



Effectiveness of educational materials designed to change knowledge and behavior about crying and shaken baby syndrome: A replication of a randomized controlled trial in Japan[☆]

Takeo Fujiwara^{a,b,*}, Fujiko Yamada^{a,b}, Makiko Okuyama^c, Isamu Kamimaki^d, Nobuaki Shikoro^d, Ronald G. Barr^e

^a Department of Social Medicine, National Research Institute for Child Health and Development, Setagaya-ku, Tokyo, Japan

^b Department of Developmental Social Medicine, Faculty of Medicine, University of Mie, Tsu-shi, Mie, Japan

^c Department of Psychosocial Medicine, National Center for Child Health and Development, Setagaya-ku, Tokyo, Japan

^d Department of Pediatrics, Saitama National Hospital, Wako-shi, Saitama, Japan

^e Department of Pediatrics, University of British Columbia, Faculty of Medicine and Developmental Neurosciences and Child Health, Child and Family Research Institute, BC Children's Hospital, Vancouver, BC, Canada

ARTICLE INFO

Article history:

Received 17 January 2012

Received in revised form 21 June 2012

Accepted 4 July 2012

Available online 4 September 2012

Keywords:

Shaken baby syndrome
Abusive head trauma
Randomized controlled trial
Prevention
Crying
Japan

ABSTRACT

Objectives: Infant crying is particularly frustrating to caregivers in the first few months of life and the most common trigger for shaking and abuse. The effectiveness of the *Period of PURPLE Crying* prevention materials (DVD and booklet) designed to increase knowledge and change behaviors related to crying and the dangers of shaking was reported in North America. The aim of this study was to replicate the effectiveness of the *PURPLE* materials with mothers of newborns in Japan.

Methods: In a randomized controlled trial, 201 parents received either *PURPLE* materials or analogous control materials on infant safety via mail within 2 weeks of birth. At 6 weeks, mothers completed a 4-day behavioral diary. At 2 months, participants completed a pre-defined 20-min structured telephone survey by an independent firm to assess knowledge and behavior.

Results: Scores on crying knowledge scales (out of 100) were significantly higher in the intervention than control groups (56.1 vs. 53.1; difference = 3.0, 95% confidence interval [CI]: 1.0–4.9, $p < 0.005$). Percentage of sharing of advice to walk away if frustrated by crying was significantly higher in the intervention than control groups (22.4% vs. 4.1%; difference = 18%, 95% CI: 7.4–29.1). Walking away during unsoothable crying was significantly higher in the intervention group than controls (0.085 vs. 0.017 events per day, rate ratio = 4.8, 95% CI: 1.1–21.2) by diary. Self-talk behavior scale (out of 100) tended to significance in the intervention group (16.6 vs. 8.9, difference = 7.7, 95% CI: –1.0 to 16.4, $p < 0.1$).

Conclusions: Crying knowledge, sharing of walk away information with others and walk away behavior when crying was unsoothable were higher for those who received intervention than control materials. The *Period of PURPLE Crying* materials may be useful in Japan as well as in North America for informing caregivers about the properties of infant crying and changing some behaviors related to infant crying and shaking. (UMIN Clinical Trials Registry register no. UMIN000001711.)

© 2012 Elsevier Ltd. All rights reserved.

[☆] This study was supported by grants from Daido Life Welfare Foundation, Kawano Masanori Memorial Foundation for Promotion of Pediatrics, and a Grant-in-aid for Scientific Research, Ministry of Education, Culture, Sports, Science and Technology. RGB was supported by a Canada Research Chair in Community Child Health Research.

* Corresponding author address: Department of Social Medicine, National Research Institute for Child Health and Development, 2-10-1 Okura, Setagaya-ku, Tokyo 157-8535, Japan.

Introduction

Shaken baby syndrome or abusive head trauma [SBS/AHT] is caused by the violent shaking of a child 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 30 cases per 100,000 children < 12 months in Western countries (Barlow & Minns, 2000; Keenan et al., 2003). Since SBS/AHT is caregiver inflicted and because of a lack of awareness about the damage caused by shaking, shaken baby syndrome may be preventable. Because crying is a common stimulus for shaking (Barr, Trent, & Cross, 2006; Dias et al., 2005; Lee, Barr, Catherine, & Wicks, 2007; Talvik, Alexander, & Talvik, 2008), one approach to prevention is to inform caregivers about the frustrating properties of crying and behaviors to reduce the risk of shaking and abuse. In 2 randomized controlled trials in North America, the *Period of PURPLE Crying* educational materials (Barr & National Center on Shaken Baby Syndrome, 2004) showed similar effectiveness (Barr, Barr, et al., 2009; Barr, Rivara, et al., 2009). Briefly, the letters in the word “PURPLE” each stand for a property of crying in normal infants that is frustrating to caregivers: P for peak pattern of crying; U for unexpected crying; R for crying that is resistant to soothing; P for showing a pain-like face when they cry; L for long lasting cries; and E for evening clustering of crying. The materials suggest three “action steps” when caring for a crying infant: (1) increase “carry, comfort, walk and talk” responses; (2) if the crying is too frustrating, it’s OK to walk away, put the baby down in a safe place, calm yourself and then return to check on the baby, and (3) never shake or hurt a baby. The *PURPLE* materials describe what shaken baby syndrome is, and emphasize “telling other” caregivers about the *Period of PURPLE Crying*, the frustration, the dangers of shaking, and the action steps. However, there are no randomized controlled trials of materials to prevent SBS/AHT in other, non-Western, cultures.

