

RE: Concerns raised to COPE regarding journal's decision to retract article in Neurotherapeutics

Gregory Baer <gregory.baer@springer.com>

Wed 7/20/2022 9:23 PM

To: Iratxe Puebla <cope_assistant@publicationethics.org>; m.mouradian@rutgers.edu <m.mouradian@rutgers.edu>

Cc: mahmoud samy <Mahmoud.samy@fop.usc.edu.eg>

Dear Iratxe Puebla,

Thank you for your query and for your patience as we prepared our response. Please see our comments below:

A summary of the process that the journal followed to look into the concerns identified about the article.

Detailed concerns were raised about the reporting of the data for this clinical trial in this article (including overlap with another article by the same authors reporting a clinical trial with a different drug). These concerns were put to the authors. The response from the authors was assessed by the Editor-in-Chief with input from an Associate Editor. The Editor-in-Chief and the Associate Editor had further questions about the authors' response and requested raw data and evidence of IRB approval from the authors; they also found anomalies in the clinicaltrials.gov record.

Whether the journal considered other options to address the concerns about the article (e.g. a Correction or an Expression of Concern) and if that was the case, the circumstances that informed the decision to retract.

Other options were not considered. The Editor-in-Chief found the authors' final response to be unsatisfactory and no longer has confidence in the results and conclusions presented so decided to retract the article. The retraction notice reads as follows "The Editor-in-Chief has retracted this article. Concerns have been raised about the data presented. The response from the authors to these concerns has shown that there are serious issues with the ethical oversight, the reporting and the availability of audited data for this clinical trial. The Editor-in-Chief therefore no longer has confidence in the results and conclusions presented."

Information on the policies and processes in place at Neurotherapeutics to handle concerns raised about published articles.

Concerns raised about published articles are investigated following the guidelines of COPE. The Editor-in-Chief and the editorial staff are supported by the Springer Nature Research Integrity Group.

Please let us know if you have further questions or concerns.

Thank you,
Greg

Gregory Baer

(he/they)

Editor

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From: Iratxe Puebla <cope_assistant@publicationethics.org>

Sent: Tuesday, July 12, 2022 2:32 AM

To: Gregory Baer <gregory.baer@springernature.com>; m.mouradian@rutgers.edu

Cc: Mahmoud.samy@fop.usc.edu

Subject: Re: Concerns raised to COPE regarding journal's decision to retract article in Neurotherapeutics

[External - Use Caution]

Dear Dr Baer and Dr Mouradian,

I am writing to follow up on my correspondence regarding Mahmoud Abdallah's concerns about the decision by the journal *Neurotherapeutics* to retract his publication titled 'The Antidiabetic Metformin as an Adjunct to Antidepressants in Patients with Major Depressive Disorder: A Proof-of-Concept, Randomized, Double-Blind, Placebo-Controlled Trial.'

We requested comments on the journal's follow up on the concerns about the article and on Dr Abdallah's concern that the decision for retraction does not align with COPE's retraction guidelines, but we have not heard from you. We would be grateful if you could please provide your response **by July 26**.

We include below, as reference, the items on which we requested your comments:

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- A summary of
- the process that the journal followed to look into the concerns identified about the article.
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- Whether the
- journal considered other options to address the concerns about the article (e.g. a Correction or an Expression of Concern) and if that was the case, the circumstances that informed the decision to retract.
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- Information
- on the policies and processes in place at *Neurotherapeutics*
- to handle concerns raised about published articles.
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Thank you for your attention to this matter. We look forward to hearing from you.

With best wishes,

Iratxe

Iratxe Puebla

Facilitation and Integrity Officer

Committee on Publication Ethics (COPE)

www.publicationethics.org

Registered charity No 1123023

Registered in England and Wales, Company No 6389120

Registered office: COPE, New Kings Court, Tollgate, Chandler's Ford, Eastleigh, Hampshire, SO53 3LG, UK

On Mon, Jun 20, 2022 at 9:57 AM Iratxe Puebla <cope_assistant@publicationethics.org> wrote:

Dear Dr Baer and Dr Mouradian,

We are writing to you because Mahmoud Abdallah - cc-d in this email- has contacted the Committee on Publication Ethics (COPE) to raise concerns in relation to the decision by the journal *Neurotherapeutics* to retract his publication:

Abdallah, M.S., Mosalam, E.M., Zidan, AA.A. et al. The Antidiabetic Metformin as an Adjunct to Antidepressants in Patients with Major Depressive Disorder: A Proof-of-Concept, Randomized, Double-Blind, Placebo-Controlled Trial. *Neurotherapeutics* 17, 1897-1906 (2020). <https://doi.org/10.1007/s13311-020-00878-7> ^(*)

As you may know, COPE's role is primarily to provide advice about publication ethics for member editors and journals and to promote a better understanding of publication ethics. If concerns are raised to COPE's attention, we aim to provide guidance on whether the journal has taken any actions, or followed any processes, that are not aligned with the COPE Core Practices or COPE guidelines. We do not interfere with specific editorial decisions.

With this in mind, we are writing to you in the hope that we can facilitate a dialogue in relation to the concerns raised by Dr Abdallah. In order to make the process as transparent and constructive as possible, we have copied Dr Abdallah into this email and request that you do the same in your reply.

