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Comfortable Babies and Comforting Parents

Submission date
10/02/2011

Recruitment status
No longer recruiting

Registration date
22/02/2011

Overall study status
Completed

Last Edited
25/04/2012

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
05NS16

Study information

Scientific Title
Comfortable Babies and Comforting Parents: A randomised controlled trial

Acronym
CBCP

Study objectives

Parents of Neonatal Intensive Care Unit (NICU) infants who receive an intervention to increase parental involvement in infant comfort care will have less NICU-related stress (primary outcome) compared to parents who do not receive the intervention

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institute of Child Health/Great Ormond Street Hospital Research Ethics Committee approved on: 1st November 2006, ref: 06/Q0508/114

Primary study design
Interventional

Study design
Multisite randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
NICU-related stress for parents

Interventions
Intervention and Control Group Activities

1. As part of usual care, parents in both the intervention and control groups received a detailed booklet with generic information about NICU care (Parent Information Guide, published by Bliss, London, UK)
2. Parents in the intervention group received an additional booklet that provided evidence-based information about pain and comforting infants in the NICU setting. The Comforting Your Baby in Intensive Care booklet contains information in lay language on the following 5 topics:
2.1. How acute pain occurs and how it may affect infants
2.2. How infant pain is assessed and managed in the NICU
2.3. The important role parents can play in providing infant comfort
2.4. Specific instructions on comforting techniques for parents to use with their infants (e.g. skin-to-skin holding or non-nutritive sucking during heel puncture)
2.5. Advice on how parents can work in partnership with NICU staff to achieve optimal infant comfort
3. Intervention group parents also received 2 visits (approximately 45 minutes) from a research nurse to show them how to apply the comforting techniques described in the booklet. Parents were encouraged to ask nurses caring for their baby if they require further instruction.
4. Parents in the control group also received 2 visits (approximately 45 minutes) from a research nurse to listen to what parents had to say about their NICU experience (attention placebo)

A four hospital multisite restricted allocation was used, with the four NICU's match-paired and randomly assigned to the intervention or control conditions.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Parent Stressor Scale: NICU (PSS:NICU) (Miles, 1998)- A measure of NICU-related stress, 47-item self-report scale.
1.1. Scores range 1-5, for each item
0 = not applicable
higher mean score indicate higher overall stress

1.2. Subscale scores in 4 dimensions:
Infant appearance
Parental role alteration
NICU environment
Staff communication

Key secondary outcome(s)
1. Parent Attitudes about Infant Nociception (PAIN) (Franck, 2004)-A measure of parental views about infant pain and its treatment, 38-item self-report scale. Consists of scale, forced choice and free-text response items to describe parents: perceptions and concerns about infant pain and pain treatment; actual and desired level of involvement in infant pain assessment and comfort; satisfaction with staff management of infant comfort.

2. Self-Efficacy in Infant Care (SICS) (Froman, 1989)-A measure of perceived confidence and competency in infant caregiving, 40-item self-report scale (rated 0-10). Total scores range from 0-100; higher scores indicate increased parental confidence in their knowledge and skills with infant care activities in the domains of: development, diet, health and safety.

3. What Being a Parent of a New Baby is Like Revised (WBPBL-R) (Pridham, 1989)- A measure of perceptions of parental role attainment and caregiving performance, 25-item self-report scale. Scores range from 1-9 for each item; higher mean scores indicate more positive perceptions of themselves as parents and of the parenting experience, with subscale scores in 3 dimensions: evaluation (how well parent is meeting own expectations of parenting), centrality (how much the infants care and health on the parents mind) and life change (impact of infant on parents life).

4. Frequency of pain assessment documentation by nurses- Chart audit of the nursing notes. Coded as 0=no notation of pain assessments performed, 1=intermittent pain assessment documentation (by notation or pain scale), 2 = frequent pain documentation (3 or more days).

Completion date
01/08/2009

Eligibility

Key inclusion criteria
1. All parents of infants admitted to the NICUs who were over 16 years of age
2. All parents who could read and speak English

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Parents with documented psychological or psychiatric conditions
2. Parents of those infants expected to be transferred to another hospital within 10 days of admission

Date of first enrolment
20/10/2006

Date of final enrolment
01/08/2009

Locations

Countries of recruitment
United Kingdom

United States of America

Study participating centre
Family Health Care Nursing
San Francisco, CA
United States of America
94143

Sponsor information

Organisation
University College London (UCL) Institute of Child Health (UK)

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name
BLISS - The premature baby charity (UK)

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?
Results article	results	01/09/2011		Yes	No