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.

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Author’s response to reviews:

December 27, 2017

Dear Matthew Hickey,

Subject: Submission of revised paper BPSY-D-17-00606R1

Thank you for your email dated November 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: In line with ICMJE guidelines, BioMed Central requires registration of all clinical trials that are reported in manuscripts submitted to its journals. The ICMJE uses the World Health Organization (WHO) definition of a clinical trial, which is "any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes". In this instance, we refer to an intervention designed to aid in the mental health of participants.

Suitable publicly available registries are those listed on the ICMJE website as well as any of the primary registries that participate in the WHO International Clinical Trials Registry Platform, including the ISRCTN registry, which is administered and published by BioMed Central.

If your trial is not already registered, please register it retrospectively. Please include the trial registration number (TRN) and date of registration as the last line of the manuscript abstract.

(2) response: Thank you for noticing. We registered our trial retrospectively. However, the editorial curation process for registration is not completed yet. We will send you our ISRCTN as soon as we receive the number.

(1) comment of the reviewer: Thank you for providing an Ethics and consent for participation heading, please cite the specific “Dutch law and legislations” that informed the decision to not seek ethical approval for your research. Alternatively, you may supply a statement that says that a local ethics committee ruled that no formal ethics approval was required in this particular case. When doing so, please include the specific name of the ruling committee.
(2) response: Thank you for this observation. According to Dutch legislation, only medical studies need to receive the approval of the Central Committee on Research Investigating Human Subjects (CCMO). Our research does not fall under the scope of the Medical Research Involving Human Subjects Act (WMO), which includes the following criteria: 1. the research concerns medical/scientific research and 2. participants are subject to procedures or are required to follow rules of behaviour. The study was reviewed by the Scientific Committee of one of the participating mental health institution (Pro Persona Mental Health Institution) and they confirmed our decision. The following reference is now added to the paper (Declarations section) on page 14 and (References section) on page 18 to support this point: ‘Centrale Commissie Mensgebonden Onderzoek (CCMO), http://www.ccmo.nl/en/ (2015)’.

(1) comment of the reviewer: Thank you for providing an Authors’ contributions statement for the Declarations section. However, please provide more justification for the contributions of authors. Currently, the contributions of Adriaan Hoogendoorn do not automatically qualify for authorship. Please amend your manuscript accordingly.

An 'author' is generally considered to be someone who has made substantive intellectual contributions to a published study. We recommend that that you adhere to the guidelines for authorship that are applicable in your research field or, in the absence of any guidelines, to the International Committee of Medical Journal Editors (ICMJE) guidelines. According to the ICMJE guidelines, to qualify as an author one should have:

- made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data;

- been involved in drafting the manuscript or revising it critically for important intellectual content;
- given final approval of the version to be published. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content; and

- agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Acquisition of funding, collection of data, or general supervision of the research group, alone, does not usually justify authorship.

(2) response: Thank you for pointing this out. We think all authors fulfill the criteria of authorship and are responsible and accountable for the specific parts of the work that he or she has done. We would like to identify the role of the authors more clearly. The changes are described as follows and shown in bold, on page 14:

‘’YG was the project leader and principal investigator. YG, BS and BvM designed the study and chose together with AH the appropriate statistical methodology to analyze the data. YG conducted the study, performed the literature search, performed the statistical analyses and wrote the manuscript. BS and BvM supervised the study and commented on the draft versions of the manuscript. AH supervised the statistical analyses. JB and BvR were the trainers in this project and performed data collection, together with YG. JB and BvR also provided the information needed to describe the training sessions precisely. YG, BS, BvM, JB and BvR developed the SEQ (Self-Efficacy Questionnaire). All authors had access to any data and read and approved the final manuscript. Also, all authors agreed to be accountable for the aspect of the work they were responsible for.’’

(1) comment of the reviewer: Please remove any figure titles and captions from the figure files as these files should contain the image graphics only. Upon doing this, please place the
titles/captions at the end of the main manuscript after the References section under a newly created “Figure legend” heading.

(2) response: Thank you for noticing. The newly created heading “Figure legend” is now added on page 19, and the figure files are adjusted as well.