

Effectiveness of Educational Materials Designed to Change Knowledge and Behaviors Regarding Crying and Shaken-Baby Syndrome in Mothers of Newborns: A Randomized, Controlled Trial

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What's Known on This Subject

Infant crying is the most common stimulus for SBS. SBS is probably largely preventable through education of caregivers about crying and the dangers of shaking. There have been no randomized, controlled trials of the effectiveness of interventions to prevent SBS.

What This Study Adds

The PURPLE education materials produced some differences in knowledge and behaviors relevant to preventing SBS in mothers of newborn infants when provided at the time of prenatal classes, maternity stays, and pediatric office visits. They may be useful in community-based prevention programs to reduce SBS.

ABSTRACT

BACKGROUND. Infant crying is an important precipitant for shaken-infant syndrome.

OBJECTIVE. To determine if parent education materials (*The Period of PURPLE Crying* [PURPLE]) change maternal knowledge and behavior relevant to infant shaking.

METHODS. This study was a randomized, controlled trial conducted in prenatal classes, maternity wards, and pediatric practices. There were 1374 mothers of newborns randomly assigned to the PURPLE intervention and 1364 mothers to the control group. Primary outcomes were measured by telephone 2 months after delivery. These included 2 knowledge scales about crying and the dangers of shaking; 3 scales about behavioral responses to crying generally and to unsoothable crying, and caregiver self-talk in response to unsoothable crying; and 3 questions concerning the behaviors of sharing of information with others about crying, walking away if frustrated, and the dangers of shaking.

RESULTS. The mean infant crying knowledge score was greater in the intervention group (69.5) compared with controls (63.3). Mean shaking knowledge was greater for intervention subjects (84.8) compared with controls (83.5). For reported maternal behavioral responses to crying generally, responses to unsoothable crying, and for self-talk responses, mean scores for intervention mothers were similar to those for controls. For the behaviors of information sharing, more intervention mothers reported sharing information about walking away if frustrated and the dangers of shaking, but there was little difference in sharing information about infant crying. Intervention mothers also reported increased infant distress.

CONCLUSIONS. Use of the PURPLE education materials seem to lead to higher scores in knowledge about early infant crying and the dangers of shaking, and in sharing of information behaviors considered to be important for the prevention of shaking. *Pediatrics* 2009;123:972–980

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Key Words

prevention, crying, shaken baby syndrome

Abbreviations

CI—confidence interval

PURPLE—*The Period of PURPLE Crying*

SBS—shaken-baby syndrome

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SHAKEN BABY SYNDROME (SBS), or inflicted traumatic brain injury, is the result of violent shaking with or without contact with a hard surface resulting in head trauma, including subdural hematomas, diffuse axonal injury, and retinal hemorrhages. The estimated rate of inflicted traumatic brain injury is 25 to 31 cases in 100 000 children <1 year of age per year.^{1,2} Because it is intentional and caregivers may lack awareness of the damage shaking causes, it may be largely preventable.³

Infant crying is a common stimulus for shaking.⁴⁻⁸ Anticipatory guidance about crying is included in policy statements for SBS prevention.^{9,10} Age-specific SBS incidence curves have a similar onset, shape, and peak pattern as crying manifested by normal infants.^{11,12} Distress (fussing, crying, and inconsolable crying) increases in the first month, peaks in the second, and decreases by 4 months of age¹³⁻¹⁵ and includes prolonged, unsoothable, and unpredictable crying bouts that cluster in the evening. They are unique to the first few months and a source of frustration and anger for parents.^{16,17} *The Period of PURPLE Crying* (PURPLE) prevention materials¹⁸ educate caregivers about the crying properties in normal infants and the possibility that their infant could be shaken, and encourage parents to share this information with all caregivers of their infant.

There have been no randomized, controlled trials of interventions to prevent SBS.¹⁹ We wished to estimate the effects of the PURPLE materials on knowledge and behaviors relevant to SBS prevention. Because SBS incidence increases during the first month and peaks during the third,^{1,11,12} prevention information needs to be received before or soon after the infant's birth. We offered the materials to women recruited from prenatal classes, maternity wards, and pediatricians' offices.

