PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Patient reported outcomes at hospital discharge from Heart Centres, a national cross-sectional survey with register based follow-up: The DenHeart study protocol.
AUTHORS	Berg, Selina; Svanholm, Jette; Lauberg, Astrid; Borregaard, Britt; Herning, Margrethe; Mygind, Anna; Christensen, Anne; Christensen, Anne; Ekholm, Ola; Juel, Knud; Thrysøe, Lars

VERSION 1 - REVIEW

REVIEWER	M.J. Lenzen Erasmus Medical Center, Rotterdam, the Netherlands
REVIEW RETURNED	28-Feb-2014

GENERAL COMMENTS	Some of the above items on the checklist are indicated as N/A. As the manuscript focusses on the rationale and design of a study that is currently being conducted, not all questions seem relevant. In addition, I have the following comments for the authors: Patient reported outcomes at hospital discharge from Heart Centres, a national cross-sectional survey with register based follow-up: The DenHeart study protocol A well written manuscript on the rationale and design of an interesting and relevant topic: patient reported outcomes at hospital discharge. Some comments. The manuscript presents the study design and rationale of the DenHeart study, should this not be stated more clearly in the title of the manuscript (instead of “The …. Study protocol”)? Regarding the diagnostics groups, one wonders which diagnosis is leading as it is to be expected that a significant number of patients have more than one cardiovascular diagnosis (e.g. heart failure due to an ischemic heart disease, etc.). Importantly, a patient can be included in only one diagnostic group. Is there some hierarchy in defining in which diagnostic group a patient will be include, this is not discussed. It is stated (pag 6) that the questionnaires should be filled out at discharge or within 3 days of discharge and returned by mail. What does this mean? That questionnaires that are not returned within a few days will not be used? In addition (pag 16), some centres mail the questionnaires to the patients after discharge, these patient will hardly be able to fulfil this criterion. It is indicated (pag 6) that coronary artery bypass graft is an example

	of heart failure. This is not correct (should be ischemic heart disease). As part of heart valve disease a stent is mentioned, this should preferable be more specific (most stents used are placed in the coronary artery, which is not what the authors mean). The section on used questionnaires (pag 7-9) is brief, but could be more condensed, using an identical structure to provide information on the questionnaires. Importantly, the number of items should be mentioned for all (not clearly presented for EQ5D and HeartQol), the domains/dimensions, validated in which population (not mentioned for HADS). In addition, SF-12 (12 questions) + HADS (14 q) +EQ5D (6 q) + B-IPQ (8 q) + HeartQol (? q) + ESAS (10 q) + additional questions (13 q) = 63 + ?. On pg 9 it is indicated that the total amount of items is 62 (is this correct)?. Regarding Ethical issues, it is stated that according to Danish legislation no formal approval is required from an IRB (only data protection). Does this also imply that patients do not need to consent that their data will be used for scientific purposes and that they consent to fill out a number of questionnaires? Patient reported outcomes at hospital discharge from Heart Centres, a national cross-sectional survey with register based follow-up: The DenHeart study protocol A well written manuscript on the rationale and design of an interesting and relevant topic: patient reported outcomes at hospital discharge. Some comments. The manuscript presents the study design and rationale of the DenHeart study, should this not be stated more clearly in the title of the manuscript (instead of “The …. Study protocol”)? Regarding the diagnostics groups, one wonders which diagnosis is leading as it is to be expected that a significant number of patients have more than one cardiovascular diagnosis (e.g. heart failure due to an ischemic heart disease, etc.). Importantly, a patient can be included in only one diagnostic group. Is there some hierarchy in defining in which diagnostic group a patient will be include, this is not discussed. It is stated (pag 6) that the questionnaires should be filled out at discharge or within 3 days of discharge and returned by mail. What does this mean? That questionnaires that are not returned within a few days will not be used? In addition (pag 16), some centres mail the questionnaires to the patients after discharge, these patient will hardly be able to fulfil this criterion. It is indicated (pag 6) that coronary artery bypass graft is an example of heart failure. This is not correct (should be ischemic heart disease). As part of heart valve disease a stent is mentioned, this should preferable be more specific (most stents used are placed in the coronary artery, which is not what the authors mean). The section on used questionnaires (pag 7-9) is brief, but could be more condensed, using an identical structure to provide information on the questionnaires. Importantly, the number of items should be mentioned for all (not clearly presented for EQ5D and HeartQol), the domains/dimensions, validated in which population (not mentioned

