

4.	Se preocupa e sente insegurança sem ter um claro motivo.	(1)Nunca (3)As vezes	(2)Quase nunca (4)Sempre
5.	Sente medo sem ter um claro motivo.	(1)Nunca (3)As vezes	(2)Quase nunca (4)Sempre
6.	Em momentos de apuro com várias coisas para se fazer,	(1)Consegue lidar (3)Não consegue lidar como sempre lidar	(2)Consegue lidar na maioria das vezes (4)Quase não consegue lidar
7.	Dificuldade para dormir por estar infeliz	(1)Quase sempre (3)Raramente	(2)As vezes (4)Nunca
8.	Ficar triste, infeliz	(1)Quase sempre (3)As vezes	(2)Frequentemente (4)Nunca
9.	Chorar por estar infeliz	(1)Quase sempre (3)As vezes	(2)Frequentemente (4)Nunca
10.	Ideia de se ferir	(1)Quase sempre (3)As vezes	(2)Frequentemente (4)Nunca

11. Quantos amigos ou parentes você tem por perto para fazer consultas sobre a criação dos filhos?

pessoas

Caso tenha alguém que possa consultar, quem é esta pessoa? No caso de「Outros」, favor preencher sua relação com esta pessoa.

Favor marcar com um  as respectivas respostas no quadro da direita. No caso de「Sim」, preencher o número de pessoas.

1.	Esposo (Companheiro)	(1)Sim	(2)Não
2.	Próprios pais / Sogros	(1)Sim ( ) pessoas	(2)Não
3.	Parentes (Irmãos, cunhados)	(1)Sim ( ) pessoas	(2)Não
4.	Amigo / conhecido que vive próximo	(1)Sim ( ) pessoas	(2)Não
5.	Amigo / conhecido que não vive próximo	(1)Sim ( ) pessoas	(2)Não
6.	Outros (Relação: )	(1)Sim ( ) pessoas	(2)Não

#### D. Perguntas sobre sua relação com a criança.

Marcar com um  a resposta mais próxima. 「Esta criança」 no texto está se referindo à criança sujeita a este exame.

		Sempre acho	Acho um pouco	Não acho muito	Não acho
1.	Quero muito minha criança	1	2	3	4
2.	Quando está inquieto, não sei o que fazer	1	2	3	4
3.	Sensação desagradável com esta criança	1	2	3	4
4.	Nenhum sentimento especial com esta criança	1	2	3	4
5.	Sinto raiva com esta criança	1	2	3	4
6.	Estou me divertindo ao cuidar desta criança	1	2	3	4
7.	Se não fosse esta criança...	1	2	3	4
8.	Quero proteger esta criança	1	2	3	4
9.	Se não tivesse esta criança...	1	2	3	4
10.	Sinto muito perto esta criança	1	2	3	4
11.	Esta criança chora demais	1	2	3	4

Marcar com um ○ a resposta mais próxima.

		Raramente	1~2 vezes/mês	1~2 vezes/semana	3~4 vezes/semana	Quase todos os dias
12.	Oportunidade de ler um livro para a criança.	1	2	3	4	5
13.	Oportunidade de brincar junto com a criança (passar tempo).	1	2	3	4	5
14.	Oportunidade de levar a criança para passear em parques, etc.	1	2	3	4	5
15.	Visitar parentes ou amigos com crianças da mesma idade.	1	2	3	4	5

Marcar com um ○ quantas vezes fez durante 1 mês.

		0 vezes	1~2 vezes	3~5 vezes	6~10 vezes	Mais de 11 vezes
16.	Quantas vezes deixou o lugar onde estava para levar a criança à um lugar seguro para fazê-la dormir ao chorar sem parar?	1	2	3	4	5
17.	Quantas vezes sacudiu violentamente a criança quando estava a chorar ou fazendo barulho?	1	2	3	4	5
18.	Quantas vezes você tampou a boca da criança com a mão ou travesseiro quando ela estava a chorar ou fazendo barulho?	1	2	3	4	5

#### E. Pergunta sobre sua situação financeira.

(1)Estável (2)Consegue viver (3)Difícil (4)Penoso

#### F. Pergunta sobre seu trabalho e de seu esposo (companheiro).

Marcar com um ○ a resposta correspondente

		Não trabalha (Do lar / Desempregado / Estudante)	Trabalha tempo integral	Trabalha tempo parcial
1.	Sua ocupação	1	2	3
2.	Esposo (Companheiro)	1	2	3

#### G. Pergunta sobre DVD sobre a assistência para criação dos filhos.

- Assistiu o DVD 「Purple Crying」 (DVD sobre o choro da criança)? (1) 2 vezes ou mais (2) 1 vez (3) Não assistiu
- Assistiu o DVD 「Integração pai e filho」? (1) 2 vezes ou mais (2) 1 vez (3) Não assistiu

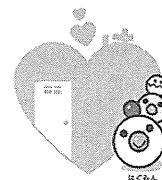
Sem mais. Obrigado pela colaboração.

