Parent Involvement in Pain Management for NICU Infants: A Randomized Controlled Trial

WHAT'S KNOWN ON THIS SUBJECT: Parents worry about the emotional and physical pain of hospitalized, high-risk infants, and this worry is associated with higher levels of parental stress. Parents want more information and greater involvement in infant pain prevention and management.

WHAT THIS STUDY ADDS: Increased parental involvement in infant pain management is feasible and enhances parental confidence with their parenting role after discharge. Parental stress during the NICU stay was not reduced, but satisfaction with pain information and preference for involvement were both increased.

abstract

OBJECTIVES: To demonstrate feasibility and estimate the effect of an intervention to increase parental involvement in infant pain management in the NICU on parents' stress and postdischarge parenting competence and confidence.

METHODS: The study involved a randomized controlled trial. Parents recruited from 4 NICUs were randomly assigned by site to receive (1) a pain information booklet and instruction on infant comforting techniques ($n = 84$ intervention) in addition to a generic NICU care booklet or (2) the generic NICU care booklet alone ($n = 85$ control). The primary outcome was postintervention Parent Stressor Scale: NICU (PSS: NICU) scores. Secondary outcomes included parent attitudes about infant pain, nursing pain assessment, and parenting competence and role attainment after discharge.

RESULTS: No differences were found between groups in PSS:NICU scores. Significant differences favoring the intervention group were found for satisfaction with pain information, parents shown infant pain cues and comforting techniques, nursing pain assessment, and parent preference for involvement during painful procedures. Role attainment after discharge was higher for the intervention group than for the control group. Both the intervention and control groups highly valued attention to infant pain and wanted information and involvement.

CONCLUSIONS: These results provide no evidence of a reduction in NICU-related stress for parents who receive an intervention to increase their understanding and involvement in infant pain management. However, parents in the intervention group were better prepared to take an active role in infant pain care and had more positive views about their role attainment in the postdischarge period. *Pediatrics* 2011;128:510–518

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KEY WORDS

NICU, neonates, parental stress, pain, randomized controlled trial

ABBREVIATIONS

PSS—Parent Stressor Scale
SICS—Self-efficacy in Infant Care Scale
WBPBL-R—What Being a Parent of a New Baby Is Like–Revised
CI—confidence interval

This trial has been registered at www.clinicaltrials.gov (identifier ISRCTN87094922).

www.pediatrics.org/cgi/doi/10.1542/peds.2011-0272

doi:10.1542/peds.2011-0272

Accepted for publication May 20, 2011

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PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FINANCIAL DISCLOSURE: *The authors have indicated they have no financial relationships relevant to this article to disclose.*

Our previous research in NICUs revealed that parents expect prevention of pain and that their worry about infant pain is associated with higher stress levels.[1–4] Other studies have revealed that parental perceived incompetence (ie, feeling helpless, not being able to protect the infant, and not knowing how to help the infant) are sources of stress for parents of high risk infants.[5–7] Parent-delivered comfort interventions have been shown to be effective in reducing infant pain responses.[8–10] Emotional distress about infant suffering in the NICU may sensitize parents to children's pain and lead to maladaptive coping styles.[11] In the home environment, parents are critical in helping infants to manage their stress reactivity and develop self-regulatory skills.[12] This occurs through regular provision of comforting touch and other methods to soothe the infant and reduce his/her distress.[13] In the NICU, such opportunities for parent-infant interaction may be limited, especially if the infant is critically ill. As a result, parents may not develop skills in soothing and comforting and infants may not develop essential self-regulatory skills. Parenting an infant who spends the first few weeks of life in the NICU is a transitional process, which can be enhanced by targeted support from health care staff.[14]

Providing detailed pain information to adults undergoing surgery has been found to decrease pain-related interference with activity and worry about pain in the postoperative period.[15] However, specific communication strategies regarding one of the most important concerns of parents (ie, relief of their child's pain) have not been evaluated. Increased parental involvement in their infant's pain care while in the NICU may help to reduce parental distress and better prepare parents to manage the infant's distress after discharge. In addition, the increased involvement of parents might influence the attention that nurses give to the assessment of infant pain and improve the generally poor rates of pain assessment documentation seen in numerous studies.[16] Therefore, we set out to investigate whether meeting parents' expressed desire for more information and involvement in infant pain management could reduce parental stress. The aims of the study were to demonstrate the feasibility and estimate the effect of an intervention to increase parental involvement in pain management for NICU infants in relation to (1) parents' NICU-related stress (primary outcome), (2) parental attitudes about infant pain and involvement, (3) nursing pain assessment, and (4) parenting competence and role attainment after discharge.

