



Information Sheet

We are inviting you to take part in a research study.

Before you decide whether you want to take part, we would like to tell you more about why the research is being done, and what it would involve. Please take some time to read the following information carefully. Feel free to discuss it with friends, relatives, health visitor, support worker or your family doctor (GP) if you wish. If you have any questions, or you would like more information, please contact the study researcher, Sukhdev Sembi on **02476 150508 (Mobile 07824 541002)**.

Consumers for Ethics in Research (CERES) publish a leaflet entitled "Medical Research and You". This leaflet gives more information about medical research and looks at some questions you may want to ask. We have enclosed a copy with this form.

What is the purpose of the study?

We want to find out whether Parents Under Pressure™, a new pioneering parenting support programme from Australia, can help families in the UK. We want to know if the programme can help improve the health and wellbeing of parents, their baby, and the parent's relationship with their baby.

The study is a randomised control trial. A randomised control trial is a study in which people are allocated to a treatment or no-treatment group by a process that ensures nobody can influence which group they are put into.

In this study you would be allocated by a computer, to receive either services as usual or the Parents under Pressure Programme (PuP) in addition to services as usual. This

will enable the researchers to compare the outcomes for mothers and babies across the two groups (see below for further information about this).

What is the 'Parents Under PressureTM' Programme?

The PuP is a new 20-week programme for parents who are receiving support from a drugs or alcohol worker and who have a child under two and a half years of age. It aims to help new parents with the task of parenting so they can give their baby a good start in life. The PuP practitioner would be there to listen and to be supportive.

Why have I been selected to take part in the study?

We are inviting parents who are on a drug treatment programme or an alcohol treatment programme to take part in the study. In order to take part, you must also be able to understand and read English, and have a baby or toddler under the age of two and a half years.

Do I have to take part?

It is up to you to decide whether or not to take part. Even if you decide to take part now, you would still be free to withdraw at any time. Your decision would not affect the care you received from your family centre, health visitor, GP or any other health or social care professional.

What if I do not wish to take part in the study?

If you decide not to take part in the study, you can simply tell the study researcher when she telephones you to ask for your decision. Again, your decision would not affect any care you or your family currently receives.

What would taking part in the study involve?

Taking part in the study would involve a number of steps: firstly the researcher will telephone you to ask if you have any questions about the study and to hear your decision about whether you are able to take part or not. If you are not sure or would like to take part, the researcher will arrange to visit you, at a time and location that is convenient to you. Then at this meeting, if you are still willing to participate, you will be asked by the researcher to sign the study consent form and asked to complete a study questionnaire. If you have any worries about the questionnaire the researcher is there to help you.

The questionnaire takes about 45 minutes to complete, and it asks you about whether you are feeling anxious or depressed, about how confident you feel as a parent, about how much support you have, whether you have had any major life events recently, and about your relationship with your baby. Your answers to these questions will help us to assess if the PuP service is making a difference to the relationship between parents and babies. You will be given a £20 Boots gift voucher following completion of the research questionnaire at each of the three data collection points to thank you for the time take to provide this information.

Once the consent form has been signed and the research questionnaire has been completed, you would be allocated to one of 2 groups, the 'PuP' Group or to the 'Usual Care' group. We do this by a method that ensures that no one can influence which group families go into. You would then be contacted to inform you which group you have been allocated to.

All participants taking part in the study will continue to receive services as usual. If you were allocated to the PuP Group you would continue to receive usual services and in addition you will also receive the support from a PuP practitioner over twenty-weeks or until such a time as you both decided to end the service.

Parents in both the groups would be asked to do the following over the next 18 months:

	Why?
a) We will ask you to complete the same questionnaire at the end of the twenty weeks and six months later.	This will enable us to see if the answers of the parent's in the PuP group are different to the answers of parents in the Usual Care group. If they are, we would be able to say that the differences were due to the PuP service.
b) We will ask you to complete a questionnaire that looks at the services you have used for yourself and your baby at the same time points as above.	This will help the research team to compare the cost of the Parents under Pressure Programme with the cost of current services.

