ISRCTN56341521 https://doi.org/10.1186/ISRCTN56341521

The Preterm Infant Parenting Study

Submission date 01/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 08/09/2005	**Overall study status** Completed	
Last Edited 01/02/2013	**Condition category** Pregnancy and Childbirth	

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

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 Stess 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?
Results article	results	01/11/2007		Yes	No
Results article	results	01/10/2009		Yes	No