METHODS

Allocation of Intervention Group

Because of the nature of the intervention and the potential for contamination of the control group with intervention information (from written materials, parents, and staff), it was not appropriate to randomly allocate individual parents simultaneously to either intervention or control. Therefore, the unit of randomization was the hospital. Restricted allocation was used first to divide the 4 NICUs into strata according to baseline characteristics (medical-surgical mix, percent inborn, ethnic mix). Then, the units were match-paired and randomly assigned to the intervention or control conditions. To detect a clinically significant difference between groups of 0.5 SDs in the primary outcome measure, the Parent Stressor Scale: NICU (PSS:NICU), with 80% power and at the 5% significance level, we needed 27 parents in each group (54 in total). Because this was a new area of research, we chose to recruit a larger sample (3 times the sample size estimate; 82 parents per group; 41 per site) for investigation of feasibility of training and implementation as well as to explore potentially influencing variables and account for expected loss to follow-up after NICU discharge. Approval for the study was obtained from an authorized committee of the United Kingdom National Research Ethics Service, and written informed consent was obtained from all parents.

Study Measures

In Table 1 we provide details on the main measures and measurement intervals for the study. The primary outcome was the PSS:NICU, a well-validated self-report instrument that measures NICU-related parent stress.[5,17] The secondary outcomes of interest during the NICU stay were parental views on infant pain and its treatment as measured by the Parent Attitudes About Infant Nociception survey.[3] In addition, we explored the impact of parent involvement in infant comfort on nursing pain assessment documentation practices.

Outcomes of interest after discharge included parental confidence and competence in infant caregiving activities as measured by the Self-efficacy in Infant Care Scale (SICS)[18,19] and parental perceptions of role attainment as measured by the What Being a Parent of a New Baby Is Like–Revised (WBPBL-R).[20] Additional measures obtained because of their potential influence on the outcomes of interest included the Spielberger State Trait Anxiety Index,[21] Edinburgh Postnatal Depression Scale,[22] and Measure of Support social support scale.[23] Questions about parent age, ethnicity, other children, the pregnancy, and the birth were included in the baseline questionnaire. Clinical data were collected from the medical charts of infants on admission, with each research nurse visit, and at discharge. Adverse events, de-

TABLE 1 Study Measures

Constructs/Details of Instrument	Measurement Frequency
Primary outcome	
PSS:NICU[5]	
NICU-related stress: 47-item self-report scale. Scores range 1–5, for each item (0: not applicable); higher mean score indicates higher overall stress, with subscale scores in 4 dimensions: infant appearance; parental role alteration; NICU environment; and staff communication	Before and ~1 wk after intervention (Questionnaires 1 and 2)
Secondary outcomes	
Parent Attitudes About Infant Nociception[3]	
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	Before and ~1 wk after intervention (Questionnaires 1 and 2)
SICS[18,19]	
Perceived confidence and competency in infant caregiving: 40-item self-report scale (rated 0–10). Total scores range from 0 to 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 mo after infant discharged to home (Questionnaire 3)
WBPBL-R[20]	
Perceptions of parental role attainment and caregiving performance: 25-item self-report scale. Scores range from 1 to 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 infant's care and health on the parent's mind); and life change (impact of infant on parent's life).	~3 mo after infant discharged to home (Questionnaire 3)
Frequency of pain assessment documentation	
Pain assessment practices 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 d)	1-wk period before the second research nurse visit with parents
Potentially influencing factors	
Spielberger State-Trait Anxiety Index[21]	
State anxiety (response to present situation) and trait anxiety (predisposition to be anxious): 40-item (20 items each dimension) self-report scale. Scores range 20–80, with higher scores indicating greater levels of anxiety	Before the intervention and ~3 mo after infant discharged to home (Questionnaires 1 and 3)
Edinburgh Postnatal Depression Score[22]	
Psychological state in the early postnatal period: 10-item, 4-point self-report scale, with higher scores indicating greater risk of perinatal depression	~3 mo after infant discharged to home (Questionnaire 3)
Measure of Support[23]	
Social support: 27-item, 5-point self-report scale, with higher scores indicating greater perceived social support in 4 domains: emotional/informational support; tangible support; affectionate support; and positive social interaction	~3 mo after infant discharged to home (Questionnaire 3)

fined as hospital clinical incident reports involving (1) harm to infants related to parent contact during pain management or (2) parents' distress, were monitored throughout the study period. Parents completed a brief questionnaire about the infant's health at home.

