Author's response to reviews

Title: Tailored implementation for chronic diseases (TICD): A protocol for process evaluation in five cluster randomized controlled trials in five European countries

Authors:

Cornelia Jaeger CJ (cornelia.jaeger@med.uni-heidelberg.de)
Tobias Freund TF (tobias.freund@med.uni-heidelberg.de)
Jost Steinhæuser JS (jost.steinhaeuser@med.uni-heidelberg.de)
Eivind Aakhus EA (eivind.aakhus@gmail.com)
Signe Flottorp SF (Signe.Flottorp@kunnskapssenteret.no)
Maciek Godycki-Cwirko MGC (maciekgc@uni.lodz.pl)
Jan van Lieshout JVL (j.vanLieshout@iq.umcn.nl)
Jane Krause JK (jk208@leicester.ac.uk)
Joachim Szecsenyi JS (joachim.szecsenyi@med.uni-heidelberg.de)
Michel Wensing MW (M.Wensing@iq.umcn.nl)

Version: 3
Date: 30 November 2013

Author's response to reviews: see over
Response to reviewer’s report
30.11.2013

Reviewer 1

Title: Tailored implementation for chronic diseases (TICD): A protocol for process evaluation in five cluster randomized controlled trials in five European countries

Version: 2 Date: 1 October 2013
Reviewer: Aleksandra Gilis-Januszewska
Reviewer’s report:
Overall Manuscript Rating (1-100): 75

1. Is the question posed by the authors new and well defined?
A manuscript “Tailored implementation for chronic diseases (TICD): A protocol for process evaluation in five cluster randomized controlled trials in five European countries”, is an article following the structure of a methodology paper. This manuscript is proposed as a part of the series of manuscripts from the European project “Tailored implementation in chronic illness care”. It describes in clear manner the protocol for the process evaluation in five cluster randomized controlled trials to improve healthcare delivery in five different chronic diseases. It is explained well how the process of evaluation across the trials will identify determinants of change in chronic conditions care, validate the method that were applied and how to study association between the implementation activities and effectiveness of the TICD. The question posed by the authors are new, very important and well defined. The manuscript adhere to the relevant standards for reporting and data deposition.

1. Is the question posed by the authors new and well defined?
The title and abstract accurately convey what the article is about. In the Abstract there is clear explanation of the background, methodology used, expected results and discussion. In the “Background” the Authors give a brief summary of what “tailored intervention” are and the history of the barriers of previous evaluations of the complex interventions.

2. Are the methods appropriate and well described, and are sufficient details provided to replicate the work?
In the “Method” the overall five phases approach in the TICD was described. The methods are detailed, well described and appropriate.

3. Are the data sound and well controlled?

4. Does the manuscript adhere to the relevant standards for reporting and data deposition?
In the Results the Authors described logic models, data collection and analysis, a survey to document implementation activities. The manuscript adhere to the relevant standards for reporting and data deposition Figures and tables are clear except for the table 3. This is unclear to whom the key questions in this table are addressed.

5. Are the discussion and conclusions well balanced and adequately supported by the data?
In the discussion it is cleared that the planned study will help to understand the determinants of change in chronic diseases and improve the tailoring of implementation programs.

7. Is the writing acceptable?
The writing is good.

Minor essential: In the title of the table 3., it is unclear to whom the key questions in this table are addressed. I would suggest to add to the title of this table this explanation.
Dear Ms. Gilis-Januszewska, thank you very much for the overall positive evaluation of our manuscript and for your useful hint concerning table 3. We have changed the title of the table to make the target group of the interview questions clear.

**Level of interest:** An article of importance in its field  
**Quality of written English:** Acceptable  
**Declaration of competing interests:** I declare that I have no competing interests' below
Reviewer 2

Title: Tailored implementation for chronic diseases (TICD): A protocol for process evaluation in five cluster randomized controlled trials in five European countries

Version: 2
Date: 25 October 2013
Reviewer: Ulrike Rothe

Reviewer’s report: Major Compulsory Revisions

1) First, please, change your structure of a methodology paper once more into: Background (with the research questions) – Methods/Designs – Discussion (remove the chapter results). Please, write the pages 4-6 under the heading “Methods/Designs”.

And, please, restructure your paper better. Thus, add the research questions 1-4 on pages 5 and 6 to the questions 1-4 at the end of the chapter “Background” and harmonize these research questions and avoid redundancy, respectively. Renumber the research questions biunique and then use the same numbers under the heading “Data analysis” (p. 5) and describe your methods to answer these questions, e.g. “In order to answer the research questions 1 and 2 we used a descriptive analysis......” and so on.

Thank you for these useful suggestions on the structure of our manuscript. We have adapted the structure of a methodology paper and numbered the research questions as proposed. The wording of the research question in the background section and in the data analysis section is now identical.

2) Furthermore, under the heading “data collection”, please, number consecutively the three main items for process evaluation with I, II and III (or A, B, C, respectively) and use these numbers also for the following headings like “Ia) A survey on perceived change of......” and Ib) A survey......and so on.

We have numbered the items as suggested and we have added the numbers to the titles of the tables referring to the respective item.

3) One question: Do you really want to prepare a quantitative meta-analysis because of the obvious differences between the outcome of the different trials? How do you justify your assumption that a pooling of data/outcome will be possible? Do you want to standardize the outcome data, won’t you?

As described on p.6 / research question 3 we will use an aggregated outcome in each trial reflection the degree of implementation of recommendations into practice. We have specified in the manuscript that the outcome will be standardized across the trials.

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests: I declare that I have no competing interests