<p>c) With your permission, at the end of the study period, we would like to make a short (3 minutes) DVD of you playing with your baby.</p> <p>If you were happy to be filmed, we would ask you to play or interact with your baby as usual. The researcher would record you and your baby together using an ipad.</p>	<p>This DVD would be assessed to tell us about your relationship with your baby.</p> <p>We would give you a copy of the DVD to share with your family and friends.</p>
<p>d) We will ask some parents if they would be willing to take part in a short interview to tell us what they liked or disliked about the PuP service</p>	<p>This would help us to know if any aspects of the service should be changed in the future. You do not have to agree to this part of the study.</p>
<p>e) We will also ask some parents if they would be willing to provide the research team with a hair sample.</p>	<p>This would be used to confirm the information provided by you with regard to your drug use. You do not have to agree to this part of the study.</p>
<p>f) With your permission we would also like to access yours and your child's social service records at the end of the six months follow-up.</p>	<p>This will enable us to see what other social services you and your child has received and what the outcome was. You do not have to agree to this part of the study.</p>

What will happen to the information I provide?

- a) The questionnaires you will be asked to complete will not have any direct means of identifying you. You will have a study number that's unique to you. Your study number will be on your questionnaires so we can link them up. They will be kept at the Warwick Medical School, in a locked cabinet, in a locked room.
- b) If you take part in an interview, it will be recorded on an audiotape and will be kept with your questionnaire, and will only be identifiable by your study number. Should you not agree for the interview to be recorded, the researcher conducting the interview would take notes. **Anonymous** quotations might be used for the purpose of reporting the findings of the study or presentations to professional audiences.
- c) If you were in agreement to us making a short DVD of you playing with your baby, we would give you a copy. The video recording of you and your baby will be deleted from the ipad and stored on a DVD with your unique study number only.
- d) If you agree to provide a hair sample, this will be sent to a UK laboratory to be tested for drug and/or alcohol use. Your personal details will not be sent to the

lab with the hair sample, which will only have your unique study number. The results will be provided to the research team. We will notify you, your PuP Practitioner and/or the referring agent should we have any concerns regarding the results from the sample of hair.

All of the above information will be the property of the University of Warwick and the NSPCC who will be able to use the data for research until it is destroyed 10 years after the completion of the study.

Who will know about me taking part in the study?

The research team will know whether you have agreed to take part in the study, and *with your permission we* will also inform any other health or social care workers with whom you might be involved.

All information that you provide will be treated as confidential and we will not share information about you with anyone outside the research team unless required by law under the terms of the Children Act (1989). This means that we will only share information that is collected if there were concerns about the safety of a child.

When writing up the findings of the study the researchers will ensure that they do not reveal the identity of participants, and any quotations that are used for the purpose of reports or presentations would be anonymous.

What are the benefits of taking part?

By taking part in the study, you can help families like yours in the future by helping us to find out if the PuP service benefits parents in any way, and what if any changes to the service, need to be made.

However, we cannot be sure whether you and your family will benefit directly from taking part in this study.

Is there any potential harm involved in taking part?

We are not aware of any harm associated with participating in this study. However, if you became concerned about taking part for any reason you could do one of the following:

- a) Drop out of the study without giving any reason or explanation;
- b) Discuss your concerns with the researcher;
- c) Discuss your concerns with your key worker;

d) Make a complaint using the procedure outlined below.

Who should I contact if I wish to make a complaint?

Any complaint about the way you have been dealt with during the study or any possible harm you might have suffered will be addressed. Please address your complaint to the person below who is a senior University official entirely independent of the study:

Nicola Owen
Deputy Registrar
Deputy Registrar's Office
University of Warwick
Coventry CV4 8UW
T: 024 7652 2713 E: Nicola.Owen@warwick.ac.uk

What will happen to the results of the research study?

The results of the study will be written up in a final report and the results may also be submitted for publication in professional journals. If you were interested, we would be happy to provide you with a copy of the report.

Who is organising and funding the research?

The study is being funded by the NSPCC. The study is being led by Prof. Jane Barlow, Warwick Medical School, University of Warwick, Coventry, CV4 7AL. The study researcher is Mrs. Sukhdev Sembi.

Who has reviewed the study?

The study has been reviewed by the NSPCC who are funding the service and evaluation, and also by the Warwick University: Biomedical Research Ethics Committee (BREC).

What if I want further information about the study?

If you want any further information about the study you can telephone the study researcher **Mrs Sukhdev Sembi** on **02476 150508 (Mobile 07824 541002)**.

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Thank you for taking the time to read this information sheet