

# Comfortable Babies and Comforting Parents

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<b>Registration date</b> 22/02/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 25/04/2012	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

### **Study design**

Multisite randomised controlled trial

### **Primary study design**

Interventional

### **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?
<a href="#">Results article</a>	results	01/09/2011		Yes	No