ISRCTN72146206 https://doi.org/10.1186/ISRCTN72146206

Postnatal Infant Care (PInC) Trial, version 1.1

Submission date
01/10/2018

Recruitment status
No longer recruiting

Registration date
03/10/2018

Overall study status
Completed

Last Edited
16/03/2021

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
For women who have had an uncomplicated pregnancy and are considered 'low-risk', giving birth in a midwifery-led unit has been associated with positive birth outcomes. Much is known about the birthing experiences of women in midwifery-led units, but past research has overlooked the experiences of parents and their babies after birth (postnatal). Previous research has indicated that adequate support in the early postnatal period can improve breastfeeding outcomes and contribute to the establishment of a responsive parent-infant relationship, reducing parent-infant conflict in early years. This study aims to improve parent-infant responsivity and contact during the postnatal stay by comparing two cot types for parental use within Newcastle Birthing Centre. This study has the objectives of improving breastfeeding outcomes (initiation and continuation), reinforcing infant safety, and encouraging parent-infant responsivity and cue-based care.

Who can participate?
Women giving birth in the Newcastle Birthing Centre who have never given birth before and have indicated some intent to breastfeed after birth

What does the study involve?
Participants are randomly allocated to receive either a stand-alone cot or a portable in-bed cot. Participants are then observed using video cameras throughout the immediate postnatal period (up to 24 hours after birth) in order to understand how cot allocation influences the ease of caregiving in the postnatal period.

What are the possible benefits and risks of participating?
Participating in the study provides participants with the opportunity to influence how postnatal care is provided at Newcastle Birthing Centre. The research will contribute to the evidence base underpinning postnatal care provision in the UK and overseas, and attainment of WHO targets for maternal and infant care. The research on in-bed cots has concluded that they pose no risk to parents and infants, but the research is by no means exhaustive and there may be potential risks to infants such as the cot tipping, the infant being carried in the cot and being dropped. Any accidents involving the in-bed cot will be logged and the continuation of the project will be reconsidered if there is any indication that infant or parent safety is at risk.

Where is the study run from?
Newcastle Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
October 2017 to March 2021

Who is funding the study?
Economic and Social Research Council (UK)

Who is the main contact?
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Study website
https://www.dur.ac.uk/sleep.lab/current/pinc/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
39629

Study information

Scientific Title

Postnatal Infant Care (PInC) Trial: trialling an intervention to improve parent-infant caregiving in the immediate postnatal period

Acronym
PInC

Study objectives
This study aims to improve parent-infant responsivity and contact during the postnatal stay by comparing two cot types for parental use within Newcastle Birthing Centre.

This study has the objectives of:
1. Improving breastfeeding outcomes (initiation and continuation)
2. Reinforcing infant safety
3. Encouraging parent-infant responsivity and cue-based care

Ethics approval required
Old ethics approval format

Ethics approval(s)
NHS Research Ethics Committee, 17/09/2018, ref: 18/YH/0323

Study design
Randomised; Interventional; Design type: Process of Care, Psychological & Behavioural

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Parent caregiving in the postnatal period

Interventions
Design: This study will be a randomised trial comparing the effect of two infant care devices (discussed in A6-2): a standard cot (control condition) and an in-bed portable cot (experimental condition) on breastfeeding outcomes (initiation and continuation), reinforcing infant safety and responsive cue-based care in Newcastle Birthing Centre.

Familiarisation phase (September - December 2018): There will be a one-month period of familiarisation in which to develop effective working relationships with RVI staff and collect pilot data for the randomised trial. The data generated from this period will attempt to reduce

the risk of poor trial implementation which may decrease the internal validity and effectiveness of the trial (O'Cathain et al. 2014). Up to five pilot video recordings will be done in order to refine the videoing protocol and develop a coding scheme for data extraction. Pregnant volunteers will be identified through parenting classes and through online groups (ISIS online) to participate in pilot videoing.

The PInC trial (January 2019 - March 2020): Following on from the familiarisation phase, a randomised trial will be conducted. In order to observe parent-infant postnatal behaviour video and audio recordings will be used. The overall video study will run for 12 months using fixed cameras installed in two of the Birthing rooms in Newcastle Birthing Centre.

