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Preterm Infant Parent Programme for Attachment (PIPPA study)

Submission date
01/05/2012

Recruitment status
No longer recruiting

Registration date
31/05/2012

Overall study status
Completed

Last Edited
15/03/2018

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
We know that the relationship a baby makes with his parents is important for their future development. Babies make a special relationship called an attachment relationship to their mother and father. Feeling safe and emotionally secure has an important impact on babies development. We also know from previous research that this relationship is especially important for premature and sick babies.
Preterm birth is one of the most important public health concerns. The relationship between the infant and his or her parents is vital to the infants development, but parents may suffer anxiety, depression and post-traumatic stress following the birth. Infants may have medical problems and may need to stay in hospital for a long period of time. Parents and infants may need extra support during this time in beginning their relationship.
As part of the work of the neonatal unit, caring for preterm babies, the study team would like to learn more about how preterm babies who require admission to the neonatal intensive care unit (NICU) develop their attachment relationship with their parents and to see how babies and their parents can be supported during this time.
So that we can do this, the study team will conduct a 3 session programme which aims to support the developing relationship between the baby and his or her parents.
The aims of the study are:
To investigate whether a preterm infant-parent relationship-based programme (PIPPA) will improve the developing attachment relationship and social-emotional outcomes of preterm infants < 32 weeks gestation compared with routine care.
To investigate whether the PIPPA programme will improve parental outcomes in terms of anxiety, depression, post-traumatic stress and parenting stress.
The studys findings will help to understand and improve the supports for the developing attachment between parents and their preterm infants.

Who can participate?
Babies who are born at or less than 32 weeks in the National Maternity Hospital, Dublin and their parents, who are from the area which the hospital serves can take part.

What does the study involve?
Infants and their parents are randomly allocated to receive the PIPPA programme or to receive

routine support from medical, nursing and social work staff.
All parents who consent to take part in the study will be asked to complete a set of questionnaires at the beginning of the study and before your baby goes home. These questionnaires will ask about your mood, anxiety, stress and feelings as a parent. These questionnaires will take about half an hour to complete.
All babies and their parents who take part in the study will be asked to attend for a follow-up appointment when your baby is 6 9 months old. There will be three parts to this appointment, which will take about one hour.
As part of the study the mother and baby will be video-recorded playing together for about 5 minutes. This film can help us to see the ways babies and mothers play and communicate. The video, which will have no identifying details on it, will be looked at and coded by a specially trained person.
Your baby will have a routine clinical examination by the paediatrician.
Both mother and father will also be asked to complete questionnaires about your mood, anxiety, stress and youre experience as a parent, your babys social and emotional development.

What are the possible benefits and risks of participating?
We hope that taking part in the PIPPA study will help the infants and their parents getting started in their relationships and enjoyment of these relationships. The programme may help some parents with anxiety. Information obtained during the course of the study may help us to understand better how a premature baby forms their attachment relationship with their parents, to understand their social and emotional development better and what supports will help preterm babies and their parents in the future. We hope that taking part in the study will improve the care of babies and parents now and in the future.
Parents may find the interview about their child's birth and development an emotional experience. Parents may feel a range of emotions such as sadness, anger or anxiety as they talk about their experiences. These feelings are natural and it can be helpful to talk them through. There are no physical risks to taking part in this study for you or your baby.

Where is the study run from?
The study is being run from the National Maternity Hospital, Dublin, Ireland with support from the National Childrens Research Centre, Dublin.

When is study starting and how long is it expected to run for?
The study will begin enrolling parents and infants in May 2012 and will continue for approximately 2 years. The study will be recruiting patients for approximately 18 months.

Who is funding the study?
The National Childrens Research Centre, Dublin, Ireland is funding the study

Who is the main contact?
Dr. Aoife Twohig
atwohig@nmh.ie, aoife.twohig@gmail.com

Contact information

Type(s)
Scientific

Contact name
Prof Eleanor Molloy

Contact details
Department of Paediatrics
National Maternity Hospital
Holles Street
Dublin
Ireland
2
+353 (0)1 6373438
elesean@hotmail.com

Additional identifiers

Protocol serial number
D/11/6

Study information

Scientific Title
Preterm Infant Parent Programme for Attachment (PIPPA study): a randomised controlled trial of the preterm infant-parent relationship-focused intervention programme to support attachment and social-emotional development of preterm infants

Acronym
PIPPA

Study objectives
The hypothesis is that infants and parents receiving the PIPPA programme will have increased sensitivity and synchrony in interaction (developing attachment) and improved social emotional outcomes compared to the infants and parents receiving routine support.

