Author’s response to reviews

Title: Evaluation of an interaction-skills training for reducing the burden of family caregivers of patients with severe mental illness: a pre-posttest design.

Authors:
Yasmin Gharavi (Yasmingharavi@gmail.com)
Barbara Stringer (B.Stringer@ggzingeest.nl)
Adriaan Hoogendoorn (A.Hoogendoorn@ggzingeest.nl)
Jan Boogaarts (Janboogaarts@demat.nl)
Bas van Raaij (Bas@demat.nl)
Berno van Meijel (Berno.vanMeijel@inholland.nl)

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Author’s response to reviews:

January 26, 2018

Dear Matthew Hickey,

Subject: Submission of revised paper BPSY-D-17-00606R2

Thank you for your email dated December 28, 2017 enclosing valuable feedback to improve the manuscript. We have carefully addressed the comments. Our responses are given in a point-by-point manner below. Changes to the manuscript are marked in bold.

We hope the revised version is now suitable for publication in BMC Psychiatry and look forward to hearing from you in due course.
Sincerely,

Yasmin Gharavi, MSc

Response to Reviewer:

(1) comment of the reviewer: Thank you for providing an Ethics and consent for participation heading, please cite the specific “Dutch law and legislation” that informed the decision to not seek ethical approval for your research. As of now, you have only provided a link to the general CCMO home page, which remains unacceptable for publication.

If a local ethics committee ruled that no formal ethics approval was required in this particular case then please include the specific name of the ruling committee along with a detailed statement clearly outlining the decision of the aforementioned committee.

(2) response: Our research protocol was reviewed by the research department of Pro Persona ‘Pro Persona Research’. They have concluded that our research does not fall under the scope of the Medical Research Involving Human Subjects Act (WMO) and that further investigation is not required. This decision is based on the following argumentation: “No patients are involved in the training, only close relatives of patients participated in the training. The patients signed an agreement for the participation of their relatives in this training.”

The following text is now added to the paper (Declarations, Ethics approval and consent to participate on page 14) to support this point:

‘’Under Dutch law, no medical ethical approval was needed for our study, see CCMO [24]. According to the Medical Research Involving Human Subjects Act (WMO), research falls under the scope of the WMO if:
1. It concerns medical-scientific research and;

2. Participants are subject to procedures or are required to follow rules of behavior.

Our study does not concern medical-scientific research, since it is an evaluation study among family members (non-patients) following a training program that is offered as care as usual in several Dutch mental health institutions over the past years.

This was confirmed by the Pro Persona Research Department (February 2016).”

To reviewer/editor of BMC Psychiatry: The confirmation letter of the Pro Persona Research Department is available on request.

(1) comment of the reviewer: Please ensure that the trial registration number is included at the end of the Abstract section. When doing so, please also include the date of trial registration with the statement ‘retrospectively registered’.

(2) response: The following text has been added to the manuscript (the Abstract section on page 2): “This study was retrospectively registered in the ISRCTN registry with study ID ISRCTN44495131.”