Intervention and Control Group Activities

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 [Bliss, London, United Kingdom]). 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 Infant in Intensive Care" booklet contains information in lay language on 5 topics: (1) how acute pain occurs and how it may affect infants; (2) how infant pain is assessed and managed in the NICU; (3) the important role parents can play in providing infant comfort; (4) specific instructions on comforting techniques for parents to use with their infants (eg, skin-to-skin holding or nonnutritive sucking during heel puncture); and (5) advice on how parents can work in partnership with NICU staff to achieve optimal infant comfort. The booklet was developed in consultation with 42 experts in neonatology and developmental care in Europe, the United States, and Australia. With assistance from Bliss, 12 parents of infants who had been cared for in NICUs in the United Kingdom reviewed the content and presentation of the booklet.

Intervention group parents also received 2 visits (~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 infant if they required additional instruction. Parents in the control

group also received 2 visits (~45 minutes) from a research nurse to listen to what parents had to say about their NICU experience (attention placebo).

Nursing and medical staff in the 4 participating NICUs received written information and/or attended in-service training regarding the study protocol, with the details of the parent involvement and comforting techniques discussed only with the staff from the NICUs assigned to the intervention group. There was >80% compliance with attendance at the sessions. Research nurses attended a 2-day training session, and regular audits were performed to ensure the fidelity of the intervention and control group procedures.

Procedures

All parents of infants admitted to the NICUs who were older than 16 and who could read and speak English were eligible for participation. Parents with documented psychological or psychiatric conditions, and those of infants expected to transfer to another hospital within 10 days of admission, were excluded.

Within 3 to 7 days of admission, parents in both groups completed a baseline questionnaire. Then, they received the intervention or control booklets, and the first visit was scheduled. After the second visit (~1 week later), parents completed a second questionnaire. Parents completed a mailed questionnaire ~3 months after discharge (Table 1). For twin or triplet infants, parents were instructed to respond in relation to the infant designated as being most ill on admission. Research nurses completed forms after each visit and these were audited regularly to monitor compliance with the intervention and control protocols.

Analyses

All parents were analyzed in their assigned group, irrespective of compliance. Only the primary respondent parent (defined as the first parent to consent) was included in the analyses. Descriptive statistics are reported as mean (SD) or *n* (%) for consistency. Student's *t* tests were used to identify significant differences between groups. For continuous variables, we calculated the mean difference between groups and 95% confidence intervals (CIs). For ordinal variables, *P* values were derived from χ^2 or Mann-Whitney U statistics. A general linear modeling procedure was used to estimate group differences and corresponding 95% CIs, adjusting for variables where there were significant baseline group differences and which were associated with the outcomes.

RESULTS

Enrollment, Follow-up and Compliance

Between April 2007 and April 2009, we recruited parents of infants who received care in 4 NICUs in Greater London. During the study period, 2129 infants were admitted across the 4 sites. Of these, 1653 were excluded because they did not meet inclusion criteria primarily because of expected discharge or transfer to another hospital within 10 days of admission. Of the 476 eligible families, 68 infants (14%) died, were transferred to another hospital, or were discharged from the hospital after parents had been approached but before obtaining consent. Re-

