

The evaluation of the Parents under Pressure Programme

Submission date 18/11/2011	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 02/02/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 11/10/2021	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Research shows that the first two years of a child's life are important because the parent-infant relationship during this period influences many aspects of the child's early and later development. However, recent estimates show that maltreatment during infancy is common. Many babies in the UK are born to drug-dependent parents, and dependence on psychoactive drugs during the postnatal period is associated with high rates of child maltreatment, with around a quarter of these children being subject to a child protection plan. Parents who are dependent on psychoactive drugs are at risk of a wide range of parenting problems, and studies have found reduced sensitivity and responsiveness to both the infant's physical and emotional needs. The poor outcomes that are associated with such drug-dependency appear to be linked to the multiple difficulties experienced by such parents (e.g. drug use, mental health problems, family relationships, socioeconomic factors, etc.). An increase in the understanding of the crucial importance of early relationships for infant wellbeing, has led to a focus on the development and delivery of services that are aimed at supporting parenting and parent-infant interaction, particularly in families experiencing serious problems such as drug and alcohol dependency. The Parents under Pressure (PUP) programme is aimed at supporting 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. The intervention is also aimed at helping families to address wider problems related to housing and social factors. An evaluation of the PuP programme in Australia found a significant reduction in a number of aspects of parental wellbeing including their drug dependency, and their children's emotional and behavioural adjustment. The aims of the proposed research are to evaluate the following:

1. The acceptability and feasibility of the delivery of the Parents under Pressure Programme in specialist drug and alcohol treatment centres across the UK;
2. The short and long-term effectiveness of the Parents under Pressure programme in supporting parents to manage their drug and/or alcohol misuse more effectively compared with parents who receive usual care only;
3. The cost-effectiveness of the Parents under Pressure Programme compared with usual services.

Who can participate?

The following families are eligible to participate in the study:

1. Families in which the primary caregiver is receiving either an opioid treatment programme or an alcohol abstinence/relapse prevention programme AND
2. They have a child under the age of two AND
3. They are able to communicate in English

What does taking part in the study involve?

Participants will be randomly allocated to one of two groups. One group will receive standard care, and the second group will receive the PuP service. Families allocated to the standard care group will receive the standard services that are available in each area. Families who are allocated to receive the PuP programme will receive visits for around 20 weeks from a PuP practitioner. Both groups will be visited by study researchers at three time points to ask them to complete a questionnaire, and to talk to them about the support they are receiving, and how they are getting on.

What are the possible benefits of taking part?

We hope that participation in the study will be an interesting and satisfying experience for all families, and that in the long-term, the study will produce an advance in knowledge about what works to help families who are experiencing problems.

Where is the study being run?

The study is being conducted in five NSPCC family centres across this UK. The research is being conducted by a team of researchers at Warwick Medical School, at the University of Warwick.

When is the study starting and how long is it expected to run for?

The study starts in January 2012. Recruitment will commence in March 2012 and continue for one year. Delivery of the assessment will be completed in October 2012. One year follow-up will be conducted from March 2013 through to March 2014. The study ends in December 2014.

Who is funding the study?

National Society for the Prevention of Cruelty to Children (NSPCC).

Who is the main contact?

Professor Jane Barlow

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Contact information

Type(s)

Scientific

Contact name

Prof Jane Barlow

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

The evaluation of the Parents under Pressure Programme: a randomised controlled trial

Acronym

PuP

Study objectives

The PuP programme will be effective in reducing the potential of child abuse and improve the parent-infant relationship.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Methadone-maintained and alcohol-dependent parents

Interventions

The study will comprise a randomised controlled trial in which 140 families recruited from four drug / alcohol treatment centres will be randomly allocated to the intervention or standard treatment group.

The PuP programme has now been developed for use with parents of children less than 2 years of age. The program is home based and uses a Parent Workbook to frame the intervention. A focus on sensitivity to infant cues occurs in vivo with the therapist and mother working together to explore the infants emotional state, to increase maternal warmth and emotional connection that is genuine and spontaneous. Non hostility is also a focus with explicit links made between emotional regulation, feelings of frustration and beliefs about the infant's intentions. Use of technology as a therapeutic aid has been incorporated with mobile phones, photograph and video facilities, which allow the therapist to capture special moments to help mothers reflect on their own behaviour and that of their baby. Furthermore, mother, infant and PUP therapist engage in domestic and related activities that also provides the opportunity for further enhancement of maternal sensitivity and maternal emotional management. Shopping, collecting older children from school and managing other services such as housing, benefits (Centrelink) etc give ample opportunity for in vivo practise of emotional regulation. The intervention will last approximately 20 weeks.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Child Abuse Potential will be assessed using the Child Abuse Potential Inventory (CAP), which is a self-report questionnaire developed to identify individuals at risk for physical child abuse.