SUBJECTS AND METHODS

Study Design

This randomized, controlled trial was approved by the institutional review boards of all participating institutions. The study was registered at www.clinicaltrials.gov (NCT00105963). Individual mothers of newborns were chosen as the unit of randomization. Both study arms received booklets and a DVD. The intervention group received the PURPLE materials; the control group received injury-prevention materials.

Procedures

Mothers were recruited at 3 groups of sites: prenatal classes (10 sites), maternity wards (3 hospitals), and pediatric offices (11 practices) in Washington between December 9, 2004, and October 9, 2006.

A separate allocation sequence was generated for each of the 24 sites by using a computerized pseudorandom number generator to assign subjects to both arms by using permuted blocks randomly selected to be of size 4 or 6. Lists were prepared by an investigator with no contact with study participants.

At prenatal sites, research assistants obtained informed consent, followed by a baseline telephone interview. They then opened a sealed opaque envelope with the treatment assignment and sent the materials, a diary with written instructions, a sample diary page, and a practice page, to the mother's home. Verbal telephone instructions for diary completion were given 3 days before the diary began. At maternity sites, the procedure was similar, except that baseline interview and diary demonstration was provided in person at enrollment. In pediatric practices, office staff approached interested mothers who were contacted by project staff. The pro-

cedure was similar to that in maternity wards, but materials were delivered at a home visit. In some sites, research assistants completed enrollment at the clinic after the pediatric visit was finished. If materials were provided at maternity sites and pediatric practices, mothers did not view them at that time.

During the infant's fifth week, mothers were telephoned and reminded to complete the diary. One day after beginning the diary, another call was made to answer questions about diary completion. Diaries were returned in self-addressed stamped envelopes. Two months after birth, the mother completed a telephone interview by a professional survey firm. Up to 18 attempted calls were allowed, including nights and weekends.

Intervention Materials

The PURPLE materials consisted of an 11-page booklet and 12-minute DVD. Control materials consisted of 2 brochures and a DVD about infant safety.

The PURPLE materials were designed and produced by the National Center on Shaken Infant Syndrome.¹⁸ The letters in the word "PURPLE" each stand for a property of crying that is frustrating to caregivers: P for peak pattern, where crying increases weekly, peaks during the second month, and then declines; U for unexpected onset of crying bouts; R for resistance to soothing; P for pain-like facial grimace; L for long crying bouts; and E for evening clustering. The materials reinforce the normality of crying, suggest ways to comfort an infant, clearly state that comforting may not work sometimes, describe why unsoothable crying is frustrating, and suggest 3 "action steps" when faced with a crying infant: (1) increase "carry, comfort, walk, and talk" responses; (2) if the crying is too frustrating, it is okay to walk away, put the infant down safely, calm yourself, and return to check on your infant; and (3) never shake or hurt an infant. The materials describe SBS, and emphasize "telling other caregivers" about PURPLE, the dangers of shaking, and action steps. Consistent with the evidence,^{14-16,20} the PURPLE materials do not claim that unsoothable crying bouts are soothable if caregivers use a specific technique. Rather, they acknowledge the frustration caregivers will experience when the infant does not soothe.

Control materials included a DVD on infant safety excerpted from the I Am Your Child Foundation,²¹ American Academy of Pediatrics brochures on infant safety,²² and US Department of Health and Human Services brochures on safe sleep.²³ Control materials did not mention crying as a trigger for SBS, nor did PURPLE materials mention safe sleep or injury-prevention strategies.

Outcome Assessments

Interview

The questions addressed included the mother's knowledge concerning crying and shaking, the mother's behavioral responses in the past month to crying generally and to unsoothable crying, the number and relationship of tem-

porary caregivers, and whether the mother's behavior included sharing information with each caregiver. Because there were no previous relevant measures of crying, shaking, or safety knowledge and behaviors, all questions were created for this study.

Primary Outcomes

We defined 8 primary outcome variables. Five were scales created after data collection but before analysis: crying knowledge, shaking knowledge, responses to crying generally, responses to unsoothable crying, and caregiver self-talk responses to unsoothable crying. Because >95% of mothers "agreed" or "strongly agreed" with 4 of 12 crying-knowledge questions at baseline before intervention, only 8 questions were included in the crying knowledge scale after intervention. Scales were transformed to the range of 0 to 100; higher scores indicated better knowledge or improved reported behaviors.

