Reviewer's report

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

Version: 1 Date: 8 October 2013

Reviewer: Charlie Goldsmith

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The following suggestions are offered to improve this manuscript. The pages were numbered from 1 to 25.

1. P(age) 2, l(ine) 8. Rewrite as [be performed], ie, insert a space.
2. P 2, l 16 to 18. There are 3 outcomes at 4 times making the primary outcome have 12 chances to be declared to be statistically significant. This is not generally considered to be proper study design. Please justify how this will be conducted and provide R(eference)s to justify.
3. P 2, l 18. How will the 4 secondary outcomes be handled as well?
4. P 2, l 20. Rewrite as [p-value # 0.05].
5. P 2, l 21. Please justify that this is first with a credible literature search or tone down the claim into something like: as far as we know, … .
6. P 3, p(aragraph) 2. Provide the date of registration as well as the date the first patient was randomized.
7. P 3, p 3, l 13 and 14. What are the denominator values for these rates?
9. P 4, p 2, l 2. Delete [means of], as the words are redundant in English. Also P 13, p 2, l 4. Also P 16, p 4, l 4.
10. P 5, p 3, l 6. Either specify more or delete [etc]. Also P 14, p 1, l 10. Also P 15, p 1, l 7.
11. P 6, past b(ullet). How does the BP get interpreted with two numbers? Do both have to be exceeded?
14. P 8, p 1, l 5. Add a [d] to read [archived].
15. P 8, p 1, l 6 to 8. This method is no longer valid. All patients randomized are used in the ITT analysis, and patients are NOT replaced. One could expand the recruiting to accommodate dropouts, but all who are randomized should be used in the analysis. See 13 above.

17. P 8, p 2, l 3. The reviews of Excel before 2010 suggested that the random number generator was flawed. However, 2010 or later are okay. You would be wise to avoid using the 2007 version. How did you ensure confidentiality of the list?

18. P 9, p 3, l 2 and 3. What happened here?

19. P 10, p 2, l 7. Rewrite as [of the].

20. P 10, p 1, l 9. Replace [is] by [are]. Also P 18, p 2, l 4.


22. P 12, p 1, l 2. Replace [his] by a gender neutral phrase.

23. P 12, p 2, l 5. Rewrite as [focussing on].

24. P 12, p 2, l 16. Add an [s] to read [patients].

25. P 14, p 2. Include the database used and version number.

26. P 15, p 1, l 9. How will the study guarantee publication? The authors might, but not the study!

27. P 15, p 2. What software was used to compute the sample size?

28. P 15, p 3. How will multiplicity and missing data be handled?

29. P 18, p 2, l 5 and 6. Since ASO is the PhD student, the paper should be written by ASO rather than a company person NG. Please reconsider. The company appears to have a vested interest in the results and so should avoid writing the paper.

30. P 18, p 2, l 7. Since [or] logically includes [and], delete [and/].

31. P 20, R 7, l 4. Add [(Spanish)].

32. P 20, R 8, l 2. Include volume and pages.

33. P 21, R 16. Include the title in [square brackets] and [(Spanish)] on l 4.

34. P 21, R 18 and 19. BMC Trials likes to publish the first 30 authors before using [et al], so add some more authors.

35. P 21, R 19. Translate the title into English and include it in [square brackets] and include [(Spanish)] on l 4. Also P 22, R 20. Also P 24, R 35.

36. P 23, R 27, l 4. Include (round brackets) for [Spanish].

37. P 25. BMC Trials does not permit footnotes, so include somewhere in the text.

38. P 25. Why is the intervention group description in bold?

39. P 25, 2 diamond and 3 box, the last line seems to be severed.