As prefeituras estarão ajudando somente na distribuição e recolhimento desta pesquisa.  
Em caso de dúvidas, favor entrar em contato em um dos estabelecimentos abaixo.

[Contatos]

Centro Nacional para o Desenvolvimento e Saúde da Criança (Org. Indep.) Divisão de Desenvolvimento Médico Social (Responsável: FUJIWARA) TEL: 03-3417-2663, ou

Departamento de Saúde e Bem-Estar, Seção Infantil e Familiar da Província de Aichi, Grupo Saúde Maternal e Infantil (Responsável: IKUTA, DEGUCHI) TEL: 052-954-6283



# Using International Classification of Diseases, 10th Edition, Codes to Estimate Abusive Head Trauma in Children

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**Abstract:** Passive surveillance using ICD codes for hospital discharges has been used to estimate the incidence of abusive head trauma (AHT) utilizing ICD-9-CM, but not ICD-10, codes. There have been no incidence estimates of AHT in Canada where ICD-10 codes have been used since 2002. The Discharge Abstract Database from the Canadian Institute of Health Information (CIHI) for 2002–2007 was used for analyses conducted in 2011. A case was defined by code combinations that indexed injury specificity (narrow or broad) and degree of certainty (presumptive or probable) that the injury was inflicted. Estimated incidences for the populations at risk in those aged <12 months and 12–23 months from 2002–2007 were determined.

For those aged <12 months, the mean incidence for “narrow, presumptive” AHT was 13.0 (95% CIs= 11.3, 14.9) per 100,000 person-years; for “broad, probable” it was 15.5 (13.6, 17.6) per 100,000 person-years. For those aged 12–23 months, the “narrow, presumptive” incidence was 2.4 (1.7, 3.3) and the “broad, probable” incidence was 2.8 (2.0, 3.8) per 100,000 person-years, respectively. Month and year of age patterns were similar to previous reports. ICD-10 codes can be used to estimate incidence of AHT. Narrower classifications provide estimates consistent with those from other surveillance programs in Canada and internationally.

(Am J Prev Med 2012;43(2):215–220) © 2012 American Journal of Preventive Medicine

## Introduction

Abusive head trauma (AHT), sometimes also known as shaken baby syndrome (SBS),<sup>1</sup> is a form of intentional injury to infants and children inflicted by violent shaking with or without concomitant contact with a hard surface, resulting in head trauma including subdural hematomas, axonal injury, cerebral edema and retinal hemorrhages sometimes including fractures of the long bones or ribs, with little or no external evidence of trauma. (Many terms have been used to denote the clinical entity referred to as AHT or SBS. In 2009, the American Academy of Pediatrics published a position paper on terminology for this condition.<sup>1</sup> The recommendation was that AHT should be used for med-

ical and legal purposes while SBS could be used for public education and advocacy purposes [somewhat analogous to acute myocardial infarction and “heart attack,” respectively]. Currently, the term abusive head trauma is increasingly used more widely and more consistently.) The consequences are tragic and devastating to infants, their families, and society. Increasingly, empirically evaluated prevention initiatives are being reported<sup>2–5</sup> raising the possibility that effective regional AHT prevention could be demonstrated. Such prevention efforts require consistent and feasible measures of monitoring incidence and, ideally, the ability to compare incidence across time and in different jurisdictions.<sup>6,7</sup>

While the use of ICD-9-CM codes is standard practice for classifying hospital discharge databases in the U.S., Canada and many other countries have moved to ICD-10 codes. ICD-10 codes were adopted in six Canadian provinces by 2002, with additional provinces added in subsequent years. To date, there are no published rates of AHT using ICD-10 codes<sup>8</sup> and no published incidence estimates for Canada using passive surveillance systems. Therefore, two primary objectives of this study were to: (1) use ICD-10 data to propose definitions for cases of AHT, and (2) use these definitions to provide estimates of the incidence of AHT in available provinces in Canada.

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0749-3797/\$36.00

<http://dx.doi.org/10.1016/j.amepre.2012.04.028>

**Table 1.** Codes used to identify traumatic head injury in infants using ICD-10 diagnosis codes

Category	Code	Description
Narrow	S06.0–S06.9	Intracranial injury (e.g., subdural, subarachnoid hemorrhages)
Broad (also includes any Narrow case that also has one of the following Broad codes)	S02.0, S02.1, S02.7, S02.8, S02.9 S07.1, S07.8, S07.9 S09.7, S09.8	Skull fracture Crushing injury of head Multiple other injury of head

Absent a gold standard against which to compare incidence, a secondary objective was to derive a range of possible incidence estimates. Canadian ICD-10 data (ICD-10-CA) have not been used before to explore these aims. Given their broad use internationally, ICD 10–based estimates should inform measures of AHT incidence within and across many regions.

