Reviewer's report

Title: Study on Psychoeducation Enhancing Results of Adherence in patients with Schizophrenia (SPERA-S): Study protocol for a randomized controlled trial

Version: 7 Date: 3 July 2013

Reviewer: Charlie Goldsmith

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The following issues are raised in this version of the manuscript.

5. (age) 1, listing of locations of authors. This is duplicated at the bottom of P 18 and the top of P 19. Once is enough!

6. P 2 and 3 contains a new list of names with no comment as to why they are there. Without a justification, they should be deleted.

7. P 4, paragraph 2, line 3. Add an [s] to [permutation] to read [permutations]. Also P 8, p 4, l 7. Also P 9, p 5, l 3.

8. P 4, p 4, l 4. A justification should be provided for measuring blinding given the Sackett (reference) in the last review. Also P 10, p 2.

9. P 5, p 3, l 2. Provide the date the first patient was randomized.

10. P 6, p 3, l 7. One would expect the relapse rate for controls to be higher than the intervention group. Is this the correct order?

11. P 7, p 2, l 8 to 10. No methods are provided to validate these instruments with the lab values. This should be part of the protocol for those self-report measures that are currently not well validated.

12. P 8, p 3, l 3. Rewrite as […, with a 1:1 allocation ratio.].

13. P 8, p 4, l 3. Rewrite as [… months; admitting ages …].

14. P 8, p 4, l 8. Rewrite as [be stratified by location, …]. Also P 9, p 5, l 4.

15. P 10, p 4, l 6. Should another word besides [warm] be used here?

16. P 11, p 2, l 6. Is there a R for the 70%?

17. P 11, p 5, l 1. Suggest rewriting as [- which could be the …].

18. P 11, p 6. Beginning here there should a citation for each measurement instrument mentioned, a R for the Italian version if there is one and how they were validated in Italian. A table might be the best way to show this. Translation alone is not considered to be adequate. Interpretations for each instrument are also needed.

19. P 12, p 2, l 2. Replace [proportion] by [percentage].

20. P 12, p 3, l 2. Is R 34 a good source for CGI or just DOTBS?


22. P 15, p 4 and 5. This is a different form for Cohen’s effect size, how is It
different from the one used on P 6?

23. P 16, p 3. Provide Rs for each test and specify the software you plan to use for each.

24. P 17, p 2. Provide Rs for these safety measures.

25. P 17, p 2, last l. [CRF] is not defined on P 18.

26. P 18, p 2, l 3. Rewrite as [20% for dropping out.].

27. P 18, p 2, l 4. Replace [multivariate] by [multivariable].

28. P 24, R 63, l 3. Rewrite as [(Italian)].