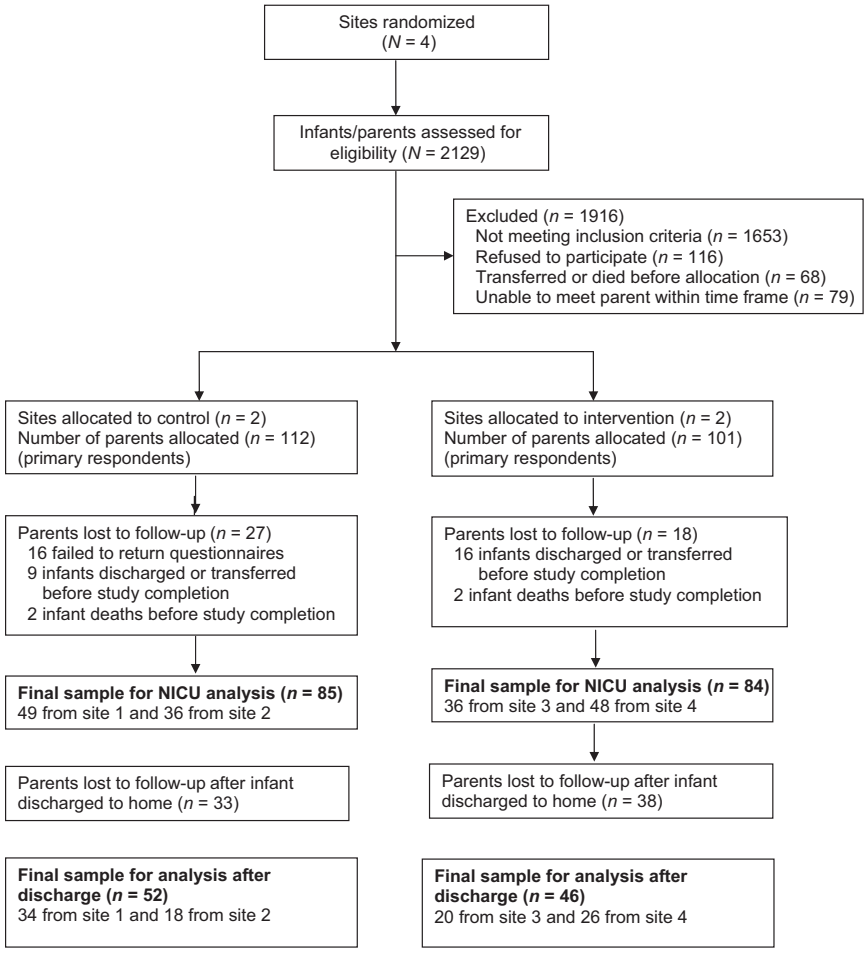

FIGURE 1
Consolidated Standards of Reporting Trials (CONSORT) flowchart.

TABLE 2 Baseline Characteristics of Primary Parent

	Control ($N = 85$)		Intervention ($N = 84$)	
From each site (%)	49 (57.7)	36 (42.4)	36 (42.9)	48 (57.1)
Mother was primary respondent, *n* (%)	81 (95.3)		82 (96.7)	
English not first language, *n* (%)	17 (20.5)		17 (20.2)	
Age, mean (SD), y	32.3 (5.8)		31.3 (5.9)	
Ethnicity, *n* (%)[a,b]				
White	57 (67.1)		43 (51.2)	
Asian	15 (17.7)		6 (7.1)	
Black	8 (9.4)		29 (34.6)	
Other	5 (5.8)		6 (7.1)	
Born outside the United Kingdom, *n* (%)	30 (35.7)		39 (47.0)	
Highest level of education was tertiary, *n* (%)	52 (62.7)		55 (72.3)	
Employed outside home, *n* (%)	59 (69.4)		55 (65.5)	
Current health (1, generally healthy, to 5, frequently unwell), mean (SD)[b]	1.41 (0.77)		1.42 (0.86)	
First infant, *n* (%)	57 (68.7)		49 (59.0)	
Medical problems with the pregnancy, *n* (%)[a]	65 (76.5)		45 (53.6)	
Prenatal diagnosis of infant condition, *n* (%)	6 (7.1)		1 (1.2)	
Normal vaginal delivery, *n* (%)	42 (49.4)		37 (44.0)	
Able to hold the infant >24 h after birth, *n* (%)[c]	45 (54.2)		58 (71.6)	
Able to visit infant several times per day, *n* (%)	68 (80.0)		60 (71.4)	
Perceived severity of illness of infant (0, low risk of dying, to 5, high risk of dying), mean (SD)[b]	1.11 (1.12)		1.27 (1.41)	
Satisfaction with NICU care (1, very satisfied, to 6, very unsatisfied), mean (SD)[b]	1.51 (0.76)		1.45 (0.71)	
State anxiety (20–80), mean (SD)[c]	48.4 (14.9)		42.7 (16.5)	
Trait anxiety (20–80), mean (SD)	38.2 (11.1)		36.6 (12.6)	
PSS:NICU (range: 1–5), mean (SD)	2.64 (0.73)		2.57 (0.68)	
How stressful is NICU experience (1, not stressful, to 5, extremely stressful), mean (SD)	3.96 (1.06)		3.95 (1.13)	

[a] Imbalance between control and intervention groups: $P < .001$.
[b] *P* values were derived from nonparametric tests.
[c] Imbalance between control and intervention groups: $P < .05$.

search nurses were unable to contact parents of 79 (17%) eligible infants; 116 parents declined to participate (24%). The most common reasons for refusal were too busy, study perceived as too time consuming, or blanket refusal to consider any research.

The 213 primary respondents were allocated according to site to the control ($n = 112$) or to the intervention ($n = 101$) groups. In 44 cases (21%), parents did not complete the study protocol. The final sample consisted of 169 parents, with $n = 85$ in the control group and $n = 84$ in the intervention group. No serious adverse events were reported, and no parents or infants were withdrawn from the study because of adverse effects of the intervention. The trial profile is shown in Fig 1.

NICU Outcomes

Baseline characteristics were similar for both groups with a few exceptions (Table 2). The control group consisted of more white (67% vs 51%) and Asian (18% vs 7%) participants but fewer black participants (9% vs 35%) than the intervention group. More control mothers had medical problems during pregnancy than did intervention mothers (80% vs 54%). The study outcomes did not differ on the basis of parent ethnicity or incidence of maternal medical problems.