In Japan, reported cases of child abuse and maltreatment have increased rapidly from 1,101 cases reported in 1990 to 44,210 cases in 2009 (Ministry of Health Labor and Welfare, 2010a) in part because of improved recognition and reporting. This trend of increasing cases is parallel to the increase in reports to police of suspected cases of abuse. Police figures indicate that 398 children were the suspected victims of child abuse in 2011. These numbers have been increasing since 1999 and reached their highest level in 2011 (Jiji Press Ltd, 2012). The increase of arrested cases was considered to be due to increases in the number of times neighbors report suspected cases to police. In addition, the Child Abuse Prevention Law was amended in 2008 and Child Guidance Centers are now able to gain entry into the house of suspected child abuse cases without the caregiver’s permission. Finally, child abuse deaths confirmed by the Ministry of Health, Labour, and Welfare have also increased from 56 in 2005 to 67 in 2008 (Ministry of Health Labor and Welfare, 2005, 2010b). Of these, about 20% reported abusive head trauma as the cause of death (Ministry of Health Labor and Welfare, 2005, 2010b). Thus, there is a clear need for an effective prevention for SBS/AHT.

However, reported risk factors for shaken baby syndrome in Japan are different from those reported in Western society, including 2 infant age peaks (7–9 months in addition to 2–3 months) or having even 1 sibling (Fujiwara, Okuyama, & Miyasaka, 2008; Fujiwara, Okuyama, Tsui, & Koenen, 2008). In addition, the perception of infant crying might also be different in Japan. For example, there is a Japanese proverb—“a crying baby develops well”—that is widely known and accepted to ease the frustration of crying among Japanese. Further, there is a traditional competition of infant crying, called “naki-sumo,” in which infants compete for how fast or how much they can cry as a way of imitating sumo wrestlers, suggesting crying infants are assumed to be strong infants in the Japanese tradition (Mail Online, 2010). As a result, prior to implementing a program like the *Period of PURPLE Crying*, it is necessary to demonstrate whether it is similarly effective in Japan. Consequently, our aim was to investigate whether providing Japanese mothers with the *Period of PURPLE Crying* materials changed their knowledge and behavior relevant to the prevention of SBS/AHT.

Methods

Sample

Based on previous studies (Barr, Barr, et al., 2009; Barr, Rivara, et al., 2009), the sample size to achieve 90% power using $\alpha = 0.05$ for a 2-sided test with an equal number of subjects in each trial arm was estimated for the most important outcome, the crying knowledge scale. Previously, scores on this scale increased 6% among intervention group participants with a 15% standard deviation. It was estimated that this could be achieved with a total sample size of 135. Allowing for dropouts or missing data, we aimed to enroll 200 participants.

Between July 2008 and January 2010, 427 participants were recruited from 2 hospitals within greater Tokyo in Japan. One hospital is in Kanagawa prefecture, south of Tokyo, and 1 in Saitama prefecture, north of Tokyo. Both prefectures were suburban, residential areas consisting primarily of middle-class families. Eligible mothers ($N = 416$) had an uneventful pregnancy, gave birth to a healthy singleton >37 weeks gestation, and had access to a DVD player. Research assistants recruited eligible mothers on maternity wards and 230 participants consented to participate in the study (Fig. 1).

Procedures

This was a randomized controlled trial approved by the Ethics Committee of the National Institute of Public Health (NIPH-IBRA#09006) and registered in the UMIN Clinical Trials Registry (UMIN000001711). After written informed consent and before randomization, research assistants demonstrated how to complete a validated diary, called Baby’s Day Diary®

