THE IMPACT OF AN EDUCATIONAL INTERVENTION ON KNOWLEDGE ABOUT INFANT CRYING AND ABUSIVE HEAD TRAUMA, AND BEHAVIORS IN RESPONSE TO INFANT CRYING

by

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ABSTRACT

This study evaluated the impact of post-partum delivery of the *Period of PURPLE Crying (PURPLE),* a crying education program in a group of first-time mothers. Frustration with a child's crying is reported as a trigger for abusive head trauma (AHT). All infants follow a predictable trajectory of increased early crying. By educating caregivers about its frustrating properties and appropriate ways to respond, AHT may be prevented. The primary objective of this study was to determine whether there was a change in knowledge about crying and shaking knowledge after exposure to *PURPLE*. We also studied factors associated with behavioral responses to crying and the uptake and perceived utility of *PURPLE*. There was a significant increase in knowledge about infant crying ($P = 0.001$) after program delivery that was predicted by low baseline crying knowledge ($P \leq 0.01$). There was a non-significant negative change in shaking knowledge ($P = 0.5$), which may have been the consequence of a high baseline knowledge of shaking. Overall, the *PURPLE* program was characterized as informative and useful by the majority of participants. Additional study is required to evaluate the impact of program delivery on other caregivers and on the rates of AHT.

LIST OF ABBREVIATIONS AND SYMBOLS USED

<	Less than
≤	Less than or equal to
>	Greater than
≥	Greater than or equal to
AHT	Abusive Head Trauma
CDC	Centre for Disease Control
CI	Confidence Interval
CT	Computerized Tomography
DHA	District Health Authority
ED	Emergency Department
FNASU	Family, Newborn and Adult Surgery Unit
ICD	International Classification of Disease
IWK	IWK Health Centre
MRI	Magnetic Resonance Imaging
N	Quantity
NICU	Neonatal Intensive Care Unit
NS	Nova Scotia, Canada
OR	Odds ratio
P	P-value
P	Page number
PEI	Prince Edward Island, Canada
PSBSPP	Perinatal Shaken Baby Syndrome Prevention Program

RCPNS	Reproductive Care Program of Nova Scotia
SBS	Shaken Baby Syndrome
SD	Standard deviation
USD	United States dollar
vs.	versus

GLOSSARY

Abusive Head Trauma	A form of physical abuse that occurs when an infant or young child is violently shaken or shaken and impacted. Defined by a well recognized grouping of physical, laboratory and imaging findings including brain injury, subdural hemorrhage, retinal hemorrhages and skeletal injury.
Computed Tomography	An x-ray procedure that combines many x-ray images with the aid of a computer to generate cross-sectional views and three-dimensional images of the internal organs and structures of the body. CT of the head is useful for detection of subdural hemorrhage.
Magnetic Resonance Imaging	Imaging produced with molecules that make up a substance of the body such as soft tissues. Magnetic resonance imaging is used to visualize body structures that do not show up well on x-rays. MRI of the head is useful for diagnosis of brain injury.
Neonatal Intensive Care Unit	Specialized unit which cares for premature or otherwise ill newborn infants.
Nuclear Bone Scintigraphy	A diagnostic imaging primarily used to evaluate bones and joints. A radioactive substance is injected into the body and the image of its distribution and uptake in the skeletal system is analyzed to detect abnormalities. Often used in conjunction with x-ray imaging to detect recent skeletal injury.
Retinal hemorrhages	Bleeding from the blood vessels in the three layered retina, the nervous tissue at the back of the eye. Not visible without an ophthalmoscope or Retcam which allows the examiner to see the back of the eyeball.
Shaken Baby Syndrome	A form of physical abuse that occurs when an infant or young child is violently shaken or shaken and impacted. Defined by a well recognized grouping of physical, laboratory and imaging findings including brain injury, subdural hemorrhage, retinal hemorrhages and skeletal injury.

Skeletal Survey	A series of x-rays taken which altogether provide imaging of the entire boney skeleton. Often performed to determine if unrecognized injury is present in infants and young children.
Subdural Hemorrhage	Bleeding that occurs within the head between the brain and one of its surrounding membranes.

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CHAPTER 1 INTRODUCTION

1.1 RATIONALE FOR THE STUDY

Shaken baby syndrome (SBS) or abusive head trauma (AHT) occurs when an infant or young child is violently shaken or shaken and impacted against a hard or soft surface. In a recent retrospective review of twenty-nine AHT cases in which there were perpetrator confessions, all perpetrators described having "violently shaken" the infant [1] and five of these reported a specific impact of the infant's head.

In recent years, SBS has come to be described in less mechanism-specific terms since shaking is only one of the many ways in which a child can sustain an inflicted traumatic brain injury. Terms such as AHT, Inflicted Childhood Neurotrauma and Non-Accidental Head Injury better reflect the potential types of forces to an infant's body including blunt force trauma, penetrating trauma and asphyxiation [2], all of which can lead to injury. In a 2009 position paper, the American Academy of Pediatrics [3] offered that the term AHT should be used for medical and legal purposes while SBS was preferred for prevention and public education messaging. The terms AHT and SBS will be used interchangeably in this work.

A number of active and passive surveillance programs have been conducted both in Canada and internationally to estimate the incidence of AHT. Reported incidence rates of AHT vary widely and are reported to be between 6.7–29 per 100,000 infants under one year of age per year.[4-7] It has been suggested that some of the variation in reported incidence may be attributed to varying study case definitions, method of surveillance and coding systems and /or to real differences in AHT prevalence between countries.[8]

Two recent surveillance studies [5, 8] found similar incidence in AHT. Using an active surveillance methodology, Bennett and colleagues reported an annual incidence rate of 14.1 cases of AHT per 100,000 for children less than 1 year of age.[5] Using the International Classification of Disease codes (ICD-10), Fujiwara and colleagues [8] reported that for those less than 1 year of age, a mean incidence of 13-15.5 per 100 000 person-years. Both studies found significantly lower incidence of AHT in the second year of life. Recently, an increased incidence of AHT has been reported in the United States during 19 months of an economic recession [9] as

compared with the incidence in the preceding 47 months suggesting that during times of increased stress, greater attention to family violence prevention programs may be required.

Reported AHT incidence is relatively low; however, the true measurable incidence is likely to be higher than reported published rates for a number of reasons. Some children who suffer AHT may not be brought to medical attention and of those who are brought for care, the diagnosis is frequently missed.[10, 11] The lack of perpetrator admission of guilt may also impact the recognition or diagnosis of cases of AHT.[10, 11]

In an active national prospective surveillance program conducted through the Canadian Paediatric Surveillance Program Society (CPSP), 220 cases of AHT were reported in Canada between 2005 and 2008.[5] In this series of reported cases of AHT, the median age at presentation was five months, with seventy-three percent of children involved being less than one year of age (n=141). Of the confirmed cases, 7% (16) were from Eastern (including Nova Scotia) and