	for HADS). In addition, SF-12 (12 questions) + HADS (14 q) +EQ5D (6 q) + B-IPQ (8 q) + HeartQol (? q) + ESAS (10 q) + additional questions (13 q) = 63 + ?. On pg 9 it is indicated that the total amount of items is 62 (is this correct)?. Regarding Ethical issues, it is stated that according to Danish legislation no formal approval is required from an IRB (only data protection). Does this also imply that patients do not need to consent that their data will be used for scientific purposes and that they consent to fill out a number of questionnaires?

REVIEWER	Kari Hanne Gjeilo St. Olavs Hospital, Trondheim University Hospital, Trondheim, Norway
REVIEW RETURNED	07-Apr-2014

GENERAL COMMENTS	Thank you for the opportunity to review this interesting protocol. It is an important study, which will give clinical important information on different groups of cardiac patients. It is a strength that the study is national. As stated above I have some concerns and suggestions for improvement. The main concern is that the protocol should be published before the study is completed. According to the study protocol the recruitment of patients are completed by April 15th 2014, except for one of the centres. Hence the recruitment will be finished before publishing. Specific comments - elaboration of the "no"-answers above: 4. The methods are not sufficiently described. No formal sample size calculation is undertaken, as the study aims to include all patients during one year. However concerning recruitment you write that no reminders are sent to the patients. Distribution and return rates are monitored to allow for interventions if the rates drop during data collection. A definition of "low recruitment rates" should be included to clarify when interventions are needed. Further, these possible interventions should be described and if these interventions may cause a bias or threat against the reliability of the study discussed. The rationale for choosing the measures (questionnaires) are not fully described. Especially concerning the ESAS, which is not validated for use in cardiac patients. Further, it is a measure used in palliative care for cancer patient and one may question if it is suitable for the different groups of cardiac patients included in the study (except cardiac patients needing palliative care). If validatation of ESAS is part of the project, it should be stated. Another issue is why both EQ5D and SF-12 are included as both questionnaires are generic? 5. Concerning researc ethics - information on how patient consent is collected (if needed) and how the patients are informed should be added.

	12. Are the study limitations discussed adequately? (se number 5. concerning recruitment and measures above) The spin-off projects are described very vaguely and may better be left out of the protocol. Otherwise they must be decribed in more detail.

VERSION 1 – AUTHOR RESPONSE

Reviewers comments	**Authors reply**
Reviewer Name M.J. Lenzen Institution and Country Erasmus Medical Center, Rotterdam, the Netherlands Please state any competing interests or state 'None declared': None declared Patient reported outcomes at hospital discharge from Heart Centres, a national cross-sectional survey with register based follow-up: The DenHeart study protocol A well written manuscript on the rationale and design of an interesting and relevant topic: patient reported outcomes at hospital discharge. Some comments.	Thank you very much for this review.
The manuscript presents the study design and rationale of the DenHeart study, should this not be stated more clearly in the title of the manuscript (instead of "The …. Study protocol")?	BMJ Open invites study protocols to be published and ask that the specific study type is included in the title. We looked at previous study protocols published in BMJ Open and see that they write titles the same way as we did. We would like to keep the title.
Regarding the diagnostics groups, one wonders which diagnosis is leading as it is to be expected that a significant number of patients have more than one cardiovascular diagnosis (e.g. heart failure due to an ischemic heart disease, etc.). Importantly, a patient can be included in only one diagnostic group. Is there some hierarchy in defining in which diagnostic group a patient will be include, this is not discussed.	Patients are grouped by the primary action diagnose and will only be included in one group. pp 6.
It is stated (pag 6) that the questionnaires should be filled out at discharge or within 3 days of discharge and returned by mail. What does this mean? That questionnaires that are not returned within a few days will not be used? In addition (pag 16), some centres mail the questionnaires to the patients after discharge, these patient will hardly be able to fulfil this criterion.	Even though we encourage patients to fill out the questionnaire within 3 days all questionnaires completed within 4 weeks of discharge are included in the analyses. pp.12 Mailed questionnaires are sent with overnight post service so that they can be filled out within the 3 days.pp 17.
It is indicated (pag 6) that coronary artery bypass graft is an example of heart failure. This is not correct (should be ischemic heart disease). As part of heart valve disease a stent is mentioned, this should preferable be more specific (most stents used are placed in the coronary artery, which is not what the authors mean).	Corrected pp 6.
The section on used questionnaires (pag 7-9) is	This section has been improved as suggested.