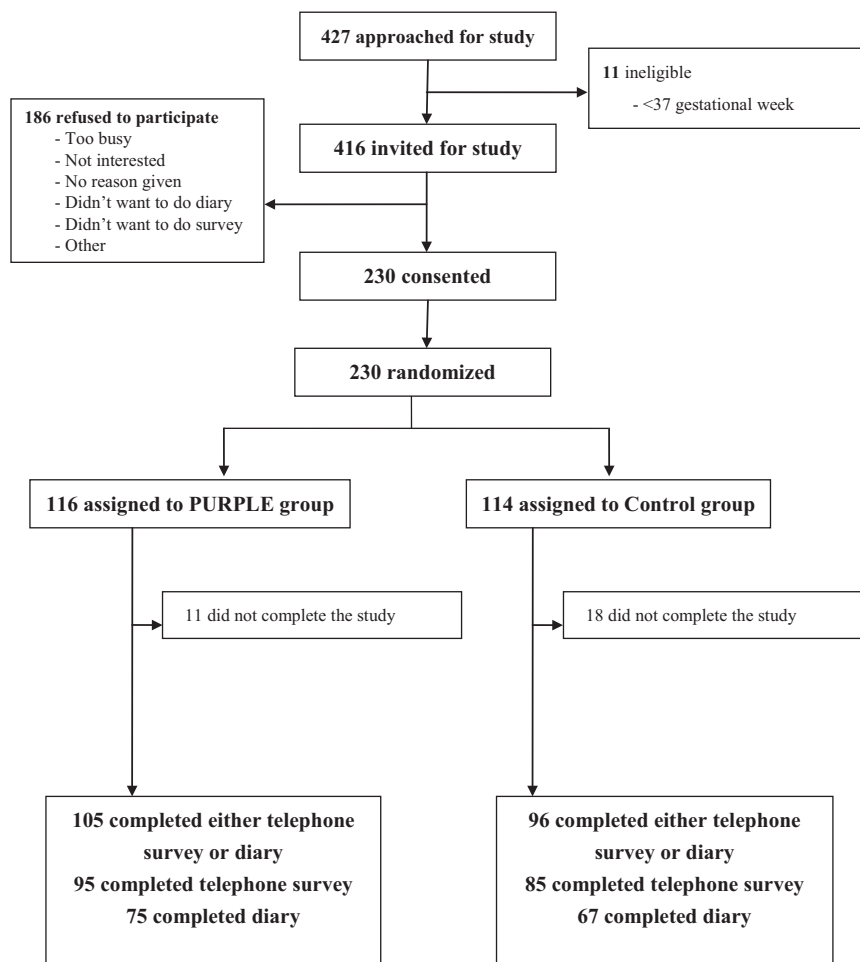


Fig. 1. CONSORT flow diagram of trial subjects from recruitment through the final analysis.

(Barr, 1985), using predefined instruction scripts. In the instruction, research assistants explained as follows: “the diary is used to record your baby’s behaviors such as feeding, sleeping, crying, and other common activities. There are two pages of instructions at the back, and I will go over it briefly with you now. We do not expect you to fill in the diary minute by minute. The goal of the diary is to have a general picture of your baby’s behaviors during the course of a day. Parents usually find it easiest to fill in the diary every 2–3 h, or at the same time as a frequent activity like feeding or changing their baby. The only thing you are asked to do is to fill in the date and the blocks of time on the diary with the available baby and parent codes and events. To make your task a little easier, the entire day is represented in 4 “rulers;” each one represents 6 h of time: for night (midnight to 6 a.m.), morning (6 a.m. to noon), afternoon (noon to 6 p.m.), and evening (6 p.m. to midnight). The rulers are divided in half, with baby codes along the top and parent codes along the bottom. It is not necessary to describe any activity that lasts less than 5 min. Most of the behaviors that we will be interested in will last at least 5 min (like fussing and crying), and often will last hours (like sleeping).” Then, a demonstration of how to fill in the baby and parent codes and events on a practice diary sheet were followed. This demonstration took about 10 min. After that, participants were randomly assigned by a computer-generated block randomization method to receive either the *Period of PURPLE Crying* prevention materials consisting of an 11-page booklet and a DVD (intervention group) or an injury prevention DVD about infant safety (control group) (Table 1).

The Japanese translation was based on two focus groups among Japanese-English speaking mothers and mothers who spoke Japanese only. The control materials consisted of a DVD translated into Japanese on infant safety that included clips from the Safe Start program at BC Children’s Hospital, British Columbia, Canada. Then, the study package was delivered via postal mail two weeks later and included a Baby’s Day Diary® (Barr, 1985), instructions for diary completion, and a sealed envelope with intervention or control materials.

Mothers were telephoned during their baby’s fifth week of life to remind them to complete the 4-day diary during the 6th week. At 2 months, participants completed a predefined 20-min structured telephone survey conducted by an independent firm to assess knowledge and behavior. Interviewers at the firm were trained on how to implement the telephone survey

Table 1

Characteristics of the mothers by intervention and control groups.

