Author’s response to reviews

Title: A randomized controlled trial of cognitive remediation for a national cohort of forensic patients with schizophrenia or schizoaffective disorder.

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Regarding: BPSY-D-18-00599R1

submission to BMC Psychiatry - BPSY-D-18-00599R1

A randomized controlled trial of cognitive remediation for a national cohort of forensic patients with schizophrenia or schizoaffective disorder.

Ken O'Reilly, DPPsychSc; Gary Donohoe, PhD; Danny O'Sullivan, DPPsychSc; Ciaran Coyle, DPPsychSc; Aiden Corvin, PhD; Padraic O'Flynn, MSc; Muireann O'Donnell, DPPsychSc; Toni Galligan, MSc; Paul O'Connell, FRCPsych; Harry G Kennedy, MD BMC Psychiatry
Dear Editor,

Thank you for your very welcome e-mail. My colleagues and I will respond to the remaining points raised as numbered by you.

1. Please state the criteria that determined whether consent could be obtained directly from the patient or from a family member or other legal guardian, and confirm that these criteria were approved by the ethics committee. Please add this information to the Ethics and consent to participate section.

   In Ireland, for adults, only the functional mental capacity to give or withhold consent is relevant. Consent cannot be given by family members and the role of legal guardians only arises in respect of wards of court and this did not arise in this study. We have now added the following explanatory sentence in the paragraph headed ‘Participants’

   “Capacity to consent to participation was assessed by the treating consultant psychiatrist. “

We have also added to the section on Ethics and Consent as follows

Ethics approval and consent to participate

This study was approved by the research ethics and effectiveness committee of the NFMHS (AREE/290814, 29th August 2014) and Faculty of Health Sciences Research Ethics committee Trinity College Dublin (8th September 2014). The study complied with the Helsinki Declaration of 1975, revised in 2008. All participants were assessed by their treating consultant psychiatrists as having the capacity to consent to the research study. All participants were supplied with a written letter of information concerning the study. After a period of seven days, all gave written, informed, and competent consent in keeping with the approval of the research ethics committees.
2. As a member of the editorial board (Harry G Kennedy) of this journal, in order to ensure transparency, please declare this in the Competing Interests section of the Declarations.

We have now amended the relevant section as follows:

Competing interests: All authors declare that they have no financial involvement (including employment, fees, share ownership) or affiliation with any organization whose financial interests may be affected by material in the manuscript, or which might potentially bias it. HGK is a member of the editorial board of BMC Psychiatry but has had no editorial involvement with the publication of this article.

3. We would also like to ask for you to provide more justification for the contributions of Paul O’Connell, Aiden Corvin, Ciaran Coyle, Toni Galligan and Muireann O’Donnell as currently they do not automatically qualify for authorship. Contribution to providing input to study design, coordinating patient recruitment or collating all data concerning patients experience of the intervention, alone, does not usually justify authorship.

We had dealt with this as follows:

“Author Contributions: Ken O’Reilly, Gary Donohoe and Harry Kennedy designed the study with input from Paul O’Connell and Aiden Corvin. Danny O’Sullivan, Ciaran Coyle, Toni Galligan, and Ken O’Reilly coordinated patient recruitment to the study. Ken O’Reilly and Danny O’Sullivan supervised and coordinated the collection of data. Ken O’Reilly, Gary Donohoe, Harry Kennedy undertook the statistical analysis. Muireann O’Donnell collated all data concerning patients experience of the intervention. Ken O’Reilly, Gary Donohoe and Harry Kennedy wrote the manuscript. All authors contributed to and have approved the final manuscript.”

We have now made a declaration in keeping with the ICMJE guidelines as follows:

Author Contributions: Ken O’Reilly is the lead author and this work forms a substantive part of his PhD thesis. All authors (KO’R, GD, DO’S, CC, AC, PO’F, MO’D, TG, PO’C, HGK) contributed to and have approved the final manuscript. All authors made
substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; all authors have been involved in drafting the manuscript or revising it critically for important intellectual content; and all authors have given their final approval of the version to be published. Each author has participated sufficiently in the work to take public responsibility for appropriate portions of the content; and each author has 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.

We hope this satisfies the requirements of ICMJE and the Journal. In the alternative we could supply a table, documenting which parts of each criterion (a) to (d) were relevant to each author, bearing in mind that some of the criteria (a) to (d) are also subdivided. Once again, each author listed fulfilled the ICJME criteria.

We hope these final revisions meet all requirements As ever, we are happy to respond to any further points arising.

Yours sincerely

Harry Kennedy

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