## Methods

### Canadian Institute of Health Information Discharge Abstract Database

The Canadian Institute of Health Information (CIHI) collects data from all Canadian provinces of hospitalized patients discharged alive or who die during their hospitalization. Each case may be coded with up to 25 ICD-10 diagnostic codes. Patient data on all children aged 0–23 months whose files included codes relevant to injuries used to define cases of abusive head trauma were obtained.

All available data from participating provinces for the years 2002 through 2007, the most recent year available at the time of data acquisition, were obtained. By 2002, all provinces were using ICD-10 codes except New Brunswick, Manitoba and Quebec. New Brunswick and Manitoba converted in 2003 and 2004, respectively, but data from Quebec had not yet been integrated.

Cases per 100,000 person-years were estimated for four definitions of AHT based on combinations of ICD-10 codes. The presence of a head injury was defined by codes that described injuries to the head typical of abusive head trauma (Table 1). Generally, codes used to define Narrow cases were restricted to those that described intracranial injury (e.g., subdural or subarachnoid hemorrhage). Codes used to define Broad cases included those for Narrow cases and/or codes for skull fracture, crushing injury of the head, and multiple other injuries of the head. Consequently, a skull fracture due to abuse but without intracranial pathology would be included

as a Broad case. If the cases included codes for coagulation defects or birth trauma, they were excluded from the Narrow cases ( $n=4$ ); cases with codes for coagulation defects, birth trauma, or osteochondrodysplasia were excluded from the Broad cases ( $n=5$ ).

Consequently, cases were defined by using combinations of ICD-10 codes that reflected varying degrees of specificity (designated “Narrow” and “Broad,” following Wirtz and Trent<sup>9</sup>) and of certainty (designated “Presumptive” and “Probable,” as in Parks et al.<sup>10</sup>). Cases classified as “narrow, presumptive” would represent the most-specific and conservative estimates of AHT; cases classified as “broad, probable” would represent more-sensitive but less-specific estimates of AHT that would be more encompassing and include additional cases of abusive head trauma.

Degrees of certainty were defined by codes that described causes for the head injuries (Table 2). Cases with codes for poisonings or sexual abuse were excluded. Codes used to indicate Presumptive abuse (the most certain) included assault, maltreatment syndrome (except sexual abuse), or other maltreatment syndromes. Codes used to indicate Probable abuse included Presumptive codes plus undetermined intent (contact with a blunt object; falling, jumping or being pushed from a high place; other specified events; unspecified events).

### Determination of Incidence

To calculate incidence per person-year for each year, the estimated population by age (taking into account immigration and out-migration) produced by Stats Canada<sup>11</sup> was used. Because exact birth dates were not available, average exposure, equivalent to assuming everyone’s birth dates occurred in the middle of the year, was used. Person-years were calculated as the sum of half the population from the current year (e.g., 2002) and half from the previous year (e.g., 2001). To adjust for various years of entry of some provinces, the denominator for 2002 was calculated from all provinces except New Brunswick, Manitoba, and Quebec; for 2003, from all provinces except Manitoba and Quebec; and for 2004–

**Table 2.** Codes used to identify degree of certainty of abuse using ICD-10

Degree of certainty	Code	Description
Presumptive	Y00, Y01, Y04, Y08, Y09 T74.1, T74.8, T74.9 Y07.0, Y07.1, Y07.2, Y07.3, Y07.8, Y07.9	Assault Maltreatment syndrome (except sexual abuse) Other maltreatment syndrome
Probable (also includes any Presumptive case that also has one of the following Probable codes)	Y29, Y30, Y33, Y34	Undetermined intent (contact with blunt object; falling, jumping or being pushed from a high place; other specified events [e.g., using a specific weapon]; unspecified event [e.g., unspecified threats to breathing])

2007, all provinces except Quebec. The estimates were calculated in 2011–2012.

### Analytic Strategy

Incidence estimates and 95% CIs (based on the Poisson distribution) for the at-risk population were calculated for each of the four definitions of AHT for ages <12 months and 12–23 months and for each of six years (2002 to 2007). As CIHI discharge data provide cases based on an April 1 to March 31 fiscal year, incidences were calculated based on the at-risk population for a fiscal year. Next, the overall incidence was calculated for all cases from 2002 to 2007 in the same way.