	PURPLE (n = 105) (n (%))	Control (n = 96) (n (%))
Mothers' age (year)		
<25	10 (10)	11 (12)
25–29	19 (19)	21 (22)
30–34	40 (39)	37 (39)
35+	33 (32)	25 (27)
Education		
High school or less	30 (32)	27 (33)
Some college	38 (40)	36 (43)
College or more	26 (28)	20 (24)
Annual household income (million yen)		
≤4	24 (28)	25 (32)
4.1–8	51 (59)	43 (56)
≥8.1	11 (13)	9 (12)
Parity		
First baby	44 (46)	38 (45)
Recruitment site		
Kanagawa	58 (55)	51 (53)
Saitama	47 (45)	45 (47)
Exposure to DVD		
Never	19 (20)	21 (25)
Watched, but not all	4 (4)	7 (8)
Watched once	49 (52)	46 (54)
Watched many times	23 (24)	11 (13)

using the detailed manual and completed at least one practice subject. At study completion, participants received 1000 yen (approximately \$12).

Measures

The telephone survey questionnaire was used in previous studies to assess maternal knowledge concerning crying and shaking, maternal behavior in the past month in response to crying generally and unsoothable crying specifically, and maternal behavior concerning whether information was shared with each temporary caregiver (Barr, Barr, et al., 2009; Barr, Rivara, et al., 2009). Questions were translated into Japanese and then back translated; the equivalence of the back translation to the original English was confirmed by one of the authors (RGB).

Of the 8 primary outcomes, 5 were scales of (1) crying knowledge, (2) shaking knowledge, (3) responses to crying generally, (4) responses to unsoothable crying, and (5) caregiver self-talk responses to unsoothable crying. Crying and shaking knowledge scales were composed of 8 and 5 questions respectively, asking about knowledge of infant crying properties (e.g., “infant crying increases in the first few weeks of life and reaches a peak in the first 2 or 3 months before getting less.”) with 4 Likert type response options (i.e., Strongly Agree, Agree, Disagree, and Strongly Disagree) assigned values of 0–3 respectively, with the correct answer denoted by a higher score. Response to crying generally, response to unsoothable crying, and caregiver self-talk response to unsoothable crying probed for how mothers responded to unsoothable infant crying with 5, 4, and 4 questions on each scale, respectively. Response options were “did not do it”, “once or twice”, “three to five times”, “six to 10 times”, and “almost every day” during the past month, and scored 0–4 with higher scores indicating higher frequencies. Then, the score for each scale was summed and transformed to a range of 0–100 with higher scores indicating better knowledge or improved behaviors. Three further outcomes measured sharing of information behaviors defined as the per cent of mothers who shared information with at least one other caregiver for each of three topics: crying, walking away if frustrated, and the dangers of shaking.

Four secondary outcomes were derived from The Baby's Day Diary[®] (Barr, 1985). In the diary, infant behavioral states (awake alert, fussing, crying, unsoothable crying, sleeping, and feeding) were recorded on the top half of a 24 h ruler, and caregiver behavioral states (body contact: carrying and holding) on the bottom half. The smallest recordable time unit was 5 min. “Distress” was counted whenever fussing or crying or unsoothable crying was recorded. Parents indicated pre-specified events (picking up your crying infant, putting your baby down, walking away, and taking a break) that were actions recommended in the PURPLE materials. Three secondary outcomes were: (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). A fourth outcome was daily frustration using a 6-point Likert scale (from “not at all” to “extremely”) in response to the question “how frustrating to you was your baby's crying today?” in the diary.

To calculate the above-mentioned three secondary outcomes, The Baby's Day Diary[®] (Barr, 1985) recordings were transcribed into a diary counting software program (RonNicLog[®] (Barr & Calinoiu, 1997)). The Baby's Day Diary has been widely used and previously tested for reliability and validity (Barr, Kramer, Boisjoly, McVey-White, & Pless, 1988; Barr, Kramer, Pless, Boisjoly, & Leduc, 1989; Barr, Paterson, MacMartin, Lehtonen, & Young, 2005; Hunziker & Barr, 1986; Majnemer &

Table 2

Primary outcomes for knowledge scales and response to crying scale differences.

Scale	PURPLE			Control			Difference	95% CI	<i>t</i>	<i>p</i>
	<i>n</i>	Mean	SD	<i>n</i>	Mean	SD				
Crying knowledge	95	56.1	7.3	85	53.1	6.0	3.0	1.0–4.9	2.94	0.004
Shaking knowledge	95	62.7	10.3	85	61.8	7.7	0.9	–1.8 to 3.6	0.65	0.51
Crying generally	94	44.5	11.9	85	45.4	9.3	–0.9	–4.1 to 2.3	–0.57	0.57
Unsoothable crying	43	54.8	24.3	36	46.7	22.5	8.1	–2.5 to 18.7	1.52	0.13
Self talk	43	16.6	23.2	36	8.9	13.5	7.7	–1.0 to 16.4	1.76	0.08

Table 3

Percent of mothers who shared information about infant crying or shaking with other caregivers.

