Author’s response to reviews

Title: Characterizing the experience of agitation in patients with bipolar disorder and schizophrenia

Authors:
Jenna Roberts (bhazellsophee@gmail.com)
Alfredo Gracia (alfredogracia@ferrer.com)
Sophee Blanthorn-Hazell (sopheehazell@yahoo.co.uk)
Anca Boldeanu (aboldeanu@ferrer.com)
Davneet Judge (davneet.judge@adelphigroup.com)

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Author’s response to reviews:

Dear editor,

We would like to thank the reviewers for their comments and for taking the time to review our manuscript. We have revised the content accordingly. Below is a description of our response to the reviewers and the changes made to our article.

Review 3

Please clearly state in your Ethics approval and consent to participate declaration that the research presented in your manuscript has been approved by the ethical review board of Freiberger Ethik Komission international.

We have confirmed that approval was granted by this board. The text on line 310 was added to reflect this.
Thank you for including a Funding heading for the Declarations section. Please also state the role of the funding body in the design of the study and collection, analysis, and interpretation of data and in writing the manuscript. Please note that the role of the funding body specifies any function beyond the direct funding of aspects of the research or presentation of the manuscript.

Further detail has been provided in lines 297-300 to reflect the role of the funding body.

Review 2

Reviewer reports:

Ole Bernt Fasmer, M.D. (Reviewer 1): The authors have responded adequately to my questions and comments.

No further actions.

Mirko Manchia, M.D.,Ph.D. (Reviewer 2): The authors have revised the manuscript according to the reviewers' suggestion. One final, mandatory modification concerns the lack of validation of this tool. This should be reported in the Limitations.

Please see line 273-275.

Initial Review
Reviewer 1

Even though the aim of the study has not been to look at agitation as a side effect of medication (akathisia) I think this should be mentioned in the background section.

Text on akathisia has been added to the introduction section. (Page 3, lines 52-54).

I also think that lack of information on medication status should be included as a limitation.

This has been added to the limitations section of the discussion. (Page 13, lines 266-269).

Are any data available on how many patients refused to participate when specifically asked?

Unfortunately not. We acknowledge that this would be extremely valuable in terms of understanding how representative the data are but it was not possible to track this accurately due to practical constraints.

In the survey there are questions on medication used to control agitation (Q11, 12 & 13)? I think these are very interesting and relevant questions. Why are the results not reported on?

Thank you for this suggestion. We have added additional detail to the methodology section, results and discussion. As such, we have expanded on a description of coping mechanisms (methodology page 8, lines 148-153; results page 10, lines 202-207; discussion section page 12, lines 243-246).

Reviewer 2

Inclusion criteria should be reported under a separate subheading. Were there any exclusion criteria?
We have added a separate subheading. There were no exclusion criteria. (Page 5, line 93).

I wonder whether this survey instrument has been previously validated? This is a crucial methodological step in this filed of research. If this has not been previously done, I think the authors should report on face validity, internal consistency and so on.

Unfortunately we could not find any validated patient-reported measures of agitation in the existing literature and therefore had to design our own instrument to cover the range of outcomes we were interested in. Admittedly this has not been fully validated, although suitability of the questionnaire for the intended purpose was reviewed by patient representatives in each country and internal experts. Translations were performed by independent native speakers and approved/certified by a second independent translation agency. Finally, the initial data (approximately 10%) was quality checked. No issues were detected so continuation of data collection activities was permitted until the final data set was achieved which was again, further quality checked (100%).

We agree that development of a validated instrument would be of significant value, starting with a conceptual model and item generation through to validation studies. Unfortunately, this is currently out of scope.

The authors state that no formal hypothesis was tested, which is correct; however, again, the reader should be aware of the sensitivity of the instrument used to detect what is investigating.

An additional point has been added to the limitation section. (Page 13, line 275).
We hope that the above comments and amendments will address any concerns.

Best wishes,

The authors.