To determine whether there was a secular trend in incidence by year, a trend test was undertaken using Poisson regression adjusted for the differences due to the number of provinces included in each year. Finally, whether the age-specific pattern by month of age conformed to previous findings using ICD-9 data sets<sup>12,13</sup> was assessed using incidence estimates for the narrow, probable and the broad, probable classifications. Stata 9.2 was used for analysis. This study was approved by the University of British Columbia's Behavioral Research Ethics Board.

### Results

The incidences per 100,000 person-years of AHT in those aged <12 months in each year from 2002 to 2007 and overall for 2002–2007 for all four ICD-10 code-derived definitions are presented in Table 3. For the whole period, the incidences range from 13.0 cases per 100,000 person-years for the narrow, presumptive definition ( $n=203$  cases over 6 years) and 15.5 cases per 100,000 person-years for the broad, probable definition ( $n=243$  cases over 6 years). Parallel incidences in those aged 12–23 months are presented in Table 4. For this age group, the incidence was 2.4 and 2.8 cases per 100,000 person-years for the narrow, presumptive and broad, probable definitions for the whole period.

As previously reported,<sup>9,14,15</sup> incidences were much lower for those aged 12–23 months than for those aged <12 months, regardless of whether narrow, probable or broad, probable ICD-10 definitions were used (Tables 3 and 4). In addition, annual variation was similar for both narrow, probable and broad, probable definitions. No secular trends from 2002 to 2007 were observed for either age group or for any of the definitions (Tables 3 and 4, last column).

For both narrow, probable and broad, probable definitions, the patterns of monthly incidence (Figure 1) were essentially identical, and show a clear increasing and decreasing pattern reflecting a peak incidence at age 2 months (during the 3rd month of life) of 33.7 (95% CI=24.5, 45.3) cases per person-year and 37.6 (95% CI=27.8, 49.7) cases per person-year, respectively. This pattern replicated a clear skewing of AHT cases toward the younger months of age as previously reported.<sup>10,12,13,16,17</sup>

Table 3. Abusive head trauma incidence by clinical specificity and degree of certainty of abuse for those aged 0–11 months

Specificity of head injury	Degree of certainty of abuse	2002/2003	2003/2004	2004/2005	2005/2006	2006/2007	2007/2008	Total	p for trend
Narrow	Presumptive ( $n=203$ ) <sup>a</sup>	13.2 (8.9, 18.7)	11.0 (7.2, 16.0)	11.0 (7.4, 15.8)	15.8 (11.4, 21.3)	13.5 (9.5, 18.7)	13.2 (9.3, 18.3)	13.0 (11.3, 14.9)	0.55
	Probable ( $n=209$ )	14.0 (9.6, 19.7)	11.0 (7.2, 16.0)	11.4 (7.7, 16.2)	16.1 (11.7, 21.7)	13.5 (9.5, 18.7)	14.0 (9.9, 19.1)	13.4 (11.6, 15.3)	0.59
Broad	Presumptive ( $n=236$ )	15.7 (11.1, 21.6)	12.6 (8.6, 17.9)	13.6 (9.6, 18.9)	17.6 (13.0, 23.4)	16.8 (12.3, 22.4)	14.0 (9.9, 19.1)	15.1 (13.2, 17.1)	0.76
	Probable ( $n=243$ )	16.6 (11.8, 22.6)	12.6 (8.6, 17.9)	14.0 (9.9, 19.3)	18.0 (13.3, 23.9)	16.8 (12.3, 22.4)	15.0 (10.8, 20.3)	15.5 (13.6, 17.6)	0.75

Note: Years are fiscal years April 1–March 31. Incidences (95% CI) are per 100,000 person-years.

<sup>a</sup> $n$  is for row totals over 6 years

Table 4. Abusive head trauma incidence by clinical specificity and degree of certainty of abuse for those aged 12-23 months

Specificity of head injury	Degree of certainty of abuse	2002/2003	2003/2004	2004/2005	2005/2006	2006/2007	2007/2008	Total	p for trend
Narrow	Presumptive (n=38) <sup>a</sup>	2.5 (0.9, 5.4)	2.0 (0.7, 4.7)	1.5 (0.4, 3.9)	3.7 (1.8, 6.8)	2.2 (0.8, 4.8)	2.5 (1.0, 5.2)	2.4 (1.7, 3.3)	0.74
	Probable (n=38)	2.5 (0.9, 5.4)	2.0 (0.7, 4.7)	1.5 (0.4, 3.9)	3.7 (1.8, 6.8)	2.2 (0.8, 4.8)	2.5 (1.0, 5.2)	2.4 (1.7, 3.3)	0.74
Broad	Presumptive (n=43)	2.5 (0.9, 5.4)	2.0 (0.7, 4.7)	2.3 (0.8, 4.9)	3.7 (1.8, 6.8)	2.2 (0.8, 4.8)	3.6 (1.7, 6.6)	2.7 (2.0, 3.7)	0.43
	Probable (n=44)	2.5 (0.9, 5.4)	2.0 (0.7, 4.7)	2.3 (0.8, 4.9)	3.7 (1.8, 6.8)	2.2 (0.8, 4.8)	4.0 (2.0, 7.1)	2.8 (2.0, 3.8)	0.34