Three other primary outcomes were prespecified behaviors around sharing information, defined as percent of mothers who shared information with at least 1 temporary caregiver for each of 3 topics: crying, walking away if frustrated, and dangers of shaking.

Baby's Day Diary

*The Baby's Day Diary*²⁴ has been tested for reliability and validity and extensively used.^{17,25–30} Caregivers recorded infant states (awake alert, fussing, crying, unsoothable crying, sleeping, feeding) on the top half of a 24-hour ruler and caregiver carrying and holding on the bottom. "Distress" occurred whenever fussing, crying, or unsoothable crying was recorded.³¹ The smallest recordable unit was 5 minutes. As in previous studies,^{32,33} parents could indicate 4 prespecified events "above" the time rulers with event-specific symbols. Two events were actions recommended in the PURPLE materials ("pick up your crying infant" and "put your infant down, walk away, and take a break").

Diaries were transcribed into a diary-counting software program (RonNiCLog³¹). Mean interrater reliability (κ)³⁴ for duration or frequencies measures was 0.99 for behavioral states and 0.80 for event codes (3% sample of recoded diaries).

Secondary Outcomes

Six secondary outcomes agreed on before analysis included 3 measures of caregiving from diary recordings: (1) caregiver contact when the infant was distressed (minutes/day); (2) pick-up events when the infant was distressed (events/day); and (3) walk-away events when the infant cried unsoothably (events/day). The fourth outcome was a diary measure of frustration recorded once daily on a 6-point Likert scale in response to the question "How frustrating to you was your infant's crying today?" There were 2 measures of pediatric office visit frequency (all visits, and all visits for colic, crying, fussing, or feeding problems).

Missing Data

Of 2738 women enrolled, age was missing for 59 (2%), education for 60 (2%), family income for 213 (8%), and

marital status for 36 (1%). Eight primary outcomes were missing for 16% and at least 1 was missing for 33%. Women missing all 5 knowledge and behavior scale outcomes were younger (29.5 vs 31.3 years of age), less often married (67% vs 86%), had less education (14.3 vs 15.9 years) and lower incomes (\$71 000 vs \$88 000), and were less often in the intervention arm (15.5% vs 16.3%) compared with those with complete data. Four diary measures (caregiver contact when infant distressed, pick-up events when distressed, walk-away events with unsoothable crying, and daily frustration) were missing for 25% and at least 1 measure was missing for 68%. Missing data proportions were similar in both groups.

Results from parallel analyses using known data or multiple imputation techniques to account for missing data were similar. To reduce bias from nonrandom missing of data, we reported only the results by using multiple imputation. We imputed 20 sets of data that were identical concerning known information, but could differ, 1 from another, on imputed values for missing information.^{35,36} We used the method of chained equations, randomly sampling the imputed values from the posterior predictive distribution of the missing data^{37,38} with variance estimates adjusted to account for imputed values not actually being measured.³⁹

Power

Using different outcomes and a variety of assumptions, an estimated total sample of 1052 to 4058 was needed to achieve 90% power to detect a 10% mean difference between intervention and control subjects, by using $\alpha = .05$ (2-sided) and equal subject numbers in each arm. Given resource constraints, we sought to enroll ~1500 subjects in each arm.

Statistical Analyses

We compared baseline intervention and control subject characteristics by using χ^2 tests. We tested whether the probability of intervention allocation was associated with the 8 primary outcomes, adjusting for treatment assignment and enrollment center.^{40,41}

For continuous scores or measures of time outcomes, we estimated mean differences between intervention and control subjects at follow-up by using least squares linear regression.⁴² For diary events or office visit counts, we estimated incidence rate ratios by using negative binomial regression.^{43,44} Confounding by center was examined by adjusting for center in the analyses. We used linear mixed models to see if clustering by center influenced results: the effect was minimal so these models were not used.⁴⁵ We used tests of statistical interaction to examine subgroups based on education level, recruitment site, whether the intervention was read or viewed, whether this was the first infant, and whether the infant cried unsoothably. All tests of interactions included main effects terms.⁴⁶ Analyses were performed by using Stata software.⁴⁷

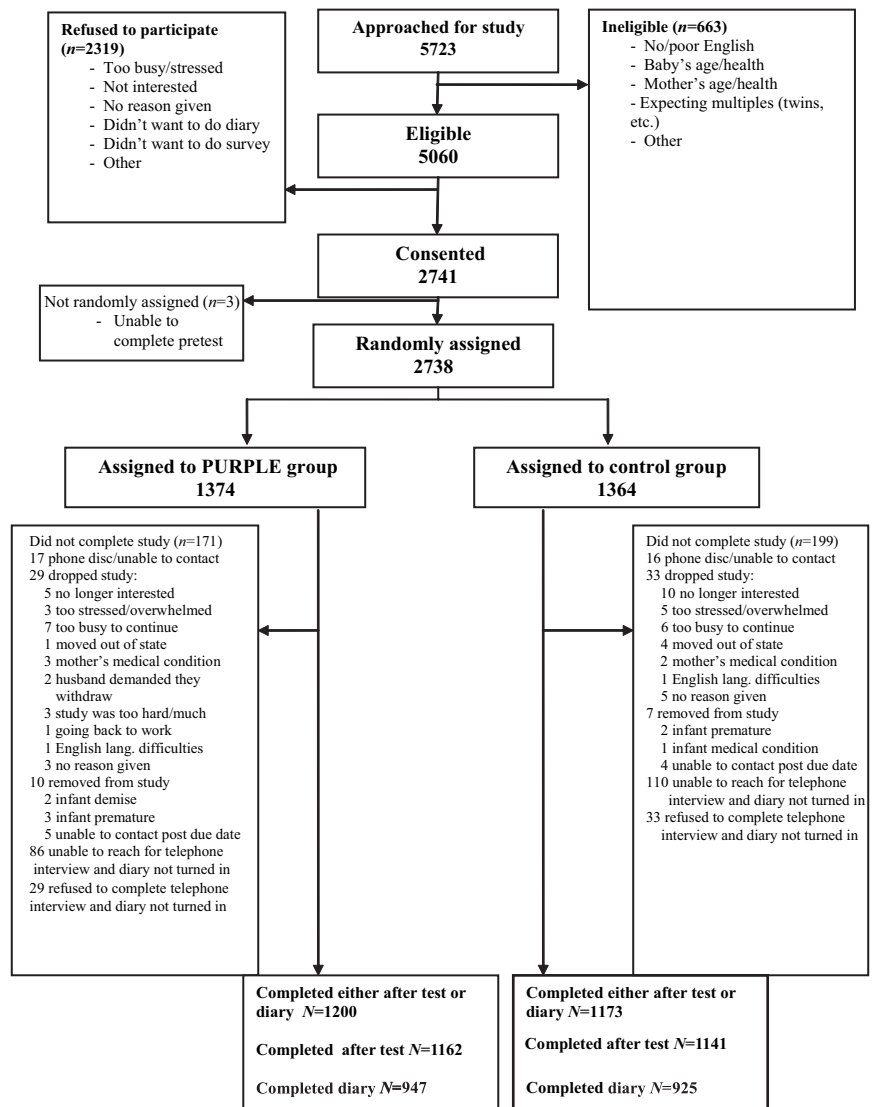


FIGURE 1
Diagram showing the flow of trial subjects from recruitment through to the final analyses.

RESULTS

Sample Characteristics

We enrolled and randomly assigned 2738 mothers (Fig 1): 1374 were assigned to the PURPLE intervention, with 1364 as controls. We found no evidence of selection bias. Baseline characteristics were similar in both groups (Table 1). Probability of allocation to the intervention was not associated with any of 8 primary outcomes ($P = .22-.87$).

Primary Outcomes

Knowledge scores were higher in intervention compared with control arms for crying (6.2-point difference) and shaking (1.3-point difference) scales (Table 2).

Behavioral responses to crying scores were higher in the intervention than control arms (a 0.2-point difference for crying generally, a 1.3-point difference for unsoothable crying, and a 1.3-point difference for self-talk), but no difference was statistically significant (Table 3).

Sharing Information Behaviors

More intervention mothers (6.5%) shared information concerning walking away if frustrated by inconsolable crying, and 5.6% more shared information about the dangers of shaking (Table 4). They were not more likely to share information about crying.

Secondary Outcomes

Diary

Compared with controls, the intervention group had 8.6 more minutes/day of contact when the infant was distressed (Table 5). Rates of picking up when distressed, of walking away when the infant cried unsoothably, or daily frustration scores were not significantly different.

The intervention group recorded significantly more distress (13.8 minutes) and each form of distress: 6.4 minutes of fussing, 5.5 minutes of crying, and 1.9 minutes of unsoothable crying (Table 6).

TABLE 1 Characteristics of Study Mothers at Enrollment, According to Intervention Arm, Using Known and Multiply Imputed Data

Characteristic	Intervention Arm (N = 1374), n (%)	Control Arm (N = 1364), n (%)
Age, y		
18–24	187 (14)	223 (16)
25–29	369 (27)	356 (26)
30–34	480 (35)	474 (35)
35–54	338 (25)	311 (23)
Education		
High school or less	195 (14)	201 (15)
Some college	285 (21)	318 (23)
College or more	894 (65)	845 (62)
Annual family income, 1000s		
\$0–\$60	496 (36)	502 (37)
\$61–\$100	448 (33)	478 (35)
>\$101	430 (31)	384 (28)
Recruitment site		
Nursery	567 (41)	558 (41)
Prenatal clinic	554 (40)	554 (41)
Other clinic	253 (18)	252 (18)
Married	1148 (84)	1127 (83)

Pediatric Visits

Incidence rates for 2 months after birth differed little: 3.9 for the intervention group and 4.0 for controls (rate ratio: 0.98 [95% confidence interval (CI): 0.87–1.09]). Rates of visits for colic, crying, fussing, or feeding problems differed little: 0.8 for the intervention group and 0.9 for controls (rate ratio: 0.86 [95% CI: 0.63–1.17]).

Subgroup Analyses

The intervention effect on crying knowledge and shaking scores was greater among women who read the booklet, watched the DVD, or both, and not related significantly to behavior scale scores (Table 7). The effect

of the intervention varied little on any primary knowledge or behavior outcome scale by parent education, recruitment site, being mother's first infant, or occurrence of unsoothable crying during the 4-day diary recording.

DISCUSSION

Of 8 primary outcomes, the PURPLE materials were associated with statistically significant improvements on 2 knowledge scales and 2 behaviors compared with controls: intervention mothers scored 6% higher in knowledge about infant crying; 1% higher in knowledge about shaking; more often (6% difference) shared advice to walk away if frustrated by crying; and more often (7% difference) warned others about the dangers of shaking. For scales concerning maternal responses about crying generally, unsoothable crying specifically, and self-talk regarding unsoothable crying, none of the small improvements were statistically significant. Intervention mothers did not increase information sharing about crying with other caregivers. Maternal-infant contact during distress was 9 minutes greater in intervention mothers. Daily frustration levels were nearly the same. Pick-up events during distress, walk-away events during unsoothable crying, and office visit rates did not differ significantly.

These results provide evidence of increases in maternal knowledge considered important to SBS prevention when materials are provided at times of prenatal classes, maternity ward stays, or pediatric visits. Because knowledge that the frustrating properties of early crying are normal is not widespread,⁴⁸ this was an important domain to effect. Awareness of the danger of shaking was expected to be high (Dias⁴⁹ reported 93% awareness); however, there was an additional small gain in intervention group mothers. Score differences were greater if mothers read or watched (or both) the materials, implying that differences were causally related to the materials. We found little evidence that intervention

TABLE 2 Primary Outcomes for Knowledge Scale Differences at the End of the Study, According to Trial Arm, Using Known and Multiply Imputed Data

Scale	Intervention Arm (N = 1374)			Control Arm (N = 1364)			Difference	95% CI
	n ^a	Mean	SD	n ^a	Mean	SD		
Crying knowledge	1138	69.5	18.5	1117	63.3	12.3	6.2	5.0–7.3
Shaking knowledge	1157	84.8	10.7	1138	83.5	9.4	1.3	0.5–2.1

Scales range from 0 to 100. A positive difference favors the PURPLE intervention arm.

