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A study working with healthcare professionals and parents/carers to explore whether giving information resources about medicines helps parents take their baby home from a neonatal unit

Submission date
02/10/2024

Recruitment status
Recruiting

Registration date
16/12/2024

Overall study status
Ongoing

Last Edited
25/04/2025

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Study PADDINGToN-1 (https://www.isrctn.com/ISRCTN17332620) was co-designed medicines information with parents and carers of babies born premature or sick. These resources aimed to support parents giving medicines to their baby at home following discharge from a neonatal unit. Parents and carers told us that they worry about making mistakes when giving medicines to their babies and cannot always find reliable information to help them when they have questions about medicines. This study will use the medicines information resources developed in PADDINGToN-1. It will share the resources with parents and carers before their baby is discharged from the neonatal unit. This study wants to find out whether the resources help parents and carers feel more confident and less anxious about giving medicines to their babies after they go home. The current study is called PADDINGToN-2 and is composed of one main study and three smaller studies. A larger study will be designed to find out if using the PADDINGToN-1 medicines information/resources helps to reduce parents' and carers' anxiety, improve confidence and improve safety. To do this the study team will research the best way to get parents and carers to take part in the study; how the team can involve a wide range of parents and carers; how they can make it easy for parents and carers to take part; and, how can they keep parents and carers engaged throughout the study. The study will also look at the best way to collect information about parents' and carers' anxiety and confidence about medicines. The answers will inform the design of a larger study (PADDINGToN-3) to find out whether using the PADDINGToN-1 medicines information resources reduces parents' and carers' anxiety, improves their confidence and improves safety.

Who can participate?
Parent advisory group - Parents/Carers whose baby has recently (ideally within 2 years but up to 5 years) been discharged from a neonatal unit and whose medication has been continued after discharge. Main study - Parents/Carers of babies receiving care on a neonatal unit who will

require medication to be continued after discharge home from the hospital. Staff on neonatal units including nurses, ANNPs, doctors, pharmacists and pharmacy technicians.

What does the study involve?
The main part of PADDINGToN-2 is a feasibility study which involves parents and carers answering brief questionnaires before and after their baby has been discharged home. There are three extra optional parts. Parents can decide whether to take part in all three or just some of them.
• Filling in a diary: diary study completed over the 12 weeks
• Conversation at a clinic visit: completed at 4 weeks after discharge home
• Interview about the medicines information - Reflection/feedback and acceptability: completed within a month of completing the main (feasibility) study

What are the possible benefits and risks of participating?
The use of the PADDINGToN medicines information resources aims to benefit parents and carers of babies who have been in a neonatal unit.

There are no expected benefits or risks for participants. No identifiable information will be collected, ensuring that all interview data remains anonymous. The information provided will help improve the design of future studies. It is hoped that the use of medicines information resources will benefit parents and carers in the future.

To understand participants' anxiety and confidence regarding medicines, questions will be asked about their experiences. Validated questionnaires will be used, and the wording of any new questions will be checked by other neonatal parents. It is not anticipated that these questions will be distressing, but participants are free to skip any questions they do not wish to answer. If any distress does occur, support details will be provided.

Where is the study run from?
Alder Hey Children’s NHS Foundation Trust (Lead site and study Sponsor)

When is the study starting and how long is it expected to run for?
September 2022 to June 2026

Who is funding the study?
The National Institute for Health and Care Research (NIHR) Research for Patient Benefit (RfPB)

Who is the main contact?
Dr Louise Bracken, Louise.Bracken@alderhey.nhs.uk

Study website
https://www.alderhey.nhs.uk/research/collaborations/paediatric-medicines

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
332404

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
CPMS 57808, NIHR206233

Study information

Scientific Title
Parent co-Designed Drug Information for parents and Guardians Taking Neonates home (PADDINGToN 2) – a Feasibility Study

Acronym
PADDINGToN-2

Study objectives
PADDINGToN-1 developed clear, understandable information about neonatal medicines administration in the home setting. The overarching question is whether the implementation of these resources makes a tangible difference to parents regarding anxiety, confidence and improved safe administration of medicines at home. This question will be the focus of a future Randomised Controlled Trial (RCT). Before conducting this RCT, a feasibility study (PADDINGToN-2) is required to assess aspects of feasibility including maximising parent recruitment and retention. These data will inform the design of the RCT and help determine the most appropriate outcome measures. Once the feasibility and acceptability of the intervention is established, a full RCT will be conducted to determine the effectiveness of the PADDINGToN resources in a randomised, controlled setting.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 24/07/2024, North West - Greater Manchester South Research Ethics Committee (Piccadilly Place, Manchester , M1 3BN, United Kingdom; +44 (0)207 104 8014; gmsouth.rec@hra.nhs.uk), ref: 24/NW/0185

Study design
Non-randomized mixed methods feasibility study involving quantitative qualitative and co-design research methods

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital, Internet/virtual

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Whether giving information resources about medicines helps parents/carers take their baby home from a neonatal unit

Interventions
Current interventions as of 25/04/2025:
The study will involve 3 work packages:

Work Package A- The preparatory phase will start with establishing the resources on an electronic platform (vCreate), allowing translation into 12 languages. The study management group and literature review will inform the implementation method for neonatal units (NNUs). Semi-structured interviews with PADDINGToN Parent Advisory Group (PPAG) members and other targeted groups will explore views on recruitment, retention, data collection and tools. Analysis of transcribed interviews will use reflexive thematic analysis.