Information category	PURPLE			Control			Difference	95% CI	<i>t</i>	<i>p</i>
	<i>n</i>	Mean	SD	<i>n</i>	Mean	SD				
Infant crying	68	20.6	40.7	72	19.4	39.9	1.1	–12.3 to 14.6	0.17	0.87
Walk away if frustrated with crying	67	22.4	42.0	73	4.1	20.0	18.3	7.4–29.1	3.33	0.001
Danger of shaking	67	40.3	49.4	73	39.7	49.3	0.5	–15.9 to 17.1	0.07	0.95

Barr, 2006; St. James-Roberts, Hurry, & Bowyer, 1993). RonNicLog[®] computes the duration and frequency of behaviors for each subject for each day.

Statistical analysis

For continuous scores or measures of time, the mean difference between participants in the intervention and control groups was estimated using *t*-tests (2-way). For diary event counts, we estimated incidence rate ratios (RRs) using negative binomial regression. We used tests of statistical interaction for crying/shaking knowledge and response to crying behaviors (five primary outcomes) to examine subgroups based on education, whether the intervention was read or viewed, baby's parity (1st vs. 2nd or more), and whether the infant manifested unsoothable crying. These variables were selected a priori because it is a reasonable assumption that those who are less well-educated, less exposed to intervention, having their first baby, or having an unsoothably crying infant may have less benefit of the educational material for crying/shaking knowledge and response to crying behaviors. In addition, these variables were used in the previous study to examine the same interaction effects (Barr, Barr, et al., 2009; Barr, Rivara, et al., 2009). Main effects terms were included for all tests of interaction (Brookes et al., 2004). All analyses were conducted using Stata/SE v10.0 software.

Results

We included those who completed either the diary or the telephone survey for analysis. The final intention to treat sample included 201 mothers (intervention: 105; control: 96). Baseline characteristics of mothers in both groups were similar, suggesting that the randomization process was effective in forming similar groups (Table 1).

Table 2 shows results for the primary outcome measures. The crying knowledge scale scores were higher among mothers who received intervention than control materials [3.0 point difference, 95% confidence interval (CI): 1.0–4.9, *t* = 2.94, *p* = 0.004]. Shaking scale scores were not statistically different (0.9 point difference, 95% CI: –1.8 to 3.6, *t* = 0.65, *p* = 0.51). Responses to unsoothable crying and self-talk responses when the infant was crying were higher in the intervention than control groups (8.1 point and 7.7 point differences, respectively) but neither exceeded 95% confidence intervals (95% CI: –2.5 to 18.7 and –1.0 to 16.4, *t* = 1.52 and 1.76, *p* = 0.13 and 0.08, respectively).

Regarding information sharing behavior with other caregivers, there was a substantial increase concerning walking away if frustrated by inconsolable crying in the percent of intervention group mothers who shared information compared to control mothers (18.3% difference, 95% CI: 7.4–29.1, *t* = 3.33, *p* = 0.001), but no increases in sharing information on infant crying and the dangers of shaking (Table 3).

Table 4 shows the results of secondary outcome measures derived from diary recordings. Walking away when an infant cried unsoothably was 4.8 times higher among intervention than control group mothers during the fifth week (95% CI: 1.1–21.2, *p* = 0.04). There were no significant differences in duration of contact when distressed, in rates of picking up the infant when distressed, or in daily frustration scores between the groups. Durations and frequencies of distress, crying, fussing, and unsoothable crying were not statistically different (all *p* > 0.3, data not shown).

Subgroup analyses are shown in Table 5. Overall, there was a significant interaction effect between the intervention and whether or not it was the mother's first baby (*p* = 0.04). Mothers whose baby was the second or later reported a higher score on crying knowledge if they received the intervention (4.9 points higher, 95% CI: 2.4–7.4, *p* < 0.001), whereas mothers who delivered their first baby showed no increased crying knowledge if they received the intervention. Similarly, among mothers who delivered more than once, the self-talk behavior during unsoothable crying was significantly higher in the intervention than control groups, while mothers who delivered their first baby did not increase their self-talk. Further, mothers who

Table 4

Diary behavior measures with means (contact duration or frustration level) or rates (pick up or walk away).

Measures	PURPLE			Control			Difference	95% CI	p
	n	Mean	SD	n	Mean	SD			
Contact when child distressed (min/day)	62	137.0	80.8	60	121.4	77.9	15.5	–12.9 to 44.0	0.28
Frustration level	62	1.45	0.9	60	1.25	0.8	0.20	–0.11 to 0.51	0.19
Pick-up events when child distressed (events per person per day)	64	6.1	3.5	60	5.3	3.4	1.12 ^a	0.87–1.43	0.38
Walk-away events when child has unsoothable crying (events per person per day)	64	0.085	0.31	60	0.017	0.08	4.77 ^a	1.07–21.18	0.04

^a Rate ratio.**Table 5**

Subgroup analysis of maternal knowledge and behaviors related to shaken baby syndrome.

