Author's response to reviews

Title: Ethical challenges in connection with the use of coercion. A focus group study of health care personnel in mental health care

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Author's response to reviews: see over
Dear Editor;

We hereby resubmit the manuscript, “Ethical challenges in connection with the use of coercion. A focus group study of health care personnel in mental health care” (MS: 1251746508133918). We appreciate the thorough review process, and realise our paper improves. In this letter, we will address the two concerns from the editor:

1. “Please also ensure that your revised manuscript conforms to the journal style (http://www.biomedcentral.com/info/ifora/medicine_journals). It is important that your files are correctly formatted”. Since we were insecure what was meant, we addressed the editor with the following email text on Nov 12: “Dear Danica Jose; Thank you for your Email, which I will address. However, I do not know what you refer to when you want me to make sure the manuscript conforms to the journal style. I went over it again and again before resubmitting it, and thought I did what was necessary. Obviously, I missed something. Could you, please, let me know what I specifically have to address? Thank you so much. Best regards, Marit Helene Hem”. On Nov 13 we received this email: “Dear Dr. Hem, Thank you for your e-mail. Please be informed that we have escalated your query to our Senior Editor. We will get back on you once response is received. Should you have any concerns, please do let me know. Warm regards, Danica». Since we did not hear from you, we believe that everything is ok the way we formatted our paper. May be the formulation was a standard one which is used in all email exchanges with all authors.

2. The last issue left to address is concerning the specific regulations which indicate that our study is exempt from ethics approval. We guess that the formulation in the text on page 8, line 7-8: “oral communication with REC South East May 2012” was causing insecurity. Hence, we have deleted it from the last version of the paper we attach here. In the paper, we have still referred to the webpages of the “Regional Committee for Medical and Health Research Ethics” (ref. no 25) and the Norwegian “Act on medical and health research (the Health Research Act)” (ref. no 24). The act is to be found here: http://www.ub.ui.no/ujur/ulovdata/lov-20080620-044-eng.pdf We would especially like to point at § 1: “The purpose of the Act is to promote good and ethically sound medical and health research”; § 2: “The Act applies to all medical and health research on human beings, human biological material or personal health data”; § 4a: “For the purposes of this Act, the following definitions shall apply: a) medical and health research: activity conducted using scientific methods to generate new knowledge about health and disease”.

The Regional Committee for Medical and Health Research Ethics defined our project being outside of the scope of the Health Research Act since its’ focus is on health care professionals’ views on ethical challenges, and not "medical and health research" (cf. § 1 and § 4 a). Hence, we did not need ethical approval by the Regional Committee for Medical and Health Research Ethics. We needed only approval by the Norwegian Social Science Data Services where aspects of privacy protection were assessed.
We would also like to mention that in the other paper from the same data material, which is also resubmitted lately to BMC Medical Ethics (no 1691029874134662 “How do health care professionals in mental health care deal with ethical challenges related to the use of coercion? A focus group study” (Molewijk, Hem and Pedersen), the question about ethics approval was not raised.

We do hope we that we by this have clarified the question on ethics approval in a satisfactory way.