Reviewer’s report

Title: Effectiveness of Dader Method for Pharmaceutical Care in patients with Bipolar I Disorder. EMDADER-TAB: Randomized Controlled Trial - NCT01750255

Version: 2

Date: 20 March 2014

Reviewer: Charlie Goldsmith

Reviewer’s report:

The replies from the authors are mostly sensible; however, there still remain a few ideas that could improve the manuscript. The title should include that this is a protocol for a trial, not a completed trial. The registration number should be in its own section, not part of the title. The pages were numbered from 1 to 28.

1. P(age) 5, p(aragraph) 1, l(ine) 3. Suggest replacing [contribute to reduce suicide risk] by [may reduce suicide risk].
2. P 10, p 2, l 12. Suggest replacing [only a] by [one].
3. P 14, p 1, l 15. Replace [this data] by [these data] since data is a plural word.
4. P 14, p 2, l 2 and 3. Delete [The total study time is 30 months.] Has been said earlier in the p.
5. P 14, p 2, l 5. Replace [revenues] by [reviews].
7. P 15, p 1, l 2. Include a space to read [physician. Monitoring …].
9. P 16, p 3, l 1. Rewrite as [The sample size and power were calculated …].
12. P 17, p 1, l 22. Rewrite as [… the Student’s t test. Multivariable …].
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.
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.
15. P 19, p 2, l 1. Insert [to our knowledge] between [Columbia,] and [this].
16. P 21, p 1, l 4. Replace [is] by [are].
17. P 21, p 1, l 4, 5 and p 3, l 2. Who is [PAM]? Should these by [PA]?
18. P 21, p 1, l 5. Delete [down].
19. P 21, p 3, l 4. Why is there a [†] between [FG] and [MD]?
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.
21. P 24, R 17. Translate into English, enclose in [square brackets] and include (Spanish) at the end if the language is correct.
24. P 26, R 27, l 4. Delete one [.].
25. P 26, R 29. Include the title in [square brackets]. Why did you include English as well as Portuguese?
27. In F(igure) 1, 4th wide box, l 3. Rewrite as [SF-36],
28. In F 1, box 5. This is usually written as a circle rather than a box.
29. In F 1, last l. Enclose the English translation in [square brackets].