Reviewer's report

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

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Reviewer: Nancy Suchman

Reviewer's report:

General comments: This study proposes to test a brief mindfulness-based intervention for substance using caregivers and their young children. The intervention is designed to provide 12 in home sessions to mothers to help mothers. The intervention aims to help mothers develop mindfulness strategies for managing their own emotional reactivity to their infants while also providing developmental guidance to mothers about their children's emerging developmental capacities. The trial will assess a number of domains, including parenting stress, parent-child interaction, and treatment alliance. Enthusiasm for the manuscript is diminished due to 1) the very limited and cursory scope of the literature review (prior related intervention studies are omitted or misrepresented), 2) the absence of careful consideration of how the mindfulness approach will be adapted to parents with very wide range of abilities and potentials to develop this capacity or how this capacity will be measured, 3) the absence of any new or innovative methodologies, and 4) the failure to specify rationale and methods for a qualitative component to the study. Each of these major concerns is specified below.

Major Compulsory Revisions:

1. The literature review on which the investigators build the rationale for the current study is incomplete and in some instances inaccurate. Rather than relying on prior literature reviews of these studies (which are few in number), the investigators should give a closer reading (and reporting) of the individual trials that have already been conducted. Some of these trials (see Pajulo et al., Dozier et al., or Suchman et al., for example) have already adopted attachment-based and mentalization-based approaches to intervening with substance using mothers of young children. These prior trials (similar to the trial described herein) also consider maternal self-regulation to be a critical intervention target for improving dyadic adjustment. Much can be learned from carefully considering the treatment and methodology approaches that have already been carefully considered and developed. The investigators should carefully review these highly relevant studies in their literature (in one case follow up findings are misrepresented). By relying solely on secondary sources to report prior work, the authors are missing an important opportunity to demonstrate their careful consideration and selection of their own intervention approach and research methods and to convince readers that their methods will truly improve upon prior work.
Given that this manuscript is describing a research protocol that will be used in a future study (and is not reporting findings from an RCT), it seems important that the methodologies described herein "should present a new experimental or computation method..." according to the journal guidelines for methodology-focused papers.

a. Unfortunately the mindfulness intervention itself is described in very general terms and it is difficult to identify its novelty in relation to previous similar trials. For example, it is not clear what the authors mean by "comprehensive assessment' used to describe the intervention initiation. Are they referring to the research assessments? It is also not clear how mindfulness - the skill that is the primary focus of the intervention - is being evaluated and how the mindfulness capacities at baseline would inform the intervention approach across the 12 delivered sessions. How will the investigators teach a parent to be mindful who is not in the habit of attending to her own mind (e.g., due to history of trauma and psychopathology). Unfortunately, it has already been demonstrated that curriculum-based, pre-formatted, psycho-educational approaches rarely demonstrated efficacy for these high-risk populations. More detail is needed on how the intervention approach is individually-tailored to the needs of the participants.

b. This study does not include any novel or new methods or procedures. Many details describing features that are generic to intervention research are included. The quantitative methods have already been extensively used in prior intervention work with high risk parents. For example, the CARE index has already been used by Pajulo and colleagues to evaluate the efficacy of a mentalization-based parenting program for substance using mothers caring for infants. There is also already an extensive literature on the CAPI in its use to test improvement in "risk for child abuse." Unfortunately, though, there are no survey measures that can accurately predict a parent's future maltreatment behavior. The CAPI may therefore have limited utility. All other measures described in this report have been used extensively in previous trials.

c. The one outcome measure that is surprisingly not included (given that it would represent the primary targeted outcome) is parental mindfulness. Since investigators are specifically defining this intervention as targeting parental mindfulness and each of the sessions includes a focus on this capacity, it is surprising that no measures of this primary outcome are included in the study protocol. If the intervention proves to be effective, how will the authors be able to evaluate whether outcomes are explained by the focus on mindfulness (vs. other more generic intervention components such as treatment alliance).

d. Although the study is described as "multi-method" and including qualitative and quantitative components, the description of the qualitative component is underdeveloped. More description is needed about the rationale of and design for the qualitative component. Are the investigators aiming to determine the feasibility of the study by asking participants to share their overall impressions and experiences? Or are they seeking a deeper understanding of the mechanisms by which the intervention is influencing participant perceptions of
parenting and children? Although qualitative research involves an inductive, exploratory process, it as important to provide a specific rationale, focus, and methodology for the qualitative component as it is for the quantitative component (e.g., it needs to be clarified what qualitative methods are being used - purposive sampling? data saturation? open and axial coding? - and how these methods directly address the research questions.

Minor Essential Revisions:
NSPCC needs to be defined.

**Level of interest:** An article of importance in its field

**Quality of written English:** Not suitable for publication unless extensively edited

**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.