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

Authors:

Jane Barlow (jane.barlow@warwick.ac.uk)
Sukhdev Sembi (sukhdev.sembi@warwick.ac.uk)
Frances Gardner (frances.gardner@spi.ox.ac.uk)
Geraldine Macdonald (geraldine.macdonald@qub.ac.uk)
Stavros Petrou (S.Petrou@warwick.ac.uk)
Paul Harnett (p.harnett@psy.uq.edu.au)
Sharon Dawe (s.dawe@griffith.edu.au)

Version: 4 Date: 19 April 2013

Author's response to reviews: see over
Dear Editors

Re: Re-submission of Study Protocol Paper entitled: The evaluation of the Parents under Pressure Programme: study protocol for an RCT of its clinical and cost-effectiveness.

We would like to resubmit our study protocol paper for consideration for publication to the Trials Journal. The protocol describes the conduct of the study that aims to evaluate the effectiveness of the Parents under Pressure Programme, a home based intervention to support parents who are dependent on psychoactive drugs or alcohol by providing them with methods of managing their emotional regulation, and of supporting their new baby’s development.

We consider Trials Journal to be the appropriate journal for the dissemination of this protocol because of its open access facility, and its focus on high quality reporting of randomised control trials and its attention to detail. This is one the first UK studies to examine the effectiveness of a programme targeting the parenting of substance-dependent parents of infants and toddlers, in terms of its effectiveness in improving the parent-infant relationship and reducing the potential of child abuse. We believe the protocol should be shared with others, and Trials Journal is one of the few journals that encourage the publication of study protocols.

The comments by the peer reviewers have been addressed in the attached document (response to reviewers letter), in summary the following changes have been made:

- We have added a line clarifying that this will be an intent-to-treat design
- We have revised considerably the material in the background section that addresses other interventions.
- Three hypotheses have been added.
- We have attempted to describe the type of intervention that might be provided as part of standard services, although this will vary across sites.
- We have clarified the issue regarding contamination between the intervention and control group.
- We have responded to the concerns regarding the sample size.
- We have provided a more detailed explanation of the economic evaluation.
- The term ‘comprehensive assessment’ has been clarified.
We have provided more information on the outcome measures used in this study.

More detail has been provided on the mixed methods approach.

We have also clarified our proposed study design, data collection methods and plans for reporting and interpretation of study results.

We hope that you consider it to be a timely submission with regard to public health concern about childhood mental health.

We look forward to hearing from you.

Yours sincerely

Professor Jane Barlow