^a Number of subjects with known data.

TABLE 3 Primary Outcomes for Responses to Crying in Past-Month Behavior Scale Differences at the End of the Study, According to Trial Arm, Using Known and Multiply Imputed Data

Scale	Intervention Arm (N = 1374)			Control Arm (N = 1364)			Difference	95% CI
	n ^a	Mean	SD	n ^a	Mean	SD		
Crying generally	1004	50.8	15.1	995	50.6	15.0	0.2	–0.9 to 1.4
Unsoothable crying	1094	35.0	29.9	1077	33.7	24.9	1.3	–0.7 to 3.2
Self talk	1093	48.9	41.3	1072	47.6	35.5	1.3	–1.6 to 4.2

All scales range from 0 to 100. A positive difference favors the PURPLE intervention arm.

^a Number of subjects with known data.

TABLE 4 Percent of Mothers Who Shared Information About Infant Crying or Shaking With Other Caregivers According to Study Arm

Information Category	Intervention Arm (N = 1374)			Control Arm (N = 1364)			Difference	95% CI
	n ^a	Mean	SD	n ^a	Mean	SD		
Infant crying	1004	53.9	58.4	994	54.3	56.4	−0.4	−4.5 to 3.6
Walk away if frustrated with crying	1004	41.4	60.7	995	34.9	53.7	6.5	2.3 to 10.6
Dangers of shaking	1004	35.3	54.6	995	29.7	53.0	5.6	1.6 to 9.6

A positive difference favors the PURPLE intervention.

^a Number of subjects with known data.

TABLE 5 Diary Behavior Measures With Means (of Minutes per Day or Frustration Level Scores) or Rates (of New Events per Person-Day as Recorded on Diaries) Using Known or Multiply Imputed Data

Measure	Intervention Arm (N = 1374)			Control Arm (N = 1364)			Difference	95% CI
	n ^a	Mean	SD	n ^a	Mean	SD		
Contact when child distressed, min/d	927	102.6	72.6	910	94.0	76.1	8.6	3.0 to 14.2
Frustration level	917	1.20	1.19	892	1.20	1.05	0.00	−0.08 to 0.09
Pick-up events when child distressed	940	3.08 ^b	3.39	917	3.03 ^b	3.21	1.02 ^c	0.95 to 1.09
Walk-away events when child has unsoothable crying	940	0.052 ^b	0.215	917	0.046 ^b	0.208	1.13 ^c	0.85 to 1.51

Intervention mothers were compared with control mothers using either differences in means or rate ratios.

^a Number of subjects with known data.

^b Events per person per day.

^c Rate ratio.

TABLE 6 Minutes of Child Distress Reported in Diaries, According to Trial Arm, Using Known and Multiply Imputed Data

Scale	Intervention Arm (N = 1374)			Control Arm (N = 1364)			Difference	95% CI
	n ^a	Mean	SD	n ^a	Mean	SD		
Crying	940	44.9	38.9	917	39.4	38.4	5.5	2.7–8.4
Unsoothable crying	940	11.1	21.5	917	9.2	16.1	1.9	0.4–3.3
Fussing	940	102.1	64.8	917	95.7	64.4	6.4	1.6–11.2
Total distress (crying, unsoothable crying, fussing)	940	158.1	84.7	917	144.3	85.9	13.8	7.6–20.0

Results are mean minutes per day. A positive difference indicates more minutes in the PURPLE intervention arm.

^a Number of subjects with known data.

effects varied with maternal education, being the mother's first child, intervention site, or occurrence of unsoothable crying. This suggests that the PURPLE program might be equally effective in other populations, unless those populations differed from ours in ways not tested.

Behaviors that increased with exposure to PURPLE materials included sharing information about walking away if frustrated and the dangers of shaking. These mothers recorded more contact time with distressed infants. Interpreting this finding is difficult because recorded minutes of distress were also greater in this group. Because mothers did not report differences on the responses to crying scales, and unsoothable crying is not changed by caregiving responses,¹⁶ the increased reporting of distress and/or contact time with distress may have been an artifact of the focus on crying in the PURPLE materials. Nevertheless, the finding of increased crying in the intervention group is of some concern and will require attention in future research.