Null Hypothesis: is that there will be no difference between the treatment groups.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the National Maternity Hospital, Dublin, 27 March 2012

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Preterm birth, attachment, social-emotional development, parental mental health

Interventions

Current interventions as of 15/03/2018:
Infants and their parents are randomly allocated to receive the PIPPA programme or to receive routine support from medical, nursing and social work staff.

Intervention Group: Preterm Infant-Parent Programme for Attachment (PIPPA)
This programme has been developed for this study drawing on previously described early intervention programmes for preterm infants, manualised psychotherapy interventions and psychodynamically informed infant observation. The intervention has been developed following review of the literature supporting the components of the intervention.
The intervention components aim to facilitate the development of the infant-parent relationship through:
1. Working with the parents to reduce anxiety and post-traumatic stress
2. Supporting the parents' formation of realistic representations of their baby
3. Helping parents to identify infant communications and supporting appropriate responses to these, thus enhancing parental sensitivity.
The program will be offered over 3 sessions during the infants admission

Detailed intervention for PIPPA study
Session 1:
Clinical Interview with the parents: 45 minutes
Outline The clinical interview with the parents aims to engage the parents in the programme and establish the relationship with the MD student/ therapist. The interview will begin with a history of the pregnancy and birth of their infant. The MD student will then discuss with the parents their emotional reactions to the pregnancy and the preterm birth and their first experiences with their baby. The interview is based on the routine psychiatric interview and a standardised interview which assesses parents representations of their child, the Working Model of the Child Interview. This will be adapted to the situation of preterm birth. The final part of the interview will outline the structure of the following infant observation session.

Session 2:
2.1. Prior to each session the Guider will conduct a chart review and also speak with the medical and nursing staff about the baby's medical progress, any issues that have arisen for the baby such as complications or new treatments and also about how the parents have been since the previous
session.
2.2. Beginning
The session will begin with the guider meeting with the parents and review together their progress and their baby's progress since last meeting. This will be flexibly arranged so that parents who wish to have time before the observation session with the baby can do so, or this part of the session occurs by the baby's incubator or cot. This part of the session aims to encourage parents to express their feelings about their experiences of their baby's admission, their own emotional processes, anxieties, fears and observations. The purpose of this is to offer the parents an opportunity to have the emotional aspects of their experience listened to, to begin to understand them, through supporting their own hypotheses about their experiences or offer alternatives, the guider will use therapeutic techniques such as empathic listening, mirroring, reframing, reflecting.
The centrality of the baby to the process of the intervention is important, so it is important to greet the baby and include the baby as participant in
the process. Wherever possible the guider will note the baby's movements, responses and state.
2.3. Observation of infant cues and communications

Gradually the guider will encourage the parents to observe their baby. Perhaps initially modelling this by saying for example 'You are breathing now so steadily as you sleep, John, he moves his chest so you can see the pattern of his breathing'. Together with the parents the baby' s state, physical qualities, strengths, and his communications of fatigue or distress can be described. The guider will listen for parents' thoughts about these observations, perhaps linking them with the baby's behaviour in the womb, with each other's personalities, or with childhood memories. By exploring these with parents as they surface, the intervention aims to identify meanings that parents attribute to infant behaviour, promote sensitivity of their responses to infant's signals and promoting parents' confidence in their parenting abilities.
At a suitable time the Guider will ask the parents for permission to make a brief video of them and their baby. The parent may be holding the baby or if the baby is in the incubator touching or talking to their baby. Efforts are made to support the parent to feel comfortable during the filming. The video is taken with a small hand held camera and is about 5 minutes long.
The Guider will then inform the parents about the next and final session, a shared review of the video of parent and infant together. Arrangements will be made to meet with them at a time to suit them and their baby. The parents will be informed that if they have any questions following this they can contact the Guider.

Session 3
3.1. Prior to the session the Guider will conduct a chart review and also speak with the medical and nursing staff about the baby's medical progress, any issues that have arisen for the baby such as complications or new treatments and also about how the parents well-being since the previous session. The Guider will also have reviewed the film of parent-infant interaction and pre-selected edited clips of optimal interaction to share with the parent/s, according to VIG principals.
3.2. Beginning
The session will begin by meeting with the parents and review together their progress and their baby's progress since the previous meeting. The aim is to find out how the parents have been emotionally and how they have been able to use the observation in the interim period. This may be evident from the parent's own observations of their baby, their ability to verbalise their emotions, positive and negative and how they have tried to understand them. For some parents who may have difficulty in verbalising emotional processes focus will be on behavioural aspects of sensitivity, such as their appreciation of the infant's routines, preferences, and their own ways of coping with the demands of looking after a preterm baby in special care. Also a discussion about social support available to parents at this time will be introduced.
The format will follow the first session where by the parents will be encouraged to talk about their developing relationship with their baby, their observations of him, what they have noticed about his development. The baby's progress in terms of approaching discharge and parents thoughts and feelings about this time will be integrated if appropriate. The Guider will then review with the parent/s preselected moments of the video with them, to highlight their sensitivity and competence.