The instrument contains 160 items in an agree/disagree format. The CAP has three validity scales:

Lie, Random Response, and Inconsistency scales that are combined to derive three validity indices: Faking Good, Faking Bad, and Random Response.

The CAP Abuse scale consists of 77 items randomly distributed throughout the questionnaire. The internal reliability of the Abuse scale is high, with KR-20 correlation coefficients ranging from .92 to .96 and good temporal stability of .91 and .83 for 1-day and 1-month intervals, respectively.

Secondary outcome measures

1. Parent-child interaction will be assessed using the CARE index, which measures three aspects of maternal behaviour:

- 1.1. Sensitivity
- 1.2. Covert and overt hostility
- 1.3. Unresponsiveness)

and four aspects of infant behaviour:

- 1.4. Cooperativeness
- 1.5. Compulsive compliance
- 1.6. Difficultness

1.7. Passivity

These scales are highly correlated with the infant Strange Situation assessment pattern of attachment and also differentiate abusing from neglecting, abusing and neglecting, marginally maltreating, and adequate dyads. Scores range from 0 to 14, higher scores indicating better sensitivity and/or co-operation etc.

2. Parenting Stress will be measured using the Parenting Stress Index (PSI) Short Form (Abidin, 1995), which is a well-validated measure of perceived stress in the parenting role. High scores on the PSI have been associated with abusive parenting with recent studies finding that parenting stress is higher in women with five or more risk factors for child abuse.

3. Infant social and emotional adjustment will be assessed using the Brief Infant and Toddler Socio-emotional Adjustment Scale which is a 42-item parent-report measure of infant-toddler (i.e. 1-3 year old children) social and emotional adjustment. It comprises two subscales competence and problems. The total for the problems subscale is produced by summing the scores across 31 items and the total for the competence subscale is produced by summing the scores across 11 items. A higher score for the competence subscale and a lower score for the problems subscale indicate better adjustment. and adequate internal consistency for the problem scale and the competence scale). It also discriminates children with clinically significant problems from matched subjects.

4. Parents object relations will be assessed using the Mothers Object Relations Scale-Short form, which is a 14-item screening tool for identifying potential areas of difficulty in the early mother-infant relationship in terms of the mothers working model of attachment by measuring maternal perceptions about:

4.1. Infants emotional warmth

4.2. Infants perceived invasiveness

This tool has been shown to possess stable and internally coherent scales.

5. Child emotional and behavioural problems will be assessed using the Strengths and Difficulties Questionnaire which is a widely used measure of child behaviour problems and has both a parent report and teacher/independent observer version that will be completed. It yields a total Problem Score as well as individual scales of Conduct Problems, Emotional Symptoms, Attention/concentration, Peer Problems.

6. Parental methadone dose will be confirmed by case records, Parental alcohol use, measured using the Timeline Followback (TLFB), which is a widely used calendar-based method of assessment. The interview is structured around a calendar in which recent events such as pay day, social events etc are used as memory aids to assist in recall. This is a reliable and valid measure of substance use. The number of days of substance use (including amphetamines, cannabis, alcohol and heroin) in the 30 days prior to assessment is recorded.

7. Incidence of child abuse will be assessed using social work records to assess the following outcomes: number of case conferences; children with Child Protection Plan in place; children removed from the home. Other outcomes will include attendance at A&E.

8. Therapist Adherence will be assessed using the PUP Therapist Adherence Measure (TAM). This measure was developed for use in the pilot study and lists the key concepts that are covered in the PUP program. It is based on the Therapist Adherence Measure developed for use in multi-systemic therapy which has found that high scores predictive of client outcome.

Overall study start date

01/01/2012

Completion date

01/12/2014

Eligibility

Key inclusion criteria

1. Participation in an opioid replacement treatment programme or an alcohol abstinence / relapse prevention programme
2. At least one child under the age of 2 years
3. Parents with an ability to understand and read English

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

140 families

Key exclusion criteria

1. Parents with severe learning disabilities
2. Unable to understand spoken English

Date of first enrolment

01/03/2012

Date of final enrolment

01/03/2013

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Warwick Medical School

Coventry

United Kingdom

CV4 7AL

Sponsor information**Organisation**

University of Warwick (UK)

Sponsor details

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Sponsor type

University/education

Website

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ROR

<https://ror.org/01a77tt86>

Funder(s)**Funder type**

Charity

Funder Name

National Society for the Prevention of Cruelty to Children (NSPCC) (UK)

Results and Publications**Publication and dissemination plan**

Not provided at time of registration

2018 results in <https://learning.nspcc.org.uk/media/1022/evaluation-parents-under-pressure.pdf>
and <https://learning.nspcc.org.uk/media/1020/evaluation-impact-process-cost-effectiveness-parents-under-pressure.pdf>.

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	11/07/2013		Yes	No
Results article	results	01/01/2019	22/01/2019	Yes	No
Results article		01/11/2021	11/10/2021	Yes	No