Author’s response to reviews

Title: Quality of health care with regard to detection and treatment of mental disorders in patients with coronary heart disease (MenDis-CHD): study protocol

Authors:

Samia Peltzer (samia.peltzer@uk-koeln.de)
Hendrik Müller (hendrik.mueller@uk-koeln.de)
Ursula Koestler (Ursula.koestler@uni-koeln.de)
Katja Blaschke (Katja.blaschke@uk-koeln.de)
Frank Schulz-Nieswandt (Schulz-nieswandt@wiso.uni-koeln.de)
Frank Jessen (Frank.jessen@uk-koeln.de)
Christian Albus (Christian.albus@uk-koeln.de)

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Author’s response to reviews:

Dear Mr. Ragen,

Please find attached the corrections for the manuscript titled:

Quality of healthcare in patients with coronary heart disease regarding the detection and treatment of mental disorders (MenDis-CHD): study protocol for publication in “BMC Psychology”.

Technical/Editor comments with detailed point-by-point response to the comments:

1. Please remove word count and ethics section of the manuscript abstract.

→---> We removed word count and ethics section of the manuscript abstract (see page 2).

2. Please detail the Clinical Trial registry name and date of registration in the appropriate section of the Abstract (both on the online submission form and in the manuscript).
We extended the Clinical Trial Registry by the full name and date of registration in the appropriate section of the abstract (see page 2).

3. Please reposition and integrate all abbreviations (including those of Figures) in an Abbreviations section at the end of the manuscript, and so as to precede the Declarations.

We repositioned and integrated all abbreviations in an abbreviations section preceding the declarations. We have also added a few abbreviations (see marked text in the abbreviations section), that we missed (see page 15 and 16).

4. Please detail the procedure for obtaining informed consent from all participants (e.g. patients, relatives and physicians) and append this information to the Ethics approval and consent to participate section of the Declarations.

We described the whole procedure for obtaining informed consent for patients, relatives and physicians in detail and append it in the section ‘declarations’ under the heading ‘ethics approval and consent to participate’ (please see page 17).

5. Please place figure titles and legends in a separate section following the references.

Thanks to your suggestion, we created a separate section after the references section on page 25. Here, we added the heading ‘figure titles and legends’ and listed the title and the legend (with abbreviations) for the figure 1 and 2, respectively.

6. Please expand and provide further details in the Methods to justify the intended sample size.

We would like to thank you for this comment and have reformulated the corresponding paragraph as follows:

“We intend to enroll adult patients (n = 400; 50% women) with angiographically documented CHD treated for stable angina pectoris, acute coronary syndromes, percutaneous coronary intervention, or bypass surgery. Participants must be able to give informed consent and have sufficient German language skills. Exclusion criteria are severe or instable physical or mental conditions (e.g., severe illnesses such as cancer, acute suicidal ideation, delirium and moderate to severe dementia). Since we are conducting a descriptive and exploratory study, but not a confirmatory one, we did not perform a sample size calculation based on a power calculation. Rather the focus of MenDis-CHD is on vulnerable subgroups. These vulnerable subgroups comprise (1) older female CHD-patients which were underrepresented in past studies, (2) CHD-patients with comorbid mental disorders and/or mild cognitive impairment (expected prevalence of MD and MCI is 30–50%), and (3) CHD-patients with congestive heart failure (expected prevalence of 30 % with a left ventricular ejection fraction of < 40% (24)). To obtain a realistic estimate of the health care situation, patients will be recruited in cardiology departments of hospitals, cardiology practices, and rehabilitation clinics.
Thus, the rational for the intended sample size are this estimated frequency of the gender distribution, mental and cognitive comorbidity and patients with congestive heart failure as well as the goal of recruiting in different sectoral areas (hospitals, rehabilitation clinics, and cardiology practices). By this rationale, we aim at a sufficiently large sample sizes to perform the statistical comparison in these vulnerable subgroups. In sum, the recruitment of a total N of 400 patients is planned. Thus, we aim to recruit n=200 women, n=130-200 patients with MD or MCI and n=120 with congestive heart failure.

All 400 patients (with and without MD) will take part in the quantitative study. N = 20 participants of the patient sample will be invited to join qualitative interviews.”

7. Please check for minor language error within the manuscript (with particular attention to the Declarations).

→---> Following this good advice, we have corrected the whole manuscript.

8. Thank you for submitting the requested documentation. We note that the ethical proof you have provided is dated 2017. Please provide up-to-date documentation that details ongoing (and expiration of) ethical approval for your study.