There were differences between the control and intervention groups with regard to how soon after birth parents were able to hold their infants. More parents in the intervention group had to wait longer than 24 hours to hold their infant for the first time compared with control parents (71.6% vs 54.2%). Parents who did not hold their infants within 24 hours of birth had higher PSS:NICU scores (2.74 ± 0.72 vs 2.41 ± 0.69). Trait anxiety was similar between the 2 groups. However, parents in the intervention group had lower mean state anxiety levels at baseline compared with controls (42.7 vs 48.4). State anxiety was associated with higher PSS:NICU scores ($r = 0.35$; $P < .001$).

Baseline characteristics of the infants also differed according to group (Table 3). Control infants had a higher gestational age (31.9 vs 29.4 weeks) and birth weight (1.77 vs 1.26 kg) and were older at the time of the intervention (20.11 vs 15.56 days of age) compared with intervention group infants. There were fewer twins or triplets in the control group (11.8% vs 23.8%) and more intervention infants were receiving intravenous feeding (48.8% vs 18.8%). Only gestational age was associated inversely with higher PSS:NICU scores ($r = -0.16$; $P < .04$).

Delivery of the Intervention

Parents in the intervention group reported that they received more verbal and written information about pain ($P < .001$) and were more satisfied with the information received than control parents ($P < .001$). Parents in the intervention group more often reported that nurses showed infant pain cues and demonstrated specific comfort techniques compared with control parents (88% vs 75%; $P < .05$).

Parent Attitudes About Infant Pain and Pain Care

Parents in the intervention group perceived that their infant experienced slightly higher pain intensity and expressed a stronger preference to be present and/or actively involved during painful procedures (90% vs 75%;

TABLE 3 Characteristics of Infants

	Control ($N = 85$)		Intervention ($N = 84$)	
At baseline				
From each site (%)	49 (57.7)	36 (42.4)	36 (42.9)	48 (57.1)
Gestational age, mean (SD), wk[a]	31.94 (5.17)		29.40 (3.17)	
Birth weight, mean (SD), kg[a]	1.77 (0.95)		1.26 (0.48)	
Female gender, *n* (%)	41 (48.2)		50 (59.5)	
Twin or triplet, *n* (%)[b]	10 (11.8)		20 (23.8)	
Apgar score at 5 min, mean (range)[c]	9 (7–10)		9 (7–10)	
Most frequent diagnoses, *n* (%)				
Respiratory	36 (42.4)		48 (57.1)	
Gastrointestinal	40 (47.1)		20 (23.8)	
Cardiac	23 (27.1)		14 (16.7)	
Level of care, *n* (%)				
Intensive care	29 (34.1)		37 (44.1)	
High dependency	21 (24.7)		13 (15.4)	
Special care	35 (41.2)		34 (40.5)	
At first visit by research nurse				
Age, mean (SD), d[a,c]	20.11 (20.10)		15.56 (27.09)	
Intubated, *n* (%)	12 (14.1)		13 (15.5)	
Method of feeding, *n* (%)[a]				
Breast/bottle	11 (12.9)		3 (3.6)	
NG/GT tube	58 (68.2)		40 (47.6)	
Intravenous	16 (18.8)		41 (48.8)	
Postnatal complication score (0, none, to 7, severe), mean (SD)[c]	2.55 (2.38)		2.87 (1.61)	
Length of stay, mean (SD), d[c]	48.7 (47.69)		53.5 (43.94)	
Discharge destination, *n* (%)				
Home	57 (67.1)		62 (73.8)	
Another hospital	24 (28.2)		18 (21.4)	
Died	4 (4.7)		4 (4.8)	

NG indicates nasogastric; GT, gastrostomy.

[a] Imbalance between control and intervention groups: $P < .001$.

[b] Imbalance between control and intervention groups: $P < .05$.

[c] *P* values were derived from nonparametric tests.

$P < .01$). However, <25% of parents in either group reported being asked by clinical staff for their preferences to be present during painful procedures (Table 4), and there were no differences between the groups in how often they were asked their preferences to be present or in the frequency of their presence during painful procedures. There were no group differences related to satisfaction with infant pain care or confidence in ability of staff to manage infant pain and support parents (Table 4).

