



**Study Information
For Referral Agencies
RCT Sites Only**

Warwick
Medical School

In partnership with the

NSPCC 
Cruelty to children must stop. **FULL STOP.**

Registered charity numbers 216401 and SC037717

1. Introduction

The Parents Under Pressure™ (PuP) study is an evaluation of a pioneering new service for drug and alcohol dependent parents with children under the age of two and a half years. The delivery and evaluation of the PuP study is being funded by the NSPCC, and the evaluation is being conducted by a research team at the University of Warwick.

The PuP study is being evaluated in six NSPCC Service Centres across the UK. The study begins in September 2012 and will end in December 2014. Referrals to the study will be taken from September 2012.

The following questions/answers and flowchart, will help referrers to understand what is involved.

2. What is the Parents Under Pressure Programme™?

The PuP programme is aimed at helping alcohol and substance dependent families of children less than two and a half years of age, to look after their children well and to promote their own emotional wellbeing. It is delivered on a one-to-one basis, in the family's home, for 20 weeks.

A therapist manual provides the theoretical overview behind the PuP programme and a parents' workbook is given to the family, this forms the basis of the treatment.

The parent workbook contains many different exercises that help the parent work towards their own parenting goals. It consists of modules that are aimed at providing families with the skills needed to manage substance use problems and difficult emotions when they are under pressure, helping them to provide 'mindful' parenting, improving families' life skills, and extending their social support networks.

An evaluation of the PuP programme in Australia found significant reductions in child abuse potential, rigid parenting attitudes, and child behaviour problems among methadone maintained parents of children aged 2-8 (Dawe and Harnett 2007). The programme has been highlighted by Professor Eileen Munro as highly promising in her independent review into child protection, and has since then been developed for delivery to alcohol/substance misusing parents of infants under the age of two and a half, in the UK.

We want to test whether the PUP programme can improve outcomes for this group and we are doing this in conjunction with researchers from the University of Warwick using a randomized controlled trial in which families who consent to take part in the study will be randomly allocated either to receive the new service or to standard services. We will ask all the study participants to provide data about themselves and their babies (e.g. mental health; feelings about their baby and drug use etc.) at baseline and after twenty weeks and then again six months later and we will compare the outcomes across the two groups.

We are now recruiting families to the study, using the process described below. Only families who meet the inclusion criteria described below and who are also willing to be randomly allocated to either the PuP study or standard services, will be consented to take part in the study.

The remainder of this leaflet describes the process by which families can be invited to take part in the PuP study, and what this would involve.

3. Which families are eligible to take part in this study?

Families who meet ALL the following criteria are eligible to take part in the study:

- The primary carer must have a child under the age of two and a half years (30 months) **AND** be either:
 - on an drug treatment programme
 - on an alcohol abstinence/relapse prevention programme

(Treatment is defined as attendance at specialist drug and alcohol treatment programmes with a named drug/alcohol worker. Those who only access self-help programmes such as AA or NA, or drop in facilities at drug clinics or needle syringe exchange programmes are not considered to be in receipt of treatment.)

- In the eventuality that the father is considered as the primary care giver, the referrer should consult with the research team at the University of Warwick.
- If subject to a child protection plan or child in need process, the case will need to have an allocated key worker in children's social care and have been assessed. Irrespective of whether they are subject to a child protection plan, they are still eligible.
- Parents will also need to be able to understand spoken English.

4. Which families are NOT eligible to take part in the study?

We will be unable to accept the following parents into the study:

- where there is active and ongoing domestic abuse¹

¹ In many cases there will be a history of domestic abuse. It is, however, up to the practitioner to assess if this is a significant concern at the point of referral. If there is 'active' domestic abuse in the household and safety is considered to be the first priority for intervention the parents should not be included on the programme, but may need referring to other agencies for safeguarding intervention. If uncertain, you should seek advice from the research lead or PUP supervisor.

- where they are expectant mothers (unless they have an existing child under two and a half years who is resident with them or until the expectant child is born and is to be living with them). The PUP intervention starts post pregnancy, however, referrers can invite women to take part in the study at any time during pregnancy. Randomization will not usually occur until after the birth of the baby. However, it can be requested that randomization takes place prior to the birth if required, for example, if participation in PUP is to form part of a Child Protection Plan if the parent is selected for the programme and not the control group.
- who do not have a child under two and a half years old
- Parents whose child is not resident with them, unless there is a minimum of weekly contact in place and no current plan for removal. If the child is removed during the intervention, the intervention should continue on the premise that the child will be coming back.
- Who are actively psychotic or expressing active suicidal ideations.