Note: Years are fiscal years April 1-March 31. Incidences (95% CI) are per 100,000 person-years.  
<sup>a</sup>n is for row totals over 6 years

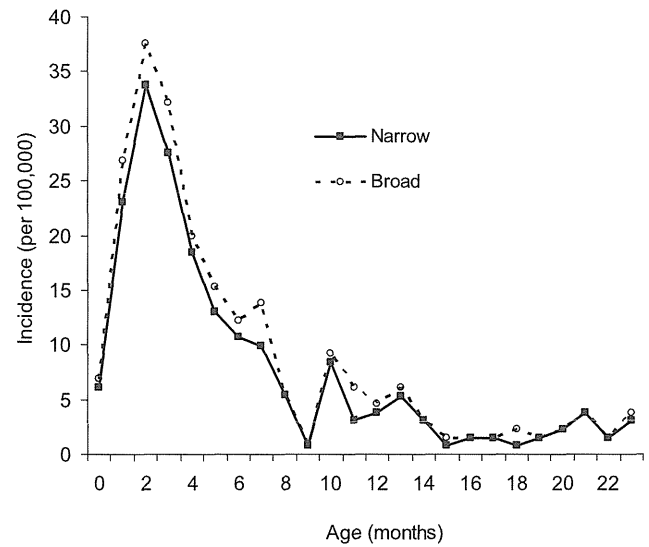


Figure 1. Incidence of abusive head trauma by month of life, narrow and broad probable cases  
 Note: Incidences are averaged for fiscal years 2002/2003-2007/2008.

In Figure 2, the incidences of cases for those aged <12 months for the narrow, probable and the broad, probable definitions are plotted with previously reported incidence estimates. Both rates were less than those reported from passive surveillance estimates using the Kids' Inpatient Database (KID)<sup>15</sup> and the Nationwide Inpatient Sample (NIS) from the Healthcare Cost and Utilisation Project<sup>10</sup> or active surveillance in the U.S.<sup>14</sup> The incidence for the broad, probable definition was within the range of the estimated incidence reported with active surveillance in the UK.<sup>16</sup> However, the incidences were very similar to

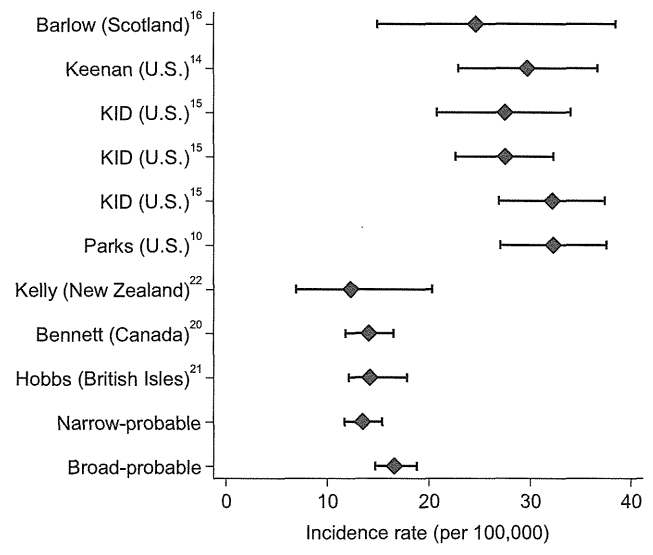


Figure 2. Comparison of abusive head trauma incidence per 100,000 person-years with 95% CI, for those aged <12 months

one report of active surveillance in Canada<sup>20</sup> and two pediatric surveillance reports from the UK<sup>21</sup> and New Zealand.<sup>22</sup>

## Discussion

The estimated incidence of AHT for infants aged <12 months was 13.0 cases (95% CI=11.3, 14.9) for the most-specific and certain classification compared to 15.5 cases (95% CI=13.6, 17.6) for the least-specific and certain classification. The corresponding incidences for infants aged 12–23 months were 2.4 (95% CI=1.7, 3.3) and 2.8 cases (95% CI=2.0, 3.8) per 100,000 person-years. This is the first report of estimated AHT incidences determined solely by using ICD-10 codes for hospitalizations.

