Reviewer's report

**Title:** The effect of family members' psycho-educational intervention on burden of caregivers and psychiatric symptoms of patients with schizophrenia in Shiraz, Southern of Iran

**Version:** 2  **Date:** 22 August 2011

**Reviewer:** Michelle P. Salyers

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This is an interesting application of testing an evidence-based practice (family psychoeducation) in a new cultural context. The strengths include clear aims, a randomized design with three assessment points, and outcome data for patients as well as their caregiver. There are several areas that could strengthen the paper.

- Major Compulsory Revisions

1. The abstract needs to have more details, including a brief description of the control condition and how long the intervention lasted. The conclusion should refer to the Iranian context as we already have several studies showing the effect of family psychoeducation in general.

2. The introduction needs to include some rationale for testing this in an Iranian population. Some of this rationale appears in the discussion, but it should be part of the introduction. For example, why might we expect findings to be different there? Also, are there any stats in Iran on how many patients live with or have regular contact with caregivers? Is mental illness viewed differently in Iran from Western countries?

3. In study design, the word “blindly” appears misused. Patients were randomly assigned to groups. But were the assessors “blind” to study condition? Clearly the patients and families would not be blind to their treatment condition, but if the assessors were, this would be a strength of the study.

4. In the design section, have a separate subsection to describe the study intervention in more detail. How was it developed? Was it based on any of the existing programs that already have evidence? The current description of the timing is confusing---one sentence says 10 sessions over 5 weeks, but the next said that families chose “4 sessions on the afternoon of their choice”. Did all families receive each of the modules or did they pick some to attend? Did consumers attend groups with families as some models of family psychoeducation do?

5. Was written consent also obtained from caregivers or just patients?

6. How were participants recruited? What was the response/participation rate?
7. The inclusion criteria for patients of no co-morbid mental illness seems very stringent, and not very feasible. How was this determined? Do the authors mean no other Axis I disorder?

8. In the description of the instruments, who completed the scales? In particular, was the assessor of patient symptoms blind to treatment condition? Has the BPRS been used in Iranian samples? What were the internal consistencies of those subscales? What is the range of scores on the family burden measure? Is there any information to describe how much burden they were experiencing (i.e., clinical significance of the changes)?

9. In the statistical analysis section, why were multiple t-tests used? Anovas could also show group, time, and groupXtime interactions. The f values for each of these should be shown in the tables. In the same paragraph, what was the rationale for examining correlations between burden and symptoms at time 2? Usually these types of analyses are done with baseline data.

10. Given the small sample and the trend level of significance for baseline differences of education and marital status, the analyses should be redone, controlling for these factors. This is particularly important as education could be a clear factor in the outcomes.

11. The figure is not very compelling as currently shown because of the different scale values for the two indices. I would recommend either deleting this, or having two figures, with the different scales on the y axis to better reflect the interaction.

12. The discussion (particularly paragraph 2) could be better organized to discuss the implications of the intervention findings separately from the correlational findings. Right now that paragraph is confusing. Similarly, the last sentence of paragraph 3 is out of place, and really belongs with the discussion of the correlational findings.

13. The discussion section suggests that the improvements in patient outcomes in the treatment group may be due to family members monitoring medication use and increasing compliance, but it is not clear that medication use and adherence was measured (and if so, should be more tentative).

14. Discussion paragraph 4 appears overstated. This is one study in Iran, with one small sample, and the findings may not generalize to all services in the Iranian mental health system.

15. The conclusions should also refer to the new cultural context that the psychoeducational findings extend to. There are many other studies of family psychoeducation, and the important contribution of this study is the applicability to the Iranian setting.

16. The limitations are underdeveloped. For example, the design is unable to determine whether effects due to social support versus active intervention.
- Minor Essential Revisions

17. In the abstract, use “experimental”, rather than case

18. In the statistical analysis section, “postulated” is misused.

19. The results 1st paragraph could refer the reader to the table for most of the demographics.

20. The second paragraph of the results section, the sentence beginning “The findings immediately…” describe several different findings together. These should be in different sentences. The correlational findings should be in their own paragraph.

21. The second paragraph of the discussion section---start the paragraph with separate sentences on the two main findings or it could be misread that the caregivers also “indicated” the improvement in BPRS scores.

22. Values for means should be one decimal. For correlations, two decimals. P values are usually shown as p < .05, .01 or .001. Or use “=” if you report exact pa values.

23. Table 1 and 2 should be reversed in the order they appear (right now table 2 is described before table 1).

24. The tables are repeated in the text. The ones that appear at the end of the manuscript are formatted well, but the ones in text are not.

25. Table 3 has a typo---the mean for depressive symptoms at time 3 cannot be below 1.0

26. The references are not formatted consistently.

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Needs some language corrections before being published

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no competing interests