

# The Preterm Infant Parenting Study

<b>Submission date</b> 01/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 08/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 01/02/2013	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Prof Andrew Whitelaw

### Contact details

Neonatal Medicine  
University of Bristol Medical School  
Southmead Hospital  
Bristol  
United Kingdom  
BS10 5NB  
+44 (0)117 959 5699  
[andrew.whitelaw@bristol.ac.uk](mailto:andrew.whitelaw@bristol.ac.uk)

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

## Study information

## **Scientific Title**

### **Acronym**

PIPS

### **Study objectives**

Does the Parent-Baby Interaction Program introduced soon after premature birth reduce stress and depression in the mother and developmental delay at 2 years in the infant?

### **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)**

Hospital

### **Study type(s)**

Treatment

### **Participant information sheet**

### **Health condition(s) or problem(s) studied**

Preterm birth

### **Interventions**

The Parent Baby Interaction Programme versus no intervention

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome measure**

1. Parental Stress Index at 3 months post term
2. Bayley Scales of Infant Development at 2 years post term

### **Secondary outcome measures**

1. Edinburgh Postnatal Depression Scale at 3 months post term
2. Home observation for measurement of the environment at 3 months post term
3. Neurobehavioural Assessment Premature Inventory (NAPI) at 35 weeks postmenstrual age
4. Nursing Child Teaching Scale at discharge from hospital
5. Postmenstrual age at discharge
6. Infant weight gain to discharge

**Overall study start date**

01/07/2002

**Completion date**

30/06/2005

## Eligibility

**Key inclusion criteria**

Infants born before 32 weeks gestation, and their mothers

**Participant type(s)**

Patient

**Age group**

Neonate

**Sex**

Both

**Target number of participants**

250

**Key exclusion criteria**

1. Congenital abnormalities and chromosome disorders recognisable at birth.
2. Mothers unable to understand English.

**Date of first enrolment**

01/07/2002

**Date of final enrolment**

30/06/2005

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Neonatal Medicine**

Bristol  
United Kingdom  
BS10 5NB

## Sponsor information

**Organisation**

University of Bristol (UK)

**Sponsor details**

Gillian Tallents  
Research and Development  
University of Bristol  
Senate House  
Tyndall Avenue  
Bristol  
England  
United Kingdom  
BS8 1TH  
gillian.tallents@bristol.ac.uk

**Sponsor type**

University/education

**ROR**

<https://ror.org/0524sp257>

## Funder(s)

**Funder type**

Charity

**Funder Name**

The Health Foundation (UK) (ref: 265/1063)

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**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?
<a href="#">Results article</a>	results	01/11/2007		Yes	No
<a href="#">Results article</a>	results	01/10/2009		Yes	No