3.3. Endings
The Guider will ask the parents how they have found the intervention overall and if they have any questions about the intervention or the process. Time will be given to reflect on the process and to allow any feelings of loss to be expressed. As this is the final session before the follow up appointment at 6 months corrected age, the process of follow-up will be explained to the parents. The session will end by congratulating them on their baby and their participation in the intervention.

Previous version:
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Detailed intervention for PIPPA study

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Session 2:
First Infant Observation: 30 minutes
Observing babies can bring an awareness of the babys experiences to parents and also caregivers. The presence of the baby in the session has been shown to facilitate parental sensitivity and engagement. The observation will be arranged at a time when the parent/s are visiting their baby.

The session will comprise of 3 parts:
1. Meeting the parents at the incubator / cot, brief review of their babys progress and their own progress since first meeting.
2. Observing the babys appearance, state of arousal, quality of movements, responses to stimuli from the environment or to internal processes and their expressions / signs of stress, defensive / shut down mechanisms, self-regulation capacities.
3. Supporting parents spontaneous and sensitive interactions with their baby parents actions, behaviours, thoughts, and expressions in relation to their baby will be facilitated through the positive alliance of the MD student / therapist with the parents.
4. Brief interview with parents 15 minutes
This follow up meeting will review parents reflections on the infant observation session, their own observations of their infant. Parents will be encouraged to express their fears, anxieties and other emotional experiences. These feelings will be listened to empathically and parents helped to identify ways of coping with such feelings. Emerging representations of their infant and their relationship will be highlighted.

Session 3
This session will be conducted in two parts, with a break between.
2nd Infant Observation 30 minutes - 15 minutes video taped.
The second observation will be conducted in the same manner as the first; however half of the session will be videotaped. When possible this session will take place when the infant can be nested in skin to skin contact, held by the parents or after a feed. This will allow observation of the infant in a situation of optimal interaction with the parent. The focus of the observation will be on noting the infants forms of communication and early developing social-emotional capacities.

Interview with parents feedback on video clips 30 minutes
This is the final session before discharge. The session aims to review previous sessions with parents and jointly review the video clip of the infant observation. The feedback will involve illustrating positive interactions between infant and parents. Parents will be asked to complete questionnaires on anxiety, depression and post-traumatic stress.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Attachment will be measured using an assessment of infant mother interaction, a precursor of later attachment at 6 months corrected gestational age.

Infant Assessment of Attachment- Care Index
The CARE-Index (Crittenden, 2004) assesses mother-infant interaction from birth to about two years of age based on a short, videotaped play interaction of 3-5 minutes. Coding of an interaction takes about 15-20 minutes. The measure assesses mothers on three scales: sensitivity, covert and overt hostility, and unresponsiveness. There are also four scales for infants: cooperativeness, compulsive compliance, difficultness, and passivity. These scales tend to be related to the maternal scales in the order listed. The scales are highly correlated with the infant Strange Situation assessment patterns of attachment, differentiate clinically at risk and adequate mother-infant dyads, can be used during intervention and can be used to assess the effectiveness of intervention.
The information derived from the CARE-Index can be used as quasi-continuous or categorical data. The CARE-Index will be video-taped and coded by blinded independent certified coders. The video material will be kept in a secure filing cabinet in a secure office. The tapes will be destroyed on completion of the study.

Key secondary outcome(s)
1. Ages and Stages Questionnaire Social-Emotional Development version
This is a questionnaire assessing several domains of infant social, emotional and regulatory development.
2. Parent questionnaires (State Trait Anxiety Inventory, Perinatal Post-traumatic Questionnaire, and Beck Depression Inventory) will be repeated at the 6 month follow up assessment. The Parenting Stress Index will also be administered at this time point.
3. Bayley's score at 2 years: A standardized assessment of infant development (Griffiths or Bayley scales of development) and the routine paediatric assessment will be performed at 6

months.
4. Neonatal Biomarkers, MRI - Brain at 2 years

Completion date
31/03/2014

Eligibility

Key inclusion criteria
Infants born at less than 32 weeks gestation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Key exclusion criteria
1. Known major congenital anomaly incompatible with life
2. Parents' level of English will make completion of the semi-structured interview difficult
3. Family does not live within the catchment area of National Maternity Hospital (NMH)

Date of first enrolment
14/05/2012

Date of final enrolment
31/03/2014

Locations

Countries of recruitment
Ireland

Study participating centre
Department of Paediatrics
Dublin
Ireland
2

Sponsor information

Organisation
National Children's Research Centre (Ireland)

ROR
https://ror.org/02typaz40

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
National Childrens Research Centre (Ireland)

Results and Publications

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes