Reviewer’s report

Title: The evaluation of the Parents under Pressure Programme: an RCT of its clinical and cost-effectiveness

Version: 2 Date: 18 February 2013

Reviewer: Gayle Dakof

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This is a tremendously interesting and important study. Its significance cannot be denied and the rationale is cogently stated. The intervention being tested, Parents under Pressure, is manualized and produced promising results in a previous randomized controlled study. The present study is a randomized controlled trial with widely used, valid and reliable measures; and the planned statistical analyses are appropriate.

However, there are some concerns about overall study design and details that might limit the impact of this study. These are highlighted below.

1. It is unclear whether or not this in an intent-to-treat design. This is a standard in the field, and if this study is not intent-to-treat then this would be a major weakness.

2. Certain important relevant studies are not included in the literature review; most notably the research on the Focus on Families intervention which is similar in many ways to the Parents under Pressure Programme. See among others the following references: (a) Catalano RF, Gainey RR, Fleming CB, Haggerty KP, Johnson NO (1999). An experimental intervention with families of substance abusers: One-year follow-up of the focus on families project. Addiction, 94, 241-254. (b) Haggerty KP, Skinner M, Fleming CB, Gainey RR, Catalano RF (2008) Long-term effects of the Focus on Families project on substance use disorders among children of parents in methadone treatment. Addiction, 103, 2008-2016.

3. No specific hypotheses are stated. Under the section, “Study Objective” only the overall objective is given. Specific hypotheses are needed.

4. The PuP intervention will be compared to “standard services for substance dependent parents.” However, this report does not include a description of standard services. It is difficult to evaluate the quality of the study design without a detailed description of the comparison treatment, including whether or not it varies from site to site.

5. There is a discussion of potential contamination between the two treatment conditions at the sites, yet the discussion is very vague: “Some contamination within centres may occur, and assessment of the extent to which this has occurred will be made as part of the process of data collection (i.e., interview with control families) and controlled for at the analysis stage.” More clarity and detail
about this issue is required.

6. This study is a multisite trial with a relatively small sample size (n = 114). Nineteen families will be recruited across 6 sites (centres). There is no discussion about the potential for site effects, including how the multiple sites affects the power to detect differences if there are site effects, and how site effects will be addressed in the analysis. This is a serious potential problem, and one wonders, given the relatively small sample, why the researchers did not decide to recruit all the families from one, or at the most, two centres.

7. The measures are all widely used with the target population and have demonstrated adequate validity and reliability. However, it is not perfectly clear how each measure is linked to a study hypothesis. See number 3, above, about the lack of specific hypotheses. It is difficult to evaluate the selection of measures without clearly stated hypotheses.

8. The economic analysis is poorly designed, and the authors state that it is “essentially exploratory.” Given this, the title of the protocol: “The evaluation of the Parents under Pressure Programme: an RCT of its clinical and cost-effectiveness” is misleading. What is proposed is not an adequate test of the cost-effectiveness of PuP. Perhaps the title be changed to reflect this concern.

9. The study results, as in all studies, will have limitations with respect to generalizability especially since the focus is on parents in methadone maintenance programs. It would be helpful if this is emphasized more in the protocol, especially in the title and discussion section.