Potential participants will be approached at 20-week scans and at antenatal parent education classes and provided with study information. Consent to participate will be collected when individuals come into Newcastle Birthing Centre for labour. Consented participants will complete an enrolment form providing information on their demographic characteristics and then they will be observed throughout their postnatal stay using video and audio for up to 24 hours. Using video to observe parent-infant interactions has been integral in advancing knowledge about the behaviour and dyadic relationship between parents and their infants. The collection of video is justified on the grounds that it will allow for the collection of meaningful data on parent-infant interactions and reduce the disruption to participants in the postnatal period.

In order to understand parental postnatal experiences and the acceptability of the intervention, a short semi-structured debrief interview will be conducted following the postnatal stay. The interviews will last no longer than 15 minutes and will focus on parent's experiences in the Birthing Centre and participating in the trial. The debrief interviews will be done in the Birthing Centre before the participants return home with their infants. Should participants leave the Birthing Centre without completing the debrief interview they will be contacted by telephone to complete the interview, no longer than a week after their postnatal stay.

Once collected, videos will be coded using Noldus Observer XT according to a predefined coding scheme based on behavioural taxonomies developed from the pilot videos and informed by previous studies (Ball et al. 2006; Klingaman 2009). Coded data will then be analysed statistically using SPSS statistics. Coding will provide the frequency (count) and duration (cumulative elapsed time) of observed behaviours. The primary outcome on which the study will be powered will be the successful initiation of breastfeeding, defined by the frequency of successful breastfeeding bouts identified by infant suckling and swallowing, the data for this will be extracted from the coded videos.

Sample size: We hope to recruit 120 families to participate in the trial, 60 receiving the standalone cot, 60 receiving the in-bed cot. All recruited participants will complete the postnatal debrief interview.

- Interpretation and analysis of trial data (March 2020 - June 2020)
- Preparing final report (July 2020 - March 2021)

Intervention Type
Other

Primary outcome measure
The number of successful breastfeeds per hour in the immediate postnatal period, defined on the basis of observed behaviour

Secondary outcome measures
1. Breastfeeding status at 6-8 weeks using data extracted from child health records
2. The frequency of incidents where infant safety is compromised or potentially compromised, defined on the basis of observed behaviour in the first 24 hours after birth
3. The speed of parental response to infant cues, defined on the basis of observed behaviour in the first 24 hours after birth
4. The frequency per hour of missed infant cues, defined on the basis of observed behaviour in the first 24 hours after birth
5. The amount of time that infants spend within arm's reach of their parent, defined on the basis of observed behaviour in the first 24 hours after birth
6. The acceptability of providing a portable in-bed cot for the postnatal stay, defined on the basis of observed behaviour in the first 24 hours after birth and feedback from postnatal debrief interviews up to a week after birth

Overall study start date
01/10/2017

Completion date
31/03/2021

Eligibility

Key inclusion criteria
1. Nulliparous (never given birth before)
2. Have given birth in Newcastle Birthing Centre
3. Have indicated some intent to breastfeed after birth
4. Have provided informed consent of all adults staying in the postnatal room after birth

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Planned Sample Size: 120; UK Sample Size: 120

Total final enrolment
41

Key exclusion criteria
1. Enrolled participants who do not deliver their infants in Newcastle Birthing Centre
2. No indication of an intention to breastfeed
3. Are participating in other trials that may influence breastfeeding outcomes

Date of first enrolment

01/12/2017

Date of final enrolment
31/03/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Newcastle Hospitals NHS Foundation Trust
Royal Victoria Infirmary
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Sponsor type
University/education

ROR
https://ror.org/01v29qb04

Funder(s)

Funder type

Research council

Funder Name
Economic and Social Research Council

Alternative Name(s)
ESRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The results of this study will be reported in the Chief Investigator's PhD thesis, and will also be shared via peer reviewed scientific papers, an internal report, conference presentations, and submission to regulatory bodies one year after the trial end date.

Intention to publish date
31/03/2022

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version v2.2		03/10/2018	No	Yes
HRA research summary			28/06/2023	No	No