Dr Abdallah indicates that he received a request for comments regarding the underlying data from the trial reported in his article as well as evidence of ethical oversight for the study. He provided a response to the items raised. Nonetheless, he then received a notification that the journal had decided to retract the publication. Dr Abdallah contends that the decision for retraction does not align with COPE's retraction guidelines as, in his view, there is no evidence that the findings reported in the article are unreliable. We include below a summary of Dr Abdallah's concerns.

We would be grateful if you could comment on the circumstances that led the journal to reach a decision to retract the article. Specifically, could you please provide comments on the following:

- A summary of the process that the journal followed to look into the concerns identified about the article.
- Whether the journal considered other options to address the concerns about the article (e.g. a Correction or an Expression of Concern) and if that was the case, the circumstances that informed the decision to retract.
- Information on the policies and processes in place at *Neurotherapeutics* to handle concerns raised about published articles.

Many thanks for helping us address Dr Abdallah's concerns. We look forward to hearing from you.

With best wishes,

Iratxe Puebla
Facilitation and Integrity Officer
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On behalf of

COPE Facilitation and Integrity subcommittee

Concerns raised by Mahmoud Abdallah

The Editor-in-Chief of NEUROTHERAPEUTIC journal has decided to retract our article entitled (The Antidiabetic Metformin as an Adjunct to Antidepressants in Patients with Major Depressive Disorder: A Proof-of-Concept, Randomized, Double-Blind, Placebo-Controlled Trial) due to issues with the ethical oversight, the reporting and the availability of audited data for this clinical trial. The decision is based on speculations without any evidence that we have violated ethical oversight. Concerns have been raised about the data presented. We have supplied them with all requested documents including the original data excel sheet, ELISA output, and the IRB approval timely after their request. We have replied to all concerns raised about our study. Here is our last mail to the journal that we have rejected the retraction decision.

Dear Gregory Baer,

All the authors disagree to the retraction decision. The decision is based on speculations without any evidence that we have violated the ethical oversight. The decision does not follow the Committee on Publication Ethics (COPE) Retraction Guidelines. Neurotherapeutics journal is a member of the COPE and should undergoes its principles. According to COPE's formal policy, retraction should be undertaken when there is a clear evidence that the research findings are unreliable, either as a result of major error (e.g., miscalculation or experimental error), or as a result of fabrication or falsification. The decision to retract our paper was built on an assumption of manipulation. Considering providing the full original data set timely in excel spreadsheet as a clear objective evidence of manipulation is unjustified and unacceptable, particularly when considering that our research was unfunded and was done in research settings in a low middle income country.

According to COPE formal policy, retractions are not appropriate either where the findings are inconclusive or where additional information would sufficiently address these concerns. We do respect and appreciate the editor's need to establish the integrity of findings. We are willing to submit all the documents needed to support the reported outcomes.

The authors have followed the Neurotherapeutics' journal instructions under the title "protection of human subjects research" the procedures followed were in accordance with the ethical standards of the institutional ethical committee and with the Helsinki Declaration. It is permissible for phase I/II clinical trials to rely on the monitoring and the oversight of institutional ethics committee. The authors can provide signed formal supporting documents from the head of research ethics committee about the oversight activities undertaken by the institutional IRB in our study.

Once again, our study is a proof-of-concept phase I/II trial and the FDA, and the National Institutes of Health (NIH) and National Institute on Deafness and Other Communication Disorders (NIDCD) stated that all Phase III clinical trials require monitoring by a DSMB. For earlier trials (such as Phase I and Phase II), a DSMB may be appropriate for long term studies that employ particularly high-risk interventions or involve vulnerable populations. Our trial utilized a commonly used safe drug for short term as adjuvant therapy rather than a primary therapy and did not use particularly high-risk interventions or include vulnerable populations. That's why independent DSMB was not part of the study and was not required by Research Ethical Committee. Furthermore, this role was done by the Research Ethical Committee as stated in the previously attached IRB approval

In addition, we followed the CONSORT guidelines in reporting of our trial findings. The Auditable dataset was not required to get ethical approval nor for the scientific publications. It was also not required by the Research Ethical Committee during monitoring or by the journal's author instructions during submission. Although we are recognizing its importance in evaluating the quality of RCTs, there is no method to keep auditable data set because the output is generated from ELISA software as an Excel sheet. However, we believe that dataset might be a requirement by the FDA or EMA for large clinical trials investigating new agents that were funded by institutions, organizations, or companies.

Based on the forementioned statements the authors disagree to the retraction decision and keep all their rights to take all necessary legal actions towards your decision to protect our reputation. Finally, the retraction decision is unfair to us, and we hope you will reconsider the decision. We have sent our data as requested and clarified the issues with the ethical oversight, the reporting and the availability of audited data for this trial in our previous response.

What aspects of the Core Practices do you believe that the member is contravening, and why.

According to COPE's formal policy, retraction should be undertaken when there is a clear evidence that the research findings are unreliable, either as a result of major error (e.g., miscalculation or experimental error), or as a result of fabrication or falsification. The decision to retract our paper was built on an assumption of manipulation. Retraction should be undertaken when there is a clear evidence that the authors reports unethical research.