brief, but could be more condensed, using an identical structure to provide information on the questionnaires. Importantly, the number of items should be mentioned for all (not clearly presented for EQ5D and HeartQol), the domains/dimensions, validated in which population (not mentioned for HADS). In addition, SF-12 (12 questions) + HADS (14 q) +EQ5D (6 q) + B-IPQ (8 q) + HeartQol (? q) + ESAS (10 q) + additional questions (13 q) = 63 + ?. On pg 9 it is indicated that the total amount of items is 62 (is this correct)?.	pp 7. (note: the number items is corrected from 62 to 80. The 62 reflected the practical questionnaire set-up and not the actual number of questions)
Regarding Ethical issues, it is stated that according to Danish legislation no formal approval is required from an IRB (only data protection). Does this also imply that patients do not need to consent that their data will be used for scientific purposes and that they consent to fill out a number of questionnaires?	Elaborated on pp. 15: Patients sign informed consent stating that participation is voluntary and that further information from patient records may be obtained.
Reviewer Name Kari Hanne Gjeilo Institution and Country St. Olavs Hospital, Trondheim University Hospital, Trondheim, Norway Please state any competing interests or state 'None declared': None declared Thank you for the opportunity to review this interesting protocol. It is an important study, which will give clinical important information on different groups of cardiac patients. It is a strength that the study is national.	Thank you very much for this review.
As stated above I have some concerns and suggestions for improvement. The main concern is that the protocol should be published before the study is completed. According to the study protocol the recruitment of patients are completed by April 15th 2014, except for one of the centres. Hence the recruitment will be finished before publishing.	Yes. We submitted in Dec 2013. We hope fast publication is possible.
4. The methods are not sufficiently described. No formal sample size calculation is undertaken, as the study aims to include all patients during one year. However concerning recruitment you write that no reminders are sent to the patients. Distribution and return rates are monitored to allow for interventions if the rates drop during data collection. A definition of "low recruitment rates" should be included to clarify when interventions are needed. Further, these possible interventions should be described and if these interventions may cause a bias or threat against the reliability of the study discussed.	No specific cut off is set for low rates calling for interventions. Instead monthly discussions on each site and in the national research group is undertaken allowing for discussions and ideas for reminding the staff to hand out the questioners. pp 7.
The rationale for choosing the measures (questionnaires) are not fully described. Especially concerning the ESAS, which is not	We know that ESAS not being fully validated in cardiac patients is a limitation, which is why we make it clear. We will not validate the scale.

validated for use in cardiac patients. Further, it is a measure used in palliative care for cancer patient and one may question if it is suitable for the different groups of cardiac patients included in the study (except cardiac patients needing palliative care). If validatation of ESAS is part of the project, it should be stated. Another issue is why both EQ5D and SF-12 are included as both questionnaires are generic?	ESAS was used in cardiac populations before and there was found modest correlation to NYHA class and heart failure questionnaires. pp 9. Both EQ5D and SF-12 are generic instruments. SF-12 is included to be able to compare to a national general population pp 7 and EQ5D is included due to a different scale composition. pp7
5. Concerning researc ethics - information on how patient consent is collected (if needed) and how the patients are informed should be added.	Patient's signs informed consent that participation is voluntary and that further information from patient records may be obtained. pp. 15 Recruitment is described at pp 6.
12. Are the study limitations discussed adequately? (se number 5. concerning recruitment and measures above)	Se above.
The spin-off projects are described very vaguely and may better be left out of the protocol. Otherwise they must be decribed in more detail.	Section further reduced. However we would like to mention that spin off projects will be prepared. pp 15.