Each classification has strengths and weaknesses, depending on the use to which the estimates are put. Interestingly, all classifications behave similarly with regard to expected properties of rates reported from previous studies: (1) incidences are four to six times higher in infants aged <12 months compared to infants aged 12–23 months; (2) year-to-year patterns track in parallel across the 6 years examined; and perhaps most strikingly; (3) monthly age-specific incidences have essentially identical patterns across the 24 months. The year and the month of age differences have been robustly reproduced in previous reports, including those derived from active<sup>14,16</sup> and passive<sup>10,12,13,15,18,19</sup> surveillance methods.

If passive surveillance is used in the evaluation of regional prevention programs, broader classifications are likely to be more sensitive and provide more power for detecting differences due to successful prevention efforts, especially in jurisdictions with smaller populations. If the primary interest is in preventing AHT that includes intracranial pathology, then a narrower classification is more appropriate. If, however, the primary interest is in preventing AHT (whether or not intracranial pathology is included), then a broader classification is more relevant.

Previously, there were no prospective, active surveillance estimates of hospitalizations for AHT in Canada. However, it has been reported<sup>120</sup> from the Canadian Paediatric Surveillance Program that the incidence of “head injury secondary to suspected child maltreatment” was 14.1 (95% CI=11.8, 16.5) per 100,000 for those aged <12 months, and 3.2 (95% CI=2.2, 4.6) per 100,000 for those aged 12–23 months. These incidences are similar to the 15.5 (95% CI=13.6, 17.6) and 2.8 (95% CI=2.0, 3.8) per 100,000 rates for broad, probable cases that would be the most closely comparable definitions used here. Both include brain injury and/or serious head injury due to abuse.

Internationally, Hobbs et al.<sup>21</sup> reported an incidence of subdural haematoma and effusion due to nonaccidental head injury from the British Paediatric Surveillance Unit (United Kingdom and Republic of Ireland) derived from a similar paediatric surveillance study of 14.2 (95% CI=12.1, 17.8) per 100,000 in those aged <12 months. In New Zealand (NZ), Kelly et al.<sup>22</sup> used a mixed prospective and retrospective design utilizing the NZ Paediatric Surveillance Unit and hospital discharges (using ICD-10) from the NZ Health Information Service. They reported a minimum incidence (infants diagnosed as child abuse) of subdural hemorrhages of 12.3 (95% CI=6.9, 20.3) and maximum incidence (that included indeterminate cases) of 20.5 (95% CI=13.3, 30.3) per 100,000 among the non-Maori population.

By contrast, in the only prospective active surveillance study of pediatric intensive care unit hospitalizations in the U.S., Keenan et al.<sup>14</sup> reported an incidence of 26.4 (95% CI=19.9, 33.0) cases per 100,000 infants per year aged <12 months, excluding medical examiner cases<sup>15</sup> or 29.7 including medical examiner cases. Similarly, Barlow et al.<sup>16</sup> reported an incidence of hospitalizations and childhood deaths of 24.6 (95% CI=14.9, 38.5) for shaken impact syndrome from active surveillance in Scotland. In two studies using passive surveillance estimates in the U.S. (using ICD-9),<sup>10,15</sup> incidences ranging from 27.5 (95% CI=20.8, 34.0) to 32.3 (95% CI=27.0, 37.6) were reported.

In summary, there is an approximate doubling of incidence rates between the Canadian ICD 10–based narrow definitions (that converge with other active surveillance programs in Canada, the UK and New Zealand) compared to two active surveillance reports in the U.S. and Scotland and two ICD-9-CM–based passive surveillance reports in the U.S. (Figure 2). Given the differences in national healthcare systems, surveillance methods, potential coding biases and coding systems, it remains a substantial challenge to determine whether the apparent discrepancy between Canadian and U.S. figures represent real differences in the prevalence of AHT.

## Strengths and Limitations

There are a number of limitations to this study. First, as with all studies using administrative data sets, there is less control over factors such as coding by trained coders in the hospitals in the CIHI database. There is potential for error in assigning appropriate codes when abuse diagnoses can be complex and the level of detail in the medical record varies.<sup>23–25</sup> A relative potential strength of the Canadian data set is that ICD codes are not used for billing purposes as is the case in the U.S., reducing a potential bias as to which codes are utilized.<sup>26</sup>

Second, the incidence estimates may not be generalizable to the Canadian population as a whole since provinces made the transition to ICD-10 codes in different years and Quebec was still not integrated in 2007. However, Quebec birth rates are proportional to population and previously reported cases of AHT were proportional to the regional population,<sup>20</sup> making bias less likely. Third, CIHI data are restricted to hospitalized cases, and do not include deaths outside of hospitalization. Despite recognized limitations, hospital discharge data for abusive injuries in infants have the potential to provide accessible, consistent and reproducible estimates of conditions such as AHT that are relatively rare on a population basis, but clinically severe with tragic consequences for the victim, his or her family and society and, importantly, potentially preventable.