	Difference in mean scores (PURPLE group scores – control group scores) (95% confidence interval)				
	Crying knowledge	Shaking knowledge	Behavior for crying	Behavior for unsoothable crying	Self-talk during unsoothable crying
Education	0.41	0.86	0.62	0.68	0.85
High school or less	3.2 (0.05–6.4)	0.8 (–2.9 to 4.5)	–0.02 (–5.3 to 5.2)	14.6 (–3.2 to 32.4)	6.3 (–5.8 to 18.3)
Some college	1.7 (–1.7 to 5.0)	–0.3 (–5.3 to 4.6)	–0.9 (–4.9 to 3.0)	3.5 (–15.4 to 22.4)	7.5 (–9.3 to 24.2)
College or more	4.8 (0.6–9.0)	1.6 (–3.7 to 6.9)	0.8 (–7.3 to 8.9)	5.9 (–17.6 to 29.5)	12.7 (–6.7 to 32.0)
DVD watched	0.76	0.15	0.052	0.51	0.54
No	1.7 (–1.0 to 4.5)	–2.3 (–5.9 to 1.3)	–7.1 (–13.1 to –1.0)	13.7 (–7.1 to 34.5)	2.8 (–6.7 to 12.3)
Yes	3.0 (0.5–5.5)	1.5 (–1.9 to 4.9)	1.5 (–2.2 to 5.2)	5.5 (–7.4 to 18.4)	7.6 (–3.8 to 18.9)
First baby	0.04	0.25	0.40	0.93	0.13
No	4.9 (2.4–7.4)	2.3 (–1.1 to 5.7)	0.8 (–2.9 to 4.5)	7.9 (–6.5 to 22.3)	14.5 (2.4–26.6)
Yes	0.7 (–2.5 to 3.8)	–0.7 (–5.1 to 3.6)	–3.1 (–8.5 to 2.3)	6.6 (–9.0 to 22.3)	1.3 (–11.7 to 14.3)
Unsoothable crying	0.98	0.33	0.71	N/A	N/A
No	3.0 (0.5–5.6)	2.0 (–1.2 to 5.2)	–0.3 (–4.7 to 4.0)		
Yes	2.8 (–0.3 to 5.9)	–0.3 (–5.0 to 4.4)	–1.9 (–6.5 to 2.8)		

Values in bold are significant at the $p = 0.05$ level.

watched the DVD showed higher crying knowledge in the intervention than control groups, while mothers who did not watch the DVD did not show a difference between groups.

Discussion

We found that Japanese mothers who received *PURPLE* materials scored 3% higher than mothers who received control materials on crying knowledge scales. Several behavioral changes were also found: sharing information on walking away if frustrated with unsoothable crying was more common (18.3% difference) and frequency of walking away events when the child had unsoothable crying was 4.8 times higher. Two responses (responses to unsoothable crying and self-talk responses to unsoothable crying) were higher (8.1 and 7.7 point differences, respectively) but did not reach statistical significance.

To the best of our knowledge, this is the first randomized controlled trial investigating the effectiveness of educational materials intended to prevent child maltreatment in Japan. Although this study was neither designed nor large enough to evaluate the effectiveness of the *PURPLE* materials in reducing shaking behaviors themselves, changes in knowledge and behaviors relevant to risks of shaking behavior by caregivers were observed. The 3.0 point increase in the crying knowledge scale is consistent with increases in previous studies in North America (Seattle 6.2 points (Barr, Rivara, et al., 2009); Vancouver 5.4 points (Barr, Barr, et al., 2009)). This change represents a Cohen's effect size of 0.45 in our study that is very similar to the North America studies (Seattle 0.39 (Barr, Rivara, et al., 2009); Vancouver 0.46 (Barr, Barr, et al., 2009)). These effect sizes are about twice the average effect sizes found for short-term (0.23) or long-term (0.27) effects of 108 interventions that measured changes in parenting knowledge and attitudes (Layzer, Goodson, Bernstein, & Price, 2001).

In Japan, a large behavioral change was observed for diary recorded walk away behavior. Intervention participants were 4.8 times more likely than control participants to walk away when the infant was crying unsoothably. In Seattle and Vancouver, the increases were 1.1 times (95% CI: 0.85–1.15) (Barr, Rivara, et al., 2009) and 1.7 times (95% CI: 1.1–2.6) (Barr, Barr, et al., 2009), respectively. Thus, the *PURPLE* materials appear to be more effective for changing this behavior in Japan.