This study was neither intended nor sufficiently large to test whether PURPLE materials might prevent SBS. It was intended as a conservative assessment of the materials' effects on maternal knowledge and reported be-

haviors. Stronger effects might be observed if the materials were provided by clinicians, nurses, or instructors with clinical reinforcement, as occurred in the study of Dias et al.³ In principle, implementation would be reinforced by multiple exposures through prenatal, maternity and postnatal sites, media, and community-abuse prevention organizations. With the "Back to Sleep" campaign, the overall impact of clinician and nurse advice, reading materials, and print and broadcast media was most effective in changing behavior.⁵⁰

This study has a number of limitations. First, knowledge and behavior changes were assessed only for mothers, although males are the most common perpetrators of abuse.^{8,51–53} Besides feasibility constraints of studying males, mothers were still considered the most important group, because mothers (1) are the primary caregivers; (2) need to know about normal properties of crying, the frustration it produces, and the dangers of shaking; (3) can choose appropriate temporary caregivers and educate them; and (4) although less strong physically, remain the second or third most common perpetrators.^{8,51–53}

Second, many subjects failed to provide outcome data. Restricting analysis to persons with complete data can produce biased estimates unless data were missing

TABLE 7 Subgroup Analyses of 5 Primary Study Outcomes Using Known and Multiply Imputed Data

Subgroup	Percent of Subjects in Each Subgroup	Outcome Scale				
		Crying Knowledge	Shaking Knowledge	Crying Generally	Unsoothable Crying	Self-talk
Education, <i>P</i>		.48	.81	.19	.97	.99
High school or less	14	4.6 (1.4 to 7.7)	0.6 (−1.5 to 2.7)	−1.9 (−4.9 to 1.1)	0.9 (−4.1 to 5.9)	1.7 (−6.9 to 10.2)
Some college	22	5.9 (3.7 to 8.1)	1.4 (−0.1 to 2.8)	−0.4 (−2.9 to 2.1)	1.6 (−2.6 to 5.8)	0.9 (−4.8 to 6.6)
College or more	64	6.5 (5.2 to 7.7)	1.3 (0.4 to 2.2)	0.9 (−0.4 to 2.2)	1.2 (−1.0 to 3.4)	1.3 (−1.9 to 4.4)
Recruitment site, <i>P</i>		.27	.85	.84	.46	.05
Nursery	41	5.3 (3.4 to 7.1)	1.5 (0.3 to 2.8)	−0.2 (−2.0 to 1.7)	1.1 (−2.2 to 4.4)	−2.3 (−7.0 to 2.4)
Prenatal clinic	40	6.5 (5.0 to 8.1)	1.1 (0.0 to 2.2)	0.4 (−1.2 to 2.1)	0.4 (−2.3 to 3.2)	2.4 (−1.6 to 6.5)
Other clinic	18	7.5 (5.3 to 9.8)	1.1 (−0.5 to 2.6)	0.6 (−1.7 to 2.9)	3.5 (−0.6 to 7.6)	6.9 (1.0 to 12.9)
Intervention read or viewed, <i>P</i>		.008	.03	.84	.22	.34
Neither	8	0.4 (−2.9 to 3.8)	−1.9 (−4.3 to 0.6)	0.4 (−3.2 to 4.0)	0.3 (−6.2 to 6.8)	−5.4 (−14.6 to 3.8)
Watched video	4	5.8 (1.2 to 10.4)	1.0 (−2.3 to 4.4)	−1.0 (−5.9 to 4.0)	9.8 (1.3 to 18.4)	−1.8 (−14.3 to 10.8)
Read pamphlet	29	5.4 (3.6 to 7.2)	0.6 (−0.7 to 1.8)	−0.5 (−2.3 to 1.3)	0.0 (−3.2 to 3.2)	0.0 (−4.7 to 4.7)
Both	59	6.8 (5.2 to 8.3)	1.8 (0.8 to 2.9)	0.4 (−1.1 to 1.9)	1.3 (−1.4 to 3.9)	3.0 (−0.8 to 6.8)
First baby, <i>P</i>		.89	.77	.46	.36	.92
No	34	6.1 (4.3 to 7.9)	1.1 (−0.1 to 2.4)	−0.2 (−2.1 to 1.6)	2.5 (−0.7 to 5.8)	1.4 (−3.1 to 5.9)
Yes	66	6.2 (4.9 to 7.6)	1.4 (0.4 to 2.3)	0.5 (−0.8 to 1.8)	0.8 (−1.5 to 3.0)	1.7 (−1.8 to 5.2)
Infant had unsoothable crying, <i>P</i>		.79	.62	.35	.26	.28
No	56	6.0 (4.5 to 7.6)	1.1 (0.1 to 2.1)	−0.2 (−1.7 to 1.2)	0.3 (−2.2 to 2.9)	−0.0 (−3.8 to 3.8)
Yes	44	6.3 (4.8 to 7.9)	1.5 (0.4 to 2.6)	0.8 (−0.8 to 2.4)	2.5 (−0.3 to 5.3)	3.0 (−1.1 to 7.1)