→--> In our last mail, we send the original documents and the translation of the final ethical approval from November 20th, 2017. Since this date, the ethical approval is valid and remains valid. Moreover, we made no changes or amendments on the study, which would have needed confirmation from the Ethics Committee. Thus, we have sent you all our up-to-date documentation. Furthermore, there is no expiration of the ethical approval.

9. BMC Psychology requires ethics approval to have been obtained from all sites where the research is to take place before submission of a study protocol. Please provide a list in the Methods detailing all sites where the study will be performed.

→--> Thank you for the remark to remove these ambiguities. We like to clarify this issue by providing additional information under the heading “Procedures”:

“The university hospital of Cologne (Department of psychosomatics and psychotherapy and department of psychiatry and psychotherapy) is the only recruiting site. However, participants will be recruited in cardiology departments (University hospital Cologne, department of internal medicine, cardiology, pneumology and internal intensive care medicine; Cologne-Merheim, clinics of the city of Cologne, department of Cardiology, rhythmology and internal intensive care medicine), patients from two cardiology rehabilitation clinics (Clinic Roderbirken - rehabilitation centre for heart and circulatory diseases; AmKaRe Cologne: out-patient cardiological rehabilitation centre) and from three cardiology practices (Practice for internal medicine, cardiology, pneumology, Cologne, Wiener Platz 1; Practice for cardiology Cologne, Josef-Haubrich-Hof 5; Practice for Cardiology cologne, Wehrmannstr. 1b).”
If further information on the recruitment facilities are needed please refer to the following detailed list:

1. University Hospital Cologne, Cologne, Germany

Department of Internal Medicine (Cardiology, Pneumology and Internal Intensive Care Medicine)
Head of department: Prof. Dr. S. Baldus
Kerpener Str. 62
50937 Cologne, Germany
Phone: +49 221 – 47832511
E-Mail: sekretariat-prof-baldus@uk-koeln.de

2. Hospital Cologne-Merheim

Department of Rhythmology and Internal Intensive Care Medicine
Contact: PD Dr. H-J. Berger
Ostmerheimer Str. 200
51109 Cologne, Germany
Phone: +49 221 8907 - 13246
E-Mail: BergerHJ@kliniken-koeln.de

3. Clinic Roderbirken - Rehabilitation Centre for Heart and Circulatory Diseases

Head of department: Dr. W. Mayer-Berger
Roderbirken 1
42799 Leichlingen, Germany
Phone: +49 2175 – 824010
E-Mail: wolfgang.mayer-berger@klinik-roderbirken.de

4. AmKaRe: Ambulant cardiological rehabilitation centre

Head of department: Dr. D. Gysan
Rolshover Str. 526
51105 Cologne, Germany
Phone: +49 221 - 99879922
E-Mail: millentrup@gesundesherz.de

5. Practice for Internal Medicine, Cardiology, Pneumology

Head of department: Dr. Anselm Bäumer
Wiener Platz 5
The raised questions concerning the ethics approval will be addressed in the next paragraph.

10. If the ethical approval from the Ethics Commission of Cologne University is an umbrella approval that covers all participating sites, please clarify, and provide original and translated documentation indicating this is the case. If this is deemed unnecessary please provide a justification.

→ The ethics approval for MenDis-CHD is valid for all of the seven recruitment facilities. We provide a separate letter from the German Medical Association (see mail attachment) that declares that if the researchers from MenDis-CHD-team recruit the patients in the listed facilities exclusively and patients are not recruited by the physicians of these facilities, there is no need for an additional ethics approval. The ethics approval from the ethics committee of the University Hospital of Cologne is therefore sufficient.

We have tried to give the reader of our paper clear information on this issue by adding the following sentences under ‘Ethics approval and consent to participate’:

“The ethics approval for MenDis-CHD is valid for all of the seven recruitment facilities (please refer to ‘Procedures’ for further information). The German Medical Association approved that if the researchers from MenDis-CHD-team recruit the patients in the listed facilities exclusively and the physicians of these facilities do not recruit patients, there is no need for an additional ethics approval. The decision of the ethics committee of the University Hospital of Cologne is therefore sufficient for all recruitment facilities.”
11. We also note that the funding proofs you submitted pertain to the larger umbrella (CoRe-Net) project. Please provide additional documentation detailing specific funding for the MenDis-CHD sub-project. Please also clarify the expiration date of your funding.

Please find attached a translation of the funding approval for MenDis-CHD from the Federal Ministry of Education and Research (see mail attachment). The expiration date of the funding is January, 31th, 2020 (see translation).

Thank you for your careful revision of our manuscript and considering our study protocol for publication in BMC Psychiatry.

Best regards,

Samia Peltzer & Hendrik Müller