In contrast to previous studies, the shaking knowledge score in the control group in Japan (61.8) was lower than reported in North America (Seattle 83.5; Vancouver 83.2). This may mean that the lack of increase in shaking knowledge scores in Japan was not due to a ceiling effect. Rather, the Japanese mothers may have been reticent to adopt the information about the dangers of shaking as they do not want to think that they might shake the baby nor discuss it with others. The lack of differences on information sharing about the dangers of shaking with other caregivers might support this interpretation. Only the advice to walk away if frustrated was highly shared (18.3% difference), but the information about infant crying (1.1%

difference) and the dangers of shaking (0.5% difference) was not. Consequently, these Japanese mothers may be adopting the strategy that it is effective to educate others on how to *respond* to infant crying if frustrated by walking away, but that it is not socially desirable and/or ineffective to discuss the dangers of shaking.

The subgroup analysis on DVD exposure is consistent with the increases being due to the *PURPLE* materials: those who watched DVD showed higher differences in crying knowledge (3.0 vs. 1.7 points, respectively) although the interaction term was not statistically significant. Interestingly, we found that mothers with more than one child had greater differences on crying knowledge and self-talk responses to unsoothable crying. This may suggest that the *PURPLE* materials were more easily accepted by these mothers as they could understand the messages better based on their previous experience. This finding differs from previous North American studies that did not find an interaction between being the first baby and exposure to *PURPLE* materials.

The study has a number of limitations. Knowledge and behavior changes were assessed only for mothers whereas fathers have been reported to be the most likely perpetrators of shaking (Brewster et al., 1998; Starling, Holden, & Jenny, 1995). However, in Japan, the predominant perpetrators of child abuse death cases are mothers (Ministry of Health Labor and Welfare, 2010a). A second limitation is that the outcome measures were subjective reports and do not include actual observations of parents. In principle, the use of the Baby's Day Diaries had the advantage of recording behavior that was less likely to be susceptible to memory bias. Third, these results may not be generalizable to the Japanese population as our samples were recruited from only two maternity hospitals in Greater Tokyo.

Nonetheless, our study supported the effectiveness of *PURPLE* materials in Japan when employing a blinded, randomized controlled design and performing intention-to-treat analyses with known data. Further, we employed an easier delivery method of materials, that is, by postal mail, which was still effective in changing knowledge and behavior about infant crying. This might be able to be applied more broadly for prevention of SBS/AHT by municipalities. However, some adaptation of the *PURPLE* materials might be needed when implementing in Japan. If parents walk away from crying infants, they are likely to feel worried about the complaints from neighbors about infant crying, and even that they may be reported to the child guidance center for suspected child abuse due to the unsoothable infant crying. Thus, when implementing of the *PURPLE* materials in Japan, we would recommend that parents be encouraged to share the information on *PURPLE* crying with neighbors even if the parents do not ask neighbors to take care of their infant.

We conclude that the *PURPLE* materials appear to produce some differences in crying knowledge and walk away behavior when infants cry unsoothably that are likely to be relevant to reducing the incidence of SBS in Japan. In addition, information sharing to other caregivers on walking away if frustrated with unsoothable crying was higher as recommended. These gains were seen when materials were delivered by postal mail that is easier and more feasible for child abuse prevention policy organized by municipalities. To determine whether there is an actual reduction of shaken baby syndrome or abusive head trauma, further research is needed in which the intervention is implemented in wider community settings.

Acknowledgements

We thank Drs. Shigemasa Shiotsuka and Eiko Shiotsuka for their generosity to allow us to approach their patients. And we also thank research assistants, Mrs. Setsuko Hayashi, Mrs. Chizuko Sadanaga, and Mrs. Miwa Omori, who recruited the participants. Last but not least, we are grateful for all the participants who contributed to this study.