Parent Stress

There were no significant group differences in the mean unadjusted PSS: NICU scores (2.58 ± 0.75 [control] vs 2.62 ± 0.72 [intervention] [95% CI: −0.26 to 0.19]). Adjustment for baseline parent state anxiety, holding the infant within 24 hours of birth, and gestational age did not materially affect the result. The adjusted mean PSS: NICU scores for intervention group parents were 0.08 points higher (2.66 ± 0.73 vs 2.58 ± 0.75) than for

TABLE 4 Parent Attitudes About Infant Pain ~1 Week After the Intervention

Outcome	Control Group	Intervention Group	Difference in Means; Intervention—Control (95% CI)
Intervention delivery			
Received verbal information about pain control (1, a lot, to 4, none), mean (SD)[a,b]	3.00 (0.87)	1.88 (0.75)	−1.12 (0.87 to 1.37)
Received written information about pain control (1, a lot, to 4, none), mean (SD)[a,b]	3.51 (0.75)	2.10 (0.98)	−1.41 (1.15 to 1.68)
Satisfaction with information about pain control (1, very satisfied, to 6, very unsatisfied), mean (SD)[a,b]	3.28 (1.27)	2.10 (0.97)	−1.18 (0.83 to 1.53)
Nurses showed parent how to look for signs of pain (1, strongly agree, to 6, strongly disagree), mean (SD)[a,b]	4.04 (1.37)	2.70 (1.36)	−1.33 (0.91 to 1.76)
Nurses showed parent any comfort techniques, *n* (%)[b,c]	64 (75.3)	74 (88.1)	0.41 (0.18 to 0.94)
Parent asked preference to be present during painful procedure (always or often), *n* (%)[b]	19 (23.8)	15 (18.6)	0.73 (0.34 to 1.56)
Parent views on infant pain and pain care			
Confident staff can tell when infant in pain (1, strongly agree, to 6, strongly disagree), mean (SD)[b]	2.30 (1.16)	2.04 (1.0)	−0.26 (−.07 to 0.60)
Satisfied nurses make infant comfortable (1, strongly agree, to 6, strongly disagree), mean (SD)[b]	2.24 (1.01)	2.08 (1.05)	−0.15 (−0.16 to 0.47)
Satisfied pain medicines help infant (1, strongly agree, to 6, strongly disagree), mean (SD)[b]	2.04 (1.05)	1.98 (0.94)	−0.06 (−0.33 to 0.44)
Staff supportive of parent concerns about pain (1, strongly agree, to 6, strongly disagree), mean (SD)[b]	2.32 (0.98)	2.23 (1.01)	−0.09 (−0.24 to 0.42)
Parent preferences and presence during painful procedures			
Prefer to be present during painful procedures (always or often), *n* (%)[b,c]	62 (74.4)	73 (90.0)	3.09 (1.28 to 7.47)
Present during painful procedures (1, never, to 4, always), mean (SD)[b]	2.11 (0.76)	2.10 (0.69)	0.01 (−0.21 to 0.23)
Asked to be present during painful procedures (1, never, to 4, always), mean (SD)[b]	2.01 (0.99)	1.88 (0.89)	0.14 (−0.16 to 0.43

Parent attitudes about infant pain were selected from the Parent Attitudes About Infant Pain questionnaire.

[a] Differences between control and intervention groups: $P < .001$.

[b] *P* values were derived from nonparametric tests.

[c] Differences between control and intervention groups: $P < .05$.

control parents (95% CI: −0.34 to 0.11).

Nursing Pain Assessment Documentation

In 2 of the sites (1 intervention and 1 control group), no pain assessment information was documented in the nursing record for any infant in the week before the second research nurse visit. In the 2 sites where pain assessment documentation was recorded, the frequency of documentation in the week before the second research nurse visit was greater for the intervention group (91.7% [33 of 36 infants]) compared with controls (37% [18 of 49 infants]). The odds ratio was 18.9 (CI: 5.1–70.7).

Parenting Stress at Home

Fifty-eight percent ($n = 98$) of parents returned the postdischarge questionnaires, and 83 parents were lost to follow-up (control group $n = 43$; intervention group: $n = 40$). Baseline characteristics were similar for both groups, with a few exceptions (Table 5). The control group consisted of more white participants (81% vs 56%) but fewer black participants (6% vs 31%), and fewer parents were born outside the United Kingdom (25% vs 43.5%). More control mothers had medical problems during pregnancy than intervention mothers (81% vs 54%). SICS or WBPBL-R scores did not differ according to parent ethnicity or incidence of maternal medical problems. More parents in the intervention group had to wait longer than 24 hours to hold their infant for the first time compared with control parents (73.3% vs 49.0%). Parents who did not hold their infants within 24 hours of birth had higher SICS scores (92.90 ± 7.57 vs 88.1 ± 8.23). There were no differences between the groups for other parental characteristics.

