Reviewer's report

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

Version: 5 Date: 24 April 2013

Reviewer: Charlie Goldsmith

Reviewer's report:

There are a series of issues that should be considered to improve this protocol.

1. P(age) 1, l(ine) 1. Suggest inserting [Patients with] after [in].
2. P 4, p(aragraph) 2 does not mention the clustering or blocking suggested in the text.
3. P 4, p 3, l 4. It is not a good idea to measure blinding since it is usually not measuring blinding. See Sackett DL in Int J Epidemiol 2007;36(3):664-5. See also P 9, p 5.
4. P 4, last l. Include the date of registration and the date the first patient was randomized. If some recruiting has happened, state the current number recruited.
6. P 7, p 6. Did you consider stratifying by location? Clustering is not mentioned here.
7. P 8, p 1, l 3. Suggest rewriting as [Admitting ages varying from 18 to 55 years.]. Also P 26, l 3.
8. P 8, p 1. Consider adding the stratification and blocking to this p.
9. P 9, p 2, l 4. Cluster has not been defined and the randomization seems to be allocating individual patients, not clusters of patients. Provide R(eference)s to all methodology used.
10. P 10, p 3, l 11. Delete [means of] since the words are redundant in English after [by].
11. P 11 and following. Many of the outcome measures are not cited with Rs and there are few with Italian versions with validation. These should be added if known. All measures should have the scoring summarized as well their interpretation. If there is a minimum clinically important difference (MCID) for patients with schizophrenia then these also be added.
15. P 13, p 1, l 1. Replace [ranging] by [varying]. Also rewrite as [The scores in
each domain vary from 4 to 20.]
16. P 13, p 2, l 8 to 10. This does not appear to have been considered in the analysis section.
17. P 14, p 1, l 4 and 5. Insert a space on either side the inequality signs.
18. P 14, p 7. These analyses used here are not supported by Rs, and do not use cluster studies in their analysis.
19. P 16, p 1 needs Rs for the methods.
20. P 17, p 1, l 5. Replace [parameters] by [variables]. A parameter is a characteristic for a distribution of a variable in a population, not another name for a variable in a sample.
21. P 17, p 2, l 1. Since there is no literature search to support this phrase, suggest it be toned down to read as far the authors know.
24. P 17, p 4, l 6 to 8. This is premature until a proper economic analysis has been done. It may not indeed be true.
25. P 17, p 5, l 3. Where is inflation for loss to follow up considered?
26. P 17, p 5, l 5. Rewrite as [might well refuse blood sampling and not permit the main …].
27. P 18, p 2. Was this a peer review process? If so state it.

A random sample of 10 Rs was checked for citation accuracy. Two were in need of correction:
28. P 20, R 20, l 1. More to the title: [A Comprehensive Community-Based Approach.].
29. P 23, R 51, l 3. Delete [(Edgmont)].
30. Figure 1. Suggest inserting a break in the horizontal line between 12 and 24 months as the lengths are not correct.
31. P 28, Table 3. Suggest noting which have Italian validated scales such as BPRS and WHO QoL.
32. P 29, blinding. Suggest deleting this. See 3.