Author's response to reviews

Title: Effectiveness of the Dader Method for Pharmaceutical Care in patients with Bipolar I Disorder. EMDADER-TAB: Randomized Controlled Trial Protocol

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Author's response to reviews: see over
Subject: Response to reviewers' comments of MS: 3967372931004697 - Effectiveness of Dader Method for Pharmaceutical Care in patients with Bipolar I Disorder. EMDADER-TAB: Randomized Controlled Trial - NCT01750255

Dear editors,

By logging on to the system, we have resubmitted the re-reviewed article “Effectiveness of Dader Method for Pharmaceutical Care in patients with Bipolar I Disorder. EMDADER-TAB: Randomized Controlled Trial - NCT01750255”. The manuscript has been edited according to comments of the Senior Editor. Thus, all changes (including deletions) to the text had been underlined or highlighted, and a addressing each numbered comment (with page numbers indicating the location of change).

COMMENT(S)

1. P(age) 5, p(aragraph) 1, l(ine) 3. Suggest replacing [contribute to reduce suicide risk] by [may reduce suicide risk].
   [contribute to reduce suicide risk] has been replacing by [may reduce suicide risk]. P(age) 5, p(aragraph) 1, l(ine) 3.

2. P 10, p 2, l 12. Suggest replacing [only a] by [one].
   [only] has been replacing by [one]. P 10, p 2, l 12.

3. P 14, p 1, l 15. Replace [this data] by [these data] since data is a plural word.
   [this data] has been replacing by [these data]. P 14, p 1, l 15.
4. P 14, p 2, l 2 and 3. Delete [The total study time is 30 months.] Has been said earlier in the p.
[The total study time is 30 months] has been deleted. P 14, p 2, l 2 and 3

5. P 14, p 2, l 5. Replace [revenues] by [reviews].
[revenues] has been replaced by [reviews]. P 14, p 2, l 5.

[tor] has been replaced by [for]. 6. P 14, p 2, l 7.

7. P 15, p 1, l 2. Include a space to read [physician. Monitoring …].
space to read [physician. Monitoring...] has been included. P 15, p 1, l 2.

[Acces] has been replaced by [Access]. P 15, p 2, l 1.

9. P 16, p 3, l 1. Rewrite as [The sample size and power were calculated ...].
The simple-size and power was calculated... was rewrite as... [The sample size and power were calculated...] P 16, p 3, l 1.

[New York] has been replaced by [NY]. P 17, p 1, l 3.

[W2] has been replaced by [Chi-square]. P 17, p 1, l 13.

12. P 17, p 1, l 22. Rewrite as [… the Student’s t test. Multivariable …].
[the Student t test. Multivariate...] was rewrite as [… the Student’s t test. Multivariable ...] P 17, p 1, l 22.

13. P 18, p 2. This gap description is not credible. You should be using some imputation analyses to draw a correct inference in the presence of missing data.
See book by Little RJA and Rubin DB.
[Gaps in follow-up will be allowed during the year study period; however, missed study visits did not count toward total person-time. Thus, if a patient missed one study visit but was otherwise continuously followed for the full 52 weeks, s/he contributed only 50 weeks (0.96 person-years) of follow-up] has been deleted and rewrite as... [According to Little and Rubin (2002) [28], the missing-data mechanism will be performed through the
multiple imputation method, to replace missing values and to calculate accurate estimates of standard errors. The procedures all rest on the assumption that data are missing at random (MAR). We will include all non-missing values or outcomes at all-time points and baseline demographics in the models that generated imputed estimates (i.e., the likelihood of missing a follow-up visit can be predicted by available baseline and/or past observed data [29]). In addition, the multiple imputation method combines the likelihood-based analysis from each completed dataset is approximately equivalent to the analysis based on the observed-data likelihood, whereas the imputation uncertainty is reflected by the variation across the multiple completed data sets [30].

Three new bibliographies have been inserted in the text and at the end of the page (references).


14. P 18, p 2, l 4 and 5. This is NOT the correct definition of ITT. It is all who are randomized; not whether they received any study medication or at least one follow-up. Please correct, or provide a justification for your choice.

[The intent-to-treat will be including all persons who were randomized, received study medication, and had at least 1 follow-up visit] has been deleted and rewrite as [According to the definition of Fisher et al. (1990) [31], the intent-to-treat analysis will be include all randomized patients in the groups to which they were randomly assigned, regardless of their adherence with the entry criteria, regardless of the treatment they actually received, and regardless of subsequent withdrawal from treatment or deviation from the protocol[32]].

Two new bibliographies have been inserted in the text and at the end of the page (references).


15. P 19, p 2, l 1. Insert [to our knowledge] between [Columbia,] and [this].
[to our knowledge] has been inserted between [Columbia,] and [this]. P 19, p 2, l 1
16. P 21, p 1, l 4. Replace [is] by [are].
   [is] has been replaced by [are]. P 21, p 2, l 4.

17. P 21, p 1, l 4, 5 and p 3, l 2. Who is [PAM]? Should these by [PA]?
   [PAM] has been replaced by [PA]. P 21, p 2, l 4, 5 and P 22, p 1, l 2.

18. P 21, p 1, l 5. Delete [down].
   [down] has been deleted. P 21, p 1, l 5.

19. P 21, p 3, l 4. Why is there a [†] between [FG] and [MD]?
   †. FG died on April 2013 (It is denoted in filiation)

20. P 23, R(ference) 8. Should it be [National Mental health Study – Columbia] since Spanish is in round brackets later? On l 2, rewrite as (Spanish). Do not use the [square brackets] as well.
   Square brackets were deleted. Colombia was replaced by Columbia. P 23, R 8.
   Similar, Square brackets were deleted from R 17. P24

21. P 24, R 17. Translate into English, enclose in [square brackets] and include (Spanish) at the end if the language is correct.
   R 17 was translate to English. P 24 R17

   [Serial on the Internet] were deleted from R 19 and R 20. P 25, R19 and R20.

   extra [,] and [.] in names were deleted. P25, R23

24. P 26, R 27, l 4. Delete one [,].
   extra [,] was deleted. P26, R27

25. P 26, R 29. Include the title in [square brackets]. Why did you include English as well as Portuguese?
   [English] and [Portuguese] were deleted, because article may be consulted in English. P 26, R 29

27. In Figure 1, 4th wide box, l 3. Rewrite as [SF-36],
Sf-36 was rewrite as SF-36

28. In F 1, box 5. This is usually written as a circle rather than a box.
Box 5 was written as circle.

29. In F 1, last l. Enclose the English translation in [square brackets].
30. English translation was enclosed in [square brackets].

Thank you for your collaboration and contribution to improve our article.

Prof. Pedro Amariles
University of Antioquia