Baseline characteristics of the infants differed according to gestational age and birth weight at the time of completion of the home questionnaire because control infants had been discharged at a younger age compared with infants in the intervention group (Table 5). The 2 groups did not differ with respect to general health or need for medical care. Gestational age was negatively associated with SICS and WBPBL-R scores ($r = -0.19$ and -0.22, respectively; $P < .05$), whereas postnatal age was positively associated only with SICS score ($r = 0.24$; $P < .05$).

TABLE 5 Characteristics of Trial Participants Who Completed the Postdischarge Questionnaire

	Control ($N = 52$)		Intervention ($N = 46$)	
From each site, *n* (%)	34 (34.7)	18 (18.4)	20 (20.4)	26 (26.5)
Respondent				
Mother was primary respondent, *n* (%)	50 (96.2)		46 (100)	
English not first language, *n* (%)	7 (13.5)		9 (19.6)	
Age, mean (SD), y[a]	33.94 (5.80)		31.13 (5.92)	
Ethnicity,[b,c] *n* (%)				
White	42 (81)		25 (56)	
Asian	5 (9)		5 (11)	
Black	3 (6)		14 (31)	
Other	2 (4)		1 (2)	
Born outside the United Kingdom, *n* (%)[a,c]	13 (25)		20 (43.5)	
Highest level of education was tertiary, *n* (%)	31 (59.6)		29 (63)	
Employed outside home, *n* (%)	36 (69.2)		28 (60.9)	
First infant, *n* (%)	32 (62.7)		29 (64.4)	
Medical problems with the pregnancy, *n* (%)[b]	42 (81)		25 (54)	
Able to hold infant >24 h after birth, *n* (%)[a,c]	25 (49.0)		33 (73.3)	
State anxiety at home (20–80), mean (SD)	33.12 (12.29)		30.18 (10.43)	
Trait anxiety at baseline (20–80), mean (SD)	36.51 (10.54)		35.69 (13.74)	
Baseline PSS:NICU (range: 1–5), mean (SD)	2.52 (0.73)		2.55 (0.75)	
Current health (1, generally healthy, to 5, frequently unwell), mean (SD)[c]	1.27 (0.64)		1.46 (0.84)	
MOS, mean (SD)	4.01 (0.96)		4.06 (0.86)	
EPDS, mean (SD)	9.39 (2.36)		9.87 (3.07)	
Infant characteristics				
Gestational age, mean (SD)[b]	32.53 (4.89)		29.03 (2.82)	
Birth weight, mean (SD), kg[b]	1.83 (0.91)		1.24 (0.49)	
Female gender, *n* (%)[a,c]	25 (48.1)		32 (69.6)	
Twin or triplet	17 (13.5)		11 (23.9)	
Postnatal complication score (0, none, to 7, severe), mean (SD)[c]	2.16 (2.32)		2.65 (1.36)	
Postnatal age, mean (SD), wk[a]	14.74 (6.66)		18.67 (8.54)	
Length of time at home, mean (SD), wk	8.71 (4.94)		5.75 (0.86)	
Infant's current health (1, generally healthy, to 5, frequently unwell), mean (SD)[c]	1.39 (0.08)		1.33 (0.56)	
No. of medicines, mean (SD)	2.35 (2.79)		1.87 (1.63)	
Routine health care visits once per week or more, *n* (%)	24 (48.1)		23 (50)	
Medical care at home, *n* (%)	6 (11.8)		8 (17.4)	
Hospital stay since discharge, *n* (%)	9 (18.0)		5 (10.9)	

MOS indicates Measure of Support; EPDS, Edinburgh Postnatal Depression Scale.
[a] Differences between control and intervention groups: $P < .05$.
[b] Differences between control and intervention groups: $P < .001$.
[c] *P* values were derived from nonparametric tests.

Parent Confidence and Perceptions of Caregiving

There were no significant group differences on the SICS; however, there was a difference in the WBPBL-R ($P = .03$) (Table 6). Adjustment for gestational age reduced the significance of the results. The mean adjusted WBPBL-R scores were 0.33 higher for the intervention parents compared with controls (95% CI: −0.55 to 0.09), which indicates better role attainment and caregiving performance in relation to

