

The *Period of PURPLE Crying*[®]:
A New Way to Understand Your Baby's Crying:

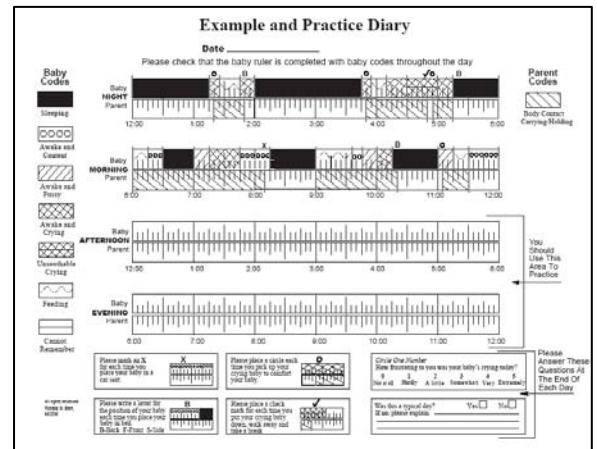
**A program of the
 National Center on Shaken Baby Syndrome, USA
 Offered by
 Prevent Shaken Baby Syndrome BC, a program of BC Children's Hospital**

**Randomized Controlled Trial on the
 Effectiveness of the *PURPLE* Materials**

From 2005 – 2007 two large randomized controlled clinical trials took place to validate the efficacy of the updated English version of the *Period of PURPLE Crying* educational materials. This was an international project with main sites in Seattle, Washington, USA and Vancouver, British Columbia, Canada. The principal investigators were Fred Rivera, MD, MPH, University of Washington, Seattle, Washington, Ronald G. Barr, MDCM, FRCPC, University of British Columbia, Vancouver, British Columbia and Marilyn Barr, Executive Director, National Center on Shaken Baby Syndrome, Utah, USA, and also Director, Prevent Shaken Baby Syndrome BC, Canada. The Canadian research was funded by the British Columbia Ministry of Children and Family Development among others, and the US research was funded by the Doris Duke Charitable Foundation and the George S. and Dolores Doré Eccles Foundation. Coordinators for the project were Emily Meredith-Benitz, USA, Nicole Catherine, and Jocelyn Conway, Canada.

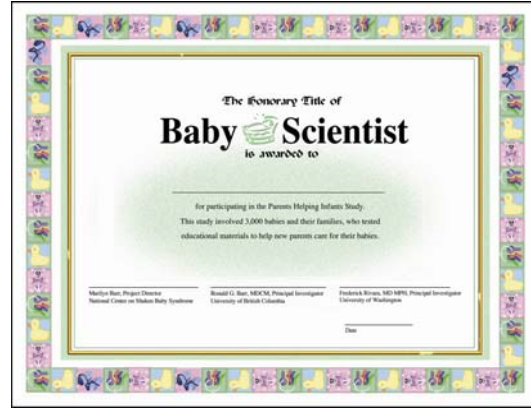
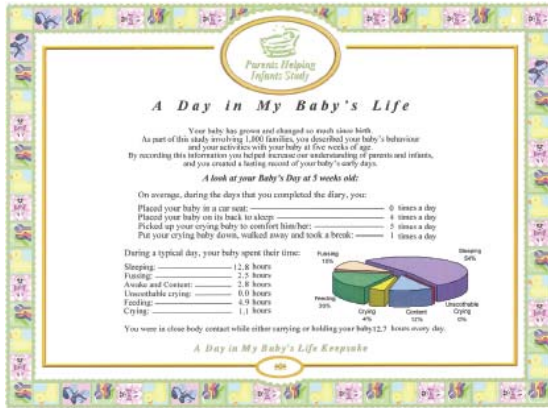
The hypothesis of the research was that the intervention materials could be effective in reducing the abuse and shaking of infants through changes in knowledge, attitudes and behaviours about early infant crying, especially inconsolable crying. The materials were delivered to the participants in four methods: in Vancouver, through public health nurse home visits and in Seattle, through maternity wards, pediatricians' offices, and prenatal classes. The subjects were randomly assigned to an intervention arm where they received the *Period of PURPLE Crying* materials (a 10-minute DVD and an 11-page booklet) or to a control arm where they received comparable information about general infant safety.

Other than the delivery mode to participants, the research protocol was the same in both sites. The instruments used to measure the subjects' potential changes were: (a) a Baby's Day Diary that mothers filled out over four consecutive days when their baby was five weeks old that included both infant and parent behaviours and (b) a 20 minute telephone survey when their baby was two months old. Potential behaviour changes were measured through the Diary and



changes in attitudes and knowledge were discerned through the telephone survey. Over 4,400 parents participated in the two studies.

As this was known to be a particularly busy time for parents, the mothers who agreed to participate received several incentives to complete the study. The participants who completed the Baby’s Day Diary received “A Day in My Baby’s Life” (a synopsis of Diary categories and information specific to their baby) and all participants received the study materials, a small teddy bear, a \$25 cheque and a Baby Scientist Certificate.



We would like to thank the following organizations for providing the ability to recruit at their site.

In British Columbia, participation was provided through the following hospitals and community/public health units:

Vancouver Coastal Health Authority:	
Hospitals	BC Women’s and Lions Gate Hospitals
Health Units	Three Bridges, North, Evergreen, Pacific Spirit, Raven Song, Parkgate, Central and West
Fraser Health Authority:	
Hospitals	Burnaby, Langley Memorial, Surrey Memorial, and Royal Columbian Hospitals.
Health Units	Burnaby, Cloverdale, Guildford, Newton, North Surrey, North and South Delta, New Westminster, Port Coquitlam and Tri-Cities Health Units.

In Seattle, Washington participation was provided through the following hospitals, pediatricians’ offices, and prenatal classes:

Seattle Hospitals	University of Washington Medical Center, Overlake Hospital Medical Center and Evergreen Hospital Medical Center
Seattle Prenatal sites	Highline Community Hospital, Valley Medical Center, Providence Everett Medical Center, Auburn Regional Medical Center, Great Starts

	Prenatal Classes, Gracewinds Perinatal Services, Stevens Hospital, Overlake Hospital Medical Center, Swedish Medical Center and University of Washington Medical Center
Seattle Pediatrician sites	Odessa Brown Children's Clinic, Valley Children's Clinic, Mercer Island Pediatrics, Pediatric Associates, Ballard Pediatrics, Virginia Mason, Skagit Pediatrics, Tacoma Pediatrics, and The Vancouver Clinic

Vancouver Health Unit Participation: The inclusion of public health nurse home visitors was a unique contribution for the BC arm of the study as the Seattle participants all received their materials from research assistants. Training was provided to all participating health units by the community program coordinator, Jocelyn Conway. Nurses were trained on how to deliver the study materials and teach mothers how to fill out the Baby's Day Diary. Usually two training sessions per health unit was needed to reach all of the approximately 262 health nurses and training sessions ranged from 1 to 1.5 hours. Overall, the nurses were enthusiastic about their contribution as they are not often involved in evidence-based research that supports their own programs by validating community health materials. A debriefing session was provided at the end of the study to all the participating health units which included a viewing of the *Period of PURPLE Crying* DVD. The nurses responded positively to the new materials.

The studies were completed in early 2007 and it took several months to analyze the data. We feel the data is encouraging and that is one reason the program is now available. Both studies found that there was a statistically significant increase in the knowledge about normal infant crying and understanding the dangers of shaking an infant. The findings were also statistically significant regarding the parents' behaviour in that they were willing to share the information with others.