Percents show the proportion of subjects in each subgroup. Each cell shows differences in mean scores PURPLE intervention mean minus control mean) with 95% CIs in parentheses. *P* values are for a test that the difference estimates are similar across subgroups.

completely at random.^{34,35} We used multiple imputation methods that require the less stringent assumption that data were missing at random conditional on the imputation variables. Bias may still occur if missing values were strongly related to factors not used in our models.

Third, the outcomes were not actual observations of parents. Behavior recorded by diaries was less susceptible to memory bias, but diary sampling was limited to 4 days. This may not have been sufficient to capture changes in response to relatively infrequent inconsolable crying bouts.

Fourth, we do not know how well the results might generalize to other populations.

The study strengths include its being a large trial using a randomized, controlled design. Those collecting data were blinded to the treatment arm of interviewed subjects. We used intention-to-treat analysis when we could. Where missing data made that difficult, we reduced bias by multiple imputation.

CONCLUSIONS

These prevention materials seem to produce some differences in knowledge that may be relevant to reducing SBS. The behaviors of sharing information with caregivers about the dangers of shaking and walking away if the crying was frustrating were higher as the PURPLE materials recommend. Knowledge differences varied with the materials used, evidence that actually reading or viewing the materials resulted in the observed differences. These results are encouraging as the first test of these materials to change knowledge and behavior. Their effectiveness in reducing SBS and other forms of inflicted infant trauma remains to be exam-

ined when implemented in clinical practice in community settings.

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FOOD ALLERGY: ADVERSE REACTIONS TO FOODS AND FOOD ADDITIVES, 4TH EDITION

Editors: Metcalfe, Dean D., MD; Sampson, Hugh A., MD; Simon, Ronald A., MD

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Reviewer: Maxcie Sikora, MD (Ochsner Clinic Foundation)

Description: This is the fourth edition of a comprehensive reference on food allergy that provides an excellent review of adverse reactions to foods and food additives as well as diagnostic criteria and treatment strategies.

Purpose: The purpose is to gain a general understanding of the background/etiology of adverse reactions to foods as well as to introduce contemporary topics encountered by physicians and nutritionists dealing with food-sensitized patients. The objectives are worthy considering there is growing recognition of adverse reactions to foods and food additives in the general population.

Audience: The book is written for pediatricians, nutritionists, general internists, family practitioners, and allergists.

Features: The five sections of the book cover basic and clinical perspectives of adverse reactions to food antigens, adverse reactions to food additives, and a variety of topics in adverse reactions to foods. This edition also reviews a variety of topics not only related to general food allergy, but also eosinophilia associated with foods, occupational exposure to food antigens, food biotechnology and genetic engineering, and toxin-related adverse food reactions. The most helpful topics are the specific treatments for food allergies, especially adequate nutritional considerations when food allergy limits certain important nutrients, as well as explanations of the different forms of testing involved in diagnosis.

Assessment: This excellent book covers a wide variety of topics pertinent to adverse reactions to foods. It contains an overview of information unparalleled by other books on general allergy or nutrition.

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