TABLE 6 Unadjusted Outcomes Measures After Discharge Home

Outcome	Control Group, *n*	Intervention Group, *n*	Control Group, Mean (SD)	Intervention Group, Mean (SD)	Difference in Means; Intervention—Control (95% CI)
SICS (range: 0–100)	52	46	90.99 (6.71)	91.25 (9.49)	−0.26 (−3.53 to 3.01)
WBPBL-R (range: 1–9)	52	46	7.20 (0.75)	7.52 (0.71)	−0.33 (−0.62 to −0.04)
Parent views on the NICU experience and infant pain					
How stressful was the NICU experience (1, not stressful, to 5, extremely stressful)	49	40	4.04 (1.02)	4.07 (1.07)	−0.03 (−0.47 to 0.41)
Confident staff can tell when infant in pain (1, strongly agree, to 6, strongly disagree)[a]	51	46	2.29 1.04)	2.13 (1.20)	0.16 (−.29 to 0.62)
Satisfied nurses make infant comfortable (1, strongly agree, to 6, strongly disagree)[a]	51	46	2.08 (1.04)	1.78 (0.92)	0.30 (−0.10 to 0.69)
Satisfied pain medicines help infant (1, strongly agree, to 6, strongly disagree)[a]	38	33	2.26 (0.98)	1.88 (0.99)	0.38 (−0.08 to 0.85)
Staff supportive of parent concerns about pain (1, strongly agree, to 6, strongly disagree)[a]	50	41	2.24 (1.02)	1.90 (0.92)	0.34 (−0.07 to 0.75)

[a] *P* values were derived from nonparametric tests.

their expectations. Parents in both groups recalled the NICU experience as very stressful, were satisfied with infant pain care, and were confident in the ability of staff to manage infant pain and support for parents (Table 6).

DISCUSSION

This is the first trial to our knowledge of an intervention specifically targeted at increasing parent understanding and involvement in pain management for NICU infants. Feasibility of the approach was demonstrated, and no adverse effects were found. The intervention aimed to inform and involve parents in 1 particular aspect of their parental role: providing comfort to their infant. This differed substantially from previous studies in which interventions were tested that were aimed at informing parents more generally about preterm infant development and increasing parental sensitivity in caregiving.[14,24] Although we found no effect of the intervention on parent stress during the NICU stay, there was a small positive effect on parents' views about their role attainment and increased satisfaction with caregiving in the early post discharge period.

Others[25] have shown parent and nurse acceptance of increased parental involvement in pain care using 1 specific technique: facilitated tucking by parents. Although the multifaceted intervention in this study was well accepted by parents and NICU staff, some staff suggested that there may have been too many different options to demonstrate to parents. The lack of effect on parent stress may also be a result of an insufficient dose of the intervention (2 visits with a research nurse). Parents may need more time with staff to assist in applying techniques with their own infant over the course of the NICU stay. Furthermore, parents (especially low literacy parents) may need better visual aids to fully comprehend the various comfort techniques. Moreover, the measures may have not been sufficiently sensitive to detect a difference in parental stress or parenting competence postdischarge.

The relationship between parent involvement in infant pain management and other forms of parent involvement in infant caregiving in the NICU deserve additional research. This is particularly so in light of our findings and those of Kleberg et al,[26] who found that mothers who participated in a Newborn Individualized Developmental Care and Assessment Program reported feeling closer to their infants but also experienced a higher level of anxiety than mothers who did not participate in the program.

Although we demonstrated a significant increase in the intervention group's perceived knowledge and satisfaction with infant comfort information, parents in both groups highly valued attention to infant pain and wanted more information and involvement, particularly during painful procedures. The desire of parents to be present and to participate in comforting infants during painful procedures increased substantially from 57% in our previous study[3] to 74% in the control group and 90% in the intervention group. This change may reflect a more general trend for increased parental involvement in their children's health care. Clinical staff may need greater preparation and support to better respond to parents' expressed desire for increased involvement in infant comfort.

The finding of greater nursing pain assessment documentation related to the intervention is intriguing and should be explored in future research to improve the partnership between parents and nursing in the care of NICU infants. Future research should examine the effects of parent delivered comforting techniques on infant responses to pain. Axelin et al[10,27] have shown that facilitated tucking by parents reduces pain-related distress in preterm in-

fants, comparable to oral glucose and more effective than oxycodone.

The findings from this study can be generalized mainly to mothers and should be interpreted with caution because of imbalances in baseline characteristics between the groups and the loss to follow-up over the study period. The study measures relied on parent self-report, and we recommend the inclusion of direct observation in future studies.

CONCLUSIONS

This study provides new information on potentially influencing variables, such as parental experiences, cognitive coping styles, and social support. Given the importance of infant pain management to parents and the continuing lack of effective pharmacological treatments for infant pain in the NICU, future studies to examine the effect of greater parent involvement in infant pain management are clearly warranted.

ACKNOWLEDGMENTS

This study was funded in part by a research grant from Bliss, the special care baby charity (London, United Kingdom).

We thank the clinical staff and the dedication of the research nurses, in particular Tim Bollard, Maria Casumpanga, Anita Ghool, Claudia Huber, Regina Jesudass and Catherine Kelvar, for their support and the parents of the NICU infants for their participation.

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Pediatrics 2011;128;510; originally published online August 22, 2011;
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