This work was supported by a grant from the British Columbia Ministry of Children and Family Development. The Ministry had no role in the study design.

RGB is supported by a Canada Research Chair in Community Child Health. TF was supported by a grant from the Ministry of Health, Labour and Welfare (H23-Seisaku-Ippan-005), Japan. No other authors reported financial disclosures.

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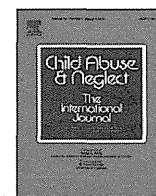
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## Child Abuse & Neglect



# 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<sup>☆</sup>

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### 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.)

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<sup>☆</sup> 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.

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## 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 (UMIN00001711). After written informed consent and before randomization, research assistants demonstrated how to complete a validated diary, called Baby’s Day Diary®

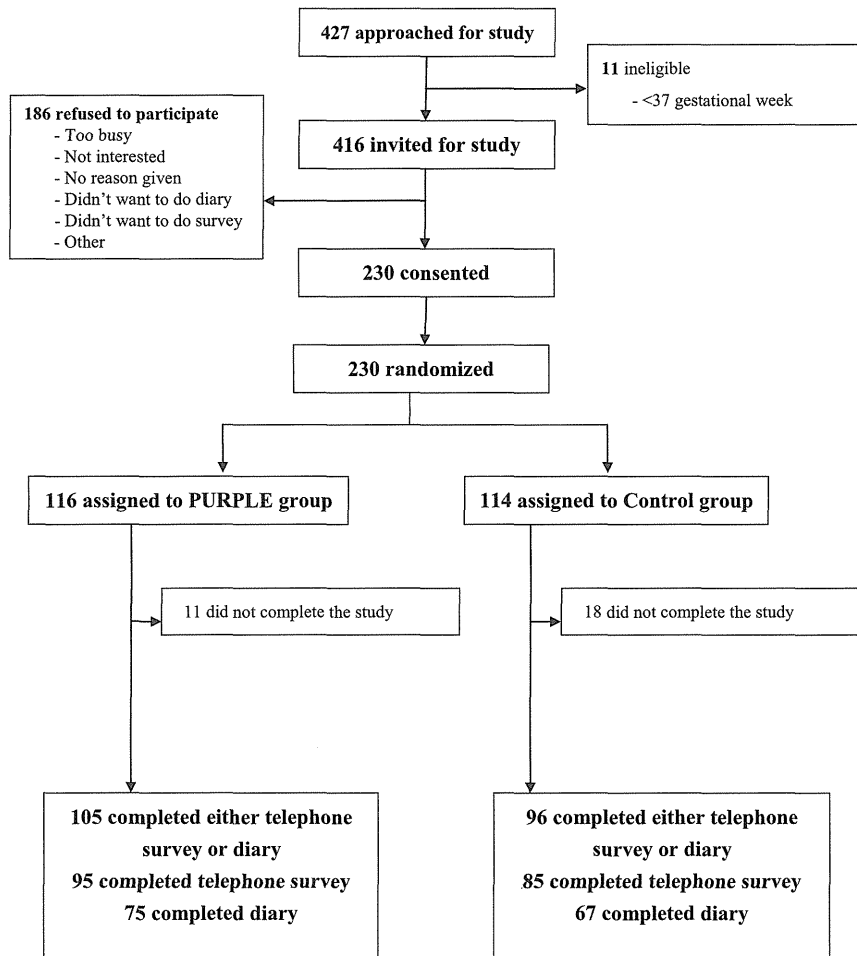


Fig. 1. CONSORT flow diagram of trial subjects from recruitment through the final analysis.

(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<sup>®</sup> (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<sup>®</sup> (Barr, 1985) recordings were transcribed into a diary counting software program (RonNicLog<sup>®</sup> (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	t	p
	n	Mean	SD	n	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	t	p
	n	Mean	SD	n	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<sup>®</sup> 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 <sup>a</sup>	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 <sup>a</sup>	1.07–21.18	0.04

<sup>a</sup> 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	<b>3.2 (0.05–6.4)</b>	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	<b>4.8 (0.6–9.0)</b>	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)	<b>–7.1 (–13.1 to –1.0)</b>	13.7 (–7.1 to 34.5)	2.8 (–6.7 to 12.3)
Yes	<b>3.0 (0.5–5.5)</b>	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	<b>0.04</b>	0.25	0.40	0.93	0.13
No	<b>4.9 (2.4–7.4)</b>	2.3 (–1.1 to 5.7)	0.8 (–2.9 to 4.5)	7.9 (–6.5 to 22.3)	<b>14.5 (2.4–26.6)</b>
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	<b>3.0 (0.5–5.6)</b>	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.