5. How are families invited to take part in the study

Eligible families can be invited to take part in the study by all health and children's social services that have contact with alcohol and substance dependent families. Families may also self-refer.

Referrers can also request that a worker from the local PuP team supports them in explaining the study to the family. It is important to note that whilst the PuP team can provide this support to referrers, they are not able to commence any other work with the family at this stage. The parent will only be an open case with the PUP team if the parent is selected for the intervention group, after randomization.

In order to make a referral, service providers should establish:

- a) Does this family meet the above inclusion criteria?
- b) Does the family have an interest in receiving some additional support aimed at helping them with their addiction and their parenting?

Families who meet these criteria should be given the brief information leaflet that has been provided by the study team. This invites the family to provide their contact details to the study researcher so that the researcher can contact the family and provide them with further information.

The referral agencies should send these contact details to the study researcher using the prepaid envelopes provided.

When the research team receives the contact details for the family they will make telephone contact with the family regarding the study within 2-3 days of receipt of those details. The researcher will describe the study to the family in detail, post them a full information sheet and give them time to think about whether they would like to take part. Please note that participants agreeing to take part in the study will be agreeing to be randomly allocated to receive either services as usual or services as usual plus the PuP programme (see below for further detail). Only participants who are happy to be randomly allocated will be consented to take part in the study.

The researcher will telephone the family again after one week to hear the family's decision. If the family would like to take part in the study, the researcher will arrange to visit them at a time and location that is convenient. At this meeting, if the family is still willing to participate, they will be asked by the researcher to sign the study consent form. After which the family will be asked to complete a study research questionnaire. If the family has any concerns about completing the questionnaire on their own the researcher can help with this. We anticipate that the questionnaire will take about 45 minutes to complete.

The study administrator will then be informed about the newly recruited participant and will initiate the randomization process by opening a sealed envelope telling them which group the participant has been allocated to. The study administrator will contact the participant to inform them. The researcher will not know which group the participant is allocated to. All the families who would like to participate in the study will be registered in the NSPCC's Services for Children and Families database.

The study administrator will notify the PuP practitioners of any new participants who have been randomized into the intervention group.

The practitioner will arrange a first visit to meet the family, they will ask the participants questions about the following aspects of their lives: overall wellbeing; depression, anxiety and stress; daily hassles; life events; social support. The responses to these questions will be recorded on the PuP Database which is a purpose built database developed and owned by the PuP programme team in Australia. Following completion of the programme, these questions will be re-administered and the data again entered on the PuP Database. This information will enable us to establish if the intervention is making a difference to the wellbeing of participants.

The researcher will also contact all the participants at the end of the study to administer the post-intervention PuP research questionnaire and ask the participants about their experiences of taking part in the PuP programme. This will enable the research team to

compare the results across the two groups. This questionnaire will also need to be completed six months later to provide a measure of the longer term impacts of the programme.

It should be stressed that this procedure is ethical because:

- It is a robust evaluation design and it minimizes bias in the selection of families;
- All families will receive usual services - no one will be deprived of a service they would have received without this study;
- If a family is selected for the control group, they are not being deprived of a service that is known to help families because this is not yet known for PuP - it is precisely the aim of this study to contribute to this evidence;
- The service only has limited funding for the first three years and it therefore has to be rationed using some means. Randomisation provides a fair way of doing this because everyone has the same chance of receiving the service.

All families who agree to participate will have the continued interest and involvement of the research team at two further data collection points, and will be given financial remuneration for their participation - usually a twenty pound Boots gift voucher at each data collection point (a total of sixty pounds over the course of the study). It should be noted that we do not inform potential respondents about the remuneration prior to their consenting to take part.

6. What if you want more information?

If after reading this you would like further information please do not hesitate to contact the research team at the following address:

Jane Barlow, Warwick Medical School, Gibbet Hill Road, Coventry, CV4 7AL

Tel: 02476 574884 or Email: jane.barlow@warwick.ac.uk.

Sukhdev Sembi, Warwick Medical School.

Tel: 02476 150508, Mobile: 07824 541002 or Email: Sukhdev.sembi@warwick.ac.uk.

You can also contact your PUP team at your local NSPCC Family Centre.

7. Recruitment Flow Diagram

