Author's response to reviews

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

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Author's response to reviews:

Warwick Infant and Family Wellbeing Unit
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14th November 2012
Editors - Trials Journal
Dear Editors

Re: Submission of Study Protocol Paper entitled: The evaluation of the Parents under Pressure Programme: an RCT of its clinical and cost-effectiveness

We would like to submit our study protocol paper for consideration for publication to the Trials Journal. The aims of the proposed study are to evaluate the acceptability and feasibility of implementing the Parents under Pressure Programme in specialist drug and alcohol treatment centres across the UK; the cost effectiveness and any long-term implications of the Parents under Pressure Programme compared with treatment as usual. The proposed study will provide a greater understanding of the most effective interventions for supporting substance dependent parents to manage their emotional regulation and support their baby’s development.

We consider Trials Journal to be the appropriate journal for its dissemination because of its open access facility, and its focus on high quality reporting on randomised control trials and its attention to detail. The study is unique in that it is underpinned by an ecological model of child development and targets multiple
domains of family functioning including the psychological functioning of individuals in the family, parent-child relationship and social contextual factors. We believe the protocol should be shared with others, and Trials Journal is one of the few journals which encourage the communication of study protocols.

The following revisions have been made:

• Trial registration with the unique ISRCTN number: ISRCTN47282925is has been included in the application at the end of your abstract.

• The study has received the amount of £250,500 funding from the NSPCC to conduct this evaluation.

• The study has received Ethical Approval from the Biomedical Research Ethics Committee (BREC) at the University of Warwick: 189-03-2012. Scanned copies of the ethics documentations have been included.

• A statement of ethical approval has been included in the Methods section of the manuscript.

• A statement describing the informed consent procedure used with your participants has been provided.

• A section explaining the PuP trial status has been provided after the ‘Discussion’ section. Recruitment for the study is due to begin in November 2012.

We hope that you consider it to be a timely resubmission with regard to public health concern about substance abuse and infant mental health.

We look forward to hearing from you.

Yours faithfully

Mrs Sukhdev Sembi