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**NOT FOR PUBLIC RELEASE**

赤ちゃんが  
こんなふうに  
泣くことを  
知っていましたか

Japanese

健康な赤ちゃんなら  
生後 5 ヶ月間はとともよく泣くもの。

### The Period of **PURPLE** Crying®

「パープル・クライング」は  
この泣き行動を理解するための新しい考え方。  
赤ちゃんに泣かれる前に、  
何が正常であり、どう心の準備をするかを  
説明します。

### The Period of **PURPLE** Crying®

パープル・クライング  
(赤ちゃんのよく泣く時期)



赤ちゃんの泣き行動を  
理解するための新しい考え方

1

The Period of **PURPLE** Crying®「パープル・クライング」と呼ぶ理由は、親を悩ます乳児の泣き行動を示す英語の頭文字にあります。

<b>P</b>	<b>U</b>	<b>R</b>	<b>P</b>	<b>L</b>	<b>E</b>
<b>PEAK OF CRYING</b>	<b>UNEXPECTED</b>	<b>RESISTS SOOTHING</b>	<b>PAIN-LIKE FACE</b>	<b>LONG LASTING</b>	<b>EVENING</b>
ピークがある	予想できない	なだめられない	痛そうな表情	長く続く	夕方
生後2週間から週を追ってさらに泣くようになり、2ヶ月目がピーク。3-5ヶ月目に和らいでいく	泣いては止み、止んでは泣き出す。どうしてなのか理由が分からない	何をしても泣き止まないときもある	たとえ痛くなくても痛そうに泣いたりする	1日5時間以上泣くことがある	午後から夕方にかけてよく泣く

2

## 赤ちゃんは泣くもの

「うちの子はほかの子よりよく泣く」と思っていないですか。でも覚えておいてください。

- 生後2週間から、週を追うごとにもっと泣くようになる
- 通常は生後2ヶ月目に最もよく泣く
- 2ヶ月以降は週ごとに泣かなくなっていく

たとえ1日に5時間泣いても  
元気で正常な赤ちゃんであり得ます。



イライラしてしまうこともあるでしょうが、The Period of **PURPLE** Crying®「パープル・クライング」には終わりが来ます。

3

## 赤ちゃんのなだめ方



赤ちゃんに泣かれたら、いろいろな方法でなだめてみましょう。

- お腹がすいていたり、眠かったり、おむつが汚れていないかを確認する
- 赤ちゃんを抱いて歩いたり、歌ったりする
- お風呂に入れてあげる
- 散歩やドライブに行く
- 抱き寄せてスキンシップする

これらが毎回うまくいくわけではありません。泣く時間を半分に減らせるかもしれませんが、なだめてもいつも効果があるとは限りません。

何か問題があつて泣いているのか、医師にいつでも相談できることを忘れないでください。

4

## 泣かれるとイライラするのはなぜ？

- 思っていたよりもよく泣く
- 考えていたよりも大変
- 何をしても泣き止んでくれない
- 自分は悪い親で、間違ったことをしているような気がする
- 疲れてしまっていて、赤ちゃんを世話できていないことに罪悪感を感じる
- 親として失格だと思ふ

怒りを感じたり動揺してもいいのです。そんな気持ちにどう対処するのが大切。泣き声からちょっと離れて、自分もいたわってあげてください。

泣かれてしまつて怒ったり、フラストレーションが高じて自分を抑えきれなくなった親が、思わず赤ちゃんを激しく揺さぶってしまうことがよくあります。



5

## 必ず覚えておくこと

泣かれてイライラするときに

1. **赤ちゃんを抱いて、なだめて、歩いて、語りかける**  
赤ちゃんが泣いているのなら、できることを何でもしてなだめてみましょう。毎回でなくても、泣き止んでくれることがあるはずです。
2. **我慢しきれなかったら**  
その場を離れてもかまわない  
赤ちゃんを安全な場所に寝かせ、数分かけて自分を落ち着かせてから戻り、赤ちゃんの様子を確認します。
3. **決して赤ちゃんを揺さぶったり、暴力を振るわないこと**



6

## 揺さぶるとなぜ危険なのか

親がわが子を揺さぶり、暴力を振るう。第一の理由が泣かれること

泣き続ける赤ちゃんにイライラする親や赤ちゃんを世話する人が、「なぜ泣き止まないの!」などと言いながら赤ちゃんを前後に激しく揺さぶってしまうことがあります。

赤ちゃんを揺さぶるのはとても危険であり、以下につながることもあります。

- 失明
- 学習障害
- けいれん
- 身体障害
- 死亡



7