Reviewer's report

Title: Study protocol: Evaluation of a parenting and stress management programme: An exploratory randomised controlled trial of Triple P Discussion Groups and Stress Control.

Version: 1 Date: 29 March 2013

Reviewer: Toshiaki Furukawa

Reviewer's report:

The authors propose an exploratory RCT to compare the low-intensity group interventions of parental training and CBT training (Triple P Discussion Groups and Stress Control) against the waiting list control among parents with children aged 3-8.

I am not a specialist in dealing with parents with children with psychosocial problems, so my following comments mainly regard the trial methodology and may not reflect the clinical realities. If the latter, please disregard my comments.

MAJOR COMPULSORY REVISIONS

1. The two primary outcome measures, PS and DASS, provide several scores each. (PS has a total score but it is hard to interpret what the total score summing up Laxness, Overreactivity and Verbosity would mean), and the whole sample size calculation is suspect because you risk serious alpha inflation then.

2. The sample size calculation is ambiguous too. By “medium effect size” I suspect that the authors are referring to ES=0.5. If so, the required sample size is 63 per arm, not 63 in total. It would be meaningful to refer to the expected SD and difference in scores between the two arms both in terms of PS and DASS, so that the authors can themselves appreciate if they can indeed expect that great a difference and/or if such differences would be clinically meaningful.

3. My greatest concern is the eligibility criteria for the participants. It seems that the participating parents may or may not score high on the primary outcomes, and given the floor effect, it will be extremely inefficient for a trial to include participants with initially low scores.

4. A corollary to this is the age range for the children. This may be specific to Scotland but to my Japanese mind, the biggest change point for children between 3 and 8, is the entrance into the elementary school at 6 (this age may be different for Scotland, I admit). The problems that children and hence their parents must face are completely different for those between 3-6 and those between 6-8 in Japan. Is this not the case in Scotland?

5. My second great concern is the quality control of the interventions provided. How much training will the group leaders have received before starting their treatment? Is there any quality assurance strategy, such as video- or audio-taping and their checks, so that the future readers of the study can rest
assured that the intended treatments (and not others) have been provided?

6. I am also not very sure what the authors mean by the term “exploratory” RCT. Please provide some explanations.

7. The authors may also wish to provide a little bit more details at least about their primary intended analyses.

DISCRETIONARY REVISIONS

8. The authors may wish to have a look at:


and


Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:

TAF has received honoraria for speaking at CME meetings sponsored by Asahi Kasei, Eli Lilly, GlaxoSmithKline, Mochida, MSD, Otsuka, Pfizer, Shionogi and Tanabe-Mitsubishi. He is diplomate of the Academy of Cognitive Therapy. He has received royalties from Igaku-Shoin, Seiwa-Shoten and Nihon Bunka Kagaku-sha. He is on advisory board for Sekisui Chemicals and Takeda Science Foundation. The Japanese Ministry of Education, Science, and Technology, the Japanese Ministry of Health, Labor and Welfare, and the Japan Foundation for Neuroscience and Mental Health have funded his research projects.