Work Package B - The feasibility phase will establish recruitment (target n=75) and retention (target n=52) rates. Reasons for attrition will be determined, and fidelity of the intervention will be tested over time and in NNUs of varying clinical designation using direct observation and feedback from parents. Parental anxiety and confidence will be assessed using a variety of tools. There are 3 optional study arms. Healthcare utilisation patterns and any association between parental confidence and medication errors will be explored in a subgroup of participants (10-15).

Work Package C: The Reflection phase will involve qualitative exploration of participant perspectives, both HCPs (10-15)and parents (10-15) on feasibility and utility of the intervention. The parent interviews will be conducted within a month of the parent completing the feasibility study. Acceptability will be assessed using Sekhon's Theoretical Framework of Acceptability. Development of an application for an RCT will also be undertaken during this phase

Parents will be asked to consent to their preferred method of contact: email, telephone, or receive SMSs via a third-party messaging service as part of the PADDINGToN-2 study. They will be asked to state their preferred method(s) on the consent form.

Previous interventions:
This project will be divided into three work packages:

Work package 1 - Project management and coordination: including oversight of Study Management Group (SMG) and Research Delivery Group (RDG), protocol development, regulatory approvals (REC, HRA), site/investigator coordination, ongoing family communication, monitoring participant recruitment, risk management and budget management.

Work package 2 - Stakeholder mapping, development of e-surveys and focus groups: Healthcare Professionals (HCPs) in national and international sites and parent/carer networks will be identified and contacted via an e-survey to identify issues faced by parents/carers of neonates and currently available or effective practices. Online interviews or face-to-face focus groups with parents/carers of premature babies with experience of transitions of care will explore these themes.

Work package 3 - Co-design of resources, evaluation and final dissemination: Caregivers willing to co-design educational and informative resources will be recruited, ensuring that content specificity, relevance and appropriate language are used in the new resources.

A mixed methods evaluation with a different group of parents/carers will explore the utility (qualitative exploration), efficacy (quantitative evaluation of knowledge acquisition) and ease of implementation (including feedback on training needs) of the educational resources developed.

HCPs will also be asked to evaluate the ease of implementation of resources. The effect size of outcomes may inform a larger effectiveness study. A multi-modal dissemination programme will ensure results are made available to stakeholders, including peer-reviewed publications.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The primary outcome measure is to recruit 75 participants in 12 months and measure the attrition rate of participants who remain in the study until the end of the follow-up at 3 months

Secondary outcome measures
1. Parental anxiety, self-efficacy and confidence data measured using the GAD-7 questionnaire at baseline and 12 weeks and a short Likert scale at 1-2 weeks, 4-6 weeks, 8 weeks
2. Acceptability assessment of the intervention sub-group of participants measured using short interviews or questionnaires and Sekhon's Theoretical Framework of Acceptability at the end of the study
3. Number of medication errors identified and relationship to parental confidence measures measured using a conversation with an HCP and demonstration of dose measurement at baseline and 4 weeks post-discharge
4. Healthcare utilisation by families following discharge measured using parent diaries throughout the 3-month study period

Overall study start date
01/09/2022

Completion date
23/06/2026

Eligibility

Key inclusion criteria
1. PPAG - Parents/Carers whose baby has recently (ideally within 2 years but up to 5 years) been discharged from the neonatal unit and whose medication has been continued after discharge
2. WPB - Parents/Carers of babies receiving care on a neonatal unit who will require medication to be continued after discharge home from the hospital
3. WPC- Parents/Carers (10-15) and HCPs (10-15) who completed Work Package- B (WP-B) Feasibility
4. All WPs - Parents/Carers who do not speak any English will be eligible to take part in the interviews. Translation services will be provided to facilitate this

5. Community Parent Champions and community health care professionals
6. HCPS providing neonatal care in any of the four study sites or stakeholder groups from PADDINGToN1

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 145; UK Sample Size: 145

Key exclusion criteria
1. Parents/Carers whose baby’s medication is likely to stop before discharge
2. Parents/Carers whose baby has a terminal diagnosis of a severe congenital abnormality or critical illness (unlikely to survive)
3. Parents/Carers unwilling to have audio-visual recordings of focus groups/interviews
4. HCPs not providing care to neonates requiring medicines

Date of first enrolment
01/10/2024

Date of final enrolment
31/03/2026

Locations

Countries of recruitment
England

Northern Ireland

United Kingdom

Study participating centre
Alder Hey Children's NHS Foundation Trust
Alder Hey Hospital
Eaton Road
West Derby
Liverpool
United Kingdom
L12 2AP

Study participating centre
Wirral University Teaching Hospital NHS Foundation Trust
Arrowe Park Hospital
Arrowe Park Road
Upton
Wirral
United Kingdom
CH49 5PE

Study participating centre
Liverpool Women's NHS Foundation Trust
Liverpool Womens Hospital
Crown Street
Liverpool
United Kingdom
L8 7SS

Study participating centre
Leeds Teaching Hospitals NHS Trust
St. James's University Hospital
Beckett Street
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LS9 7TF

Sponsor information

Organisation
Alder Hey Children's NHS Foundation Trust

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Alder Hey Hospital, Eaton Road, West Derby
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kelly.davies@alderhey.nhs.uk

Sponsor type
Hospital/treatment centre

Website

https://www.alderhey.nhs.uk/

ROR
https://ror.org/00p18zw56

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme

Alternative Name(s)
NIHR Research for Patient Benefit Programme, RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
31/05/2027

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available because the sharing of datasets was not a provision within the protocol and the consent forms for the study's different work packages. The provision states that data collected will only be included, after analysis, in study reports or publications.

IPD sharing plan summary
Not expected to be made available