPs, perhaps linked in accommodating comorbidity, the comments of the former groups seemed more weighted towards healthcare care delivery in poor access to timely, informed, coordinated care. In contrast, the HCPs seemed to be more focussed on the challenges presented by the prognostic ambiguity inherent in the cardiac conditions which might engender a reluctance to engage in difficult conversations with a risk of undermining hope for the future.

RESPONSE:We agree that while there were some common concerns about the provision of holistic care there were also distinctly separate issues raised by PCFG and HCPs. We have made changes to the discussion to reflect these differences.

Presumably the Future Care Plan would comprise elements relevant to such conversations in the early or later interview dependent on the result of randomisation. The sample future care plan which formed the basis of the discussions with the patient / carers or HCPs is not incorporating in the paper which might offer some context and perhaps it might be worth including this, even as a link, unless embargoed by the confidentiality of the proposed phase 2 study.

RESPONSE:The future care plan structure was being developed at the time of this study but is now available and being used in our trial. It is aligned with a national development in primary care which falls under the GP contract called the Key Information Summary. Further details about this are available at http://www.scimp.scot.nhs.uk/key-information-summary/

The authors suggest that the results of the focus groups discussions and interviews were used to amend the design of the structure of Future Care Plan as the intervention but no specific details are offered on the resultant changes are described.
Perhaps it might be worth including some information on this as a measure of the effect of this exercise.

RESPONSE:We have added text to the methods and discussion to explain how the design was amended following our consultation process.

I share the authors concerns that the number of participants in both the lay and professional groups are rather small and it is unclear what proportion of the patient / carer group were unaffected by heart failure. Certainly, the extension of palliative and supportive care to all cardiac conditions is to be encouraged and the relatively novel inclusion of ACS patients in this study is to be applauded.

RESPONSE:Thanks for these supportive comments.

However I have a general concern in the use of clinically stable patients or their carers to contribute to the design of an intervention specifically targeting end of life issues in those with acute or subacute instability. I think this needs to be more fully justified in the text. The influence of recent hospitalisation on decision making or advance care planning is well described.

RESPONSE:We agree that we would have liked to use more unstable patients to seek their views on the design of the trial but we felt that this was challenging to do. We have included a statement in the limitations section to highlight this issue.

VERSION 2 – REVIEW

REVIEWER	Clare Gardiner University of Auckland, New Zealand
REVIEW RETURNED	23-Jun-2014

GENERAL COMMENTS	Thank you for the opportunity to review this paper again. My comments have all been addressed and the paper now has a much clearer focus.

REVIEWER	Dr James Beattie Department of Cardiology Heart of England NHS Foundation Trust Birmingham UK
REVIEW RETURNED	06-Jun-2014

GENERAL COMMENTS	The issues I raised in my earlier review have been clarified by the authors in their revision and I am happy to propose acceptance of this paper for publication. A couple of minor points – 1) It may be appropriate to change Line 1 of the discussion to 'This qualitative study examining patients', carers' and healthcare professionals' (HCP)…' (my emphasis). 2) Discussion para 6: typo - ? arguably 3) Towards the end of the paper, the authors allude to the use of new technologies in supporting patients with advanced heat failure. Incorporating the references below might better illustrate this aspect and evolving synergies between cardiology and palliative care. This is only a suggestion and I am happy to accept the paper as is. Goldstein NE, May CW, Meier DE. Comprehensive care for mechanical circulatory support: a new frontier for synergy with palliative care. Circ Heart Fail. 2011 Jul;4(4):519-27.

	Lauck S, Garland E, Achtem L, Forman J, Baumbusch J, Boone R, Cheung A, Ye J, Wood DA, Webb JG. Integrating a palliative approach in a transcatheter heart valve program: bridging innovations in the management of severe aortic stenosis and best end-of-life practice. Eur J Cardiovasc Nurs. 2014 Apr;13(2):177-84.

VERSION 2 – AUTHOR RESPONSE

Reviewer 1 - many thanks for your expert review and comments on our manuscript which we feel have enhanced it greatly.

Reviewer 2 - I have amended the text at the beginning of the discussion to read as suggested by this reviewer (green highlight). I have also added the two references suggested by this reviewer. We are extremely grateful for your time and expertise in reviewing our manuscript.