References

- Barlow, K. M., & Minns, R. A. (2000). Annual incidence of shaken impact syndrome in young children. *Lancet*, 356(9241), 1571–1572.
- Barr, R. G. (1985). *Baby's day diary*. Montreal, QC.
- Barr, R. G., Barr, M., Fujiwara, T., Conway, J., Catherine, N., & Brant, R. (2009). Do educational materials change knowledge and behaviour about crying and shaken baby syndrome? A randomized controlled trial. *Canadian Medical Association Journal*, 180(7), 727–733.
- Barr, R. G., & Calinoiu, N. (1997). *RonNicLog baby's day diary counting program*. Montreal, QC.
- Barr, R. G., Kramer, M. S., Boisjoly, C., McVey-White, L., & Pless, I. B. (1988). Parental diary of infant cry and fuss behaviour. *Archives of Disease in Childhood*, 63(4), 380–387.
- Barr, R. G., Kramer, M. S., Pless, I. B., Boisjoly, C., & Leduc, D. (1989). Feeding and temperament as determinants of early infant crying/fussing behavior. *Pediatrics*, 84(3), 514–521.
- Barr, R. G., & National Center on Shaken Baby Syndrome. (2004). *Period of PURPLE Crying*. Ogden, UT: National Center on Shaken Baby Syndrome.
- Barr, R. G., Paterson, J. A., MacMartin, L. M., Lehtonen, L., & Young, S. N. (2005). Prolonged and unsoothable crying bouts in infants with and without colic. *Journal of Developmental and Behavioral Pediatrics*, 26(1), 14–23.
- Barr, R. G., Rivara, F. P., Barr, M., Cummings, P., Taylor, J., Lengua, L. J., & Meredith-Benitz, E. (2009). Effectiveness of educational materials designed to change knowledge and behaviors regarding crying and shaken-baby syndrome in mothers of newborns: A randomized controlled trial. *Pediatrics*, 123(3), 972–980.
- Barr, R. G., Trent, R. B., & Cross, J. (2006). Age-related incidence curve of hospitalized shaken baby syndrome cases: Convergent evidence for crying as a trigger to shaking. *Child Abuse & Neglect*, 30(1), 7–16.
- Brewster, A. L., Nelson, J. P., Hymel, K. P., Colby, D. R., Lucas, D. R., McCanne, T. R., & Milner, J. S. (1998). Victim, perpetrator, family, and incident characteristics of 32 infant maltreatment deaths in the United States Air Force. *Child Abuse & Neglect*, 22(2), 91–101.
- Brookes, S. T., Whitely, E., Egger, M., Smith, G. D., Mulheran, P. A., & Peters, T. J. (2004). Subgroup analyses in randomized trials: Risks of subgroup-specific analyses; power and sample size for the interaction test. *Journal of Clinical Epidemiology*, 57(3), 229–236. <http://dx.doi.org/10.1016/j.jclinepi.2003.08.009>
- Dias, M. S., Smith, K., DeGuehery, K., Mazur, P., Li, V., & Shaffer, M. L. (2005). Preventing abusive head trauma among infants and young children: A hospital-based, parent education program. *Pediatrics*, 115(4), e470–e477.
- Fujiwara, T., Okuyama, M., & Miyasaka, M. (2008). Characteristics that distinguish abusive from nonabusive head trauma among young children who underwent head computed tomography in Japan. *Pediatrics*, 122(4), e841–e847.

- Fujiwara, T., Okuyama, M., Tsui, H., & Koenen, K. C. (2008). Perinatal factors associated with infant maltreatment. *Clinical Medicine Insights: Pediatrics*, 1, 29–36.
- Hunziker, U. A., & Barr, R. G. (1986). Increased carrying reduces infant crying: A randomized controlled trial. *Pediatrics*, 77(5), 641–648.
- Jiji Press Ltd. (2012). *Number of arrested child abuse cases*. Retrieved from <http://www.jiji.com/jc/v?p=ve.soc.tyosa-jikenchildren-casualties>
- Keenan, H. T., Runyan, D. K., Marshall, S. W., Nocera, M. A., Merten, D. F., & Sinal, S. H. (2003). A population-based study of inflicted traumatic brain injury in young children. *Journal of the American Medical Association*, 290(5), 621–626.
- Layzer, J. I., Goodson, B. D., Bernstein, L., & Price, C. (2001). *National evaluation of family support programs. Final report. Volume A: The meta-analysis*. Cambridge, MA: Abt Associates Inc.
- Lee, C., Barr, R. G., Catherine, N., & Wicks, A. (2007). Age-related incidence of publicly reported shaken baby syndrome cases: Is crying a trigger for shaking? *Journal of Developmental and Behavioral Pediatrics*, 28(4), 288–293.
- Mail Online. (2010). Yes, it's the 'Crying Sumo' contest: Japanese wrestlers compete to see who can make a baby bawl first. Retrieved from <http://www.dailymail.co.uk/news/article-1268867/The-crying-sumo-contest-japanese-wrestlers-compete-make-baby-first.html>
- Majnemer, A., & Barr, R. G. (2006). Association between sleep position and early motor development. *Journal of Pediatrics*, 149(5), 623–629. <http://dx.doi.org/10.1016/j.jpeds.2006.05.009>
- Ministry of Health Labor and Welfare. (2005). *Results of child abuse death review, 4th report*. Tokyo: Ministry of Health Labor and Welfare.
- Ministry of Health Labor and Welfare. (2010a). *Changes in the number of receiving of consultation on child abuse in Child Guidance Center. Annual health, labour and welfare report*. Tokyo.
- Ministry of Health Labor and Welfare. (2010). *Results of child abuse death review, 6th report*. Tokyo: Ministry of Health Labor and Welfare.
- St. James-Roberts, I., Hurry, J., & Bowyer, J. (1993). Objective confirmation of crying durations in infants referred for excessive crying. *Archives of Disease in Childhood*, 68(1), 82–84.
- Starling, S. P., Holden, J. R., & Jenny, C. (1995). Abusive head trauma: The relationship of perpetrators to their victims. *Pediatrics*, 95(2), 259–262.
- Talvik, I., Alexander, R. C., & Talvik, T. (2008). Shaken baby syndrome and a baby's cry. *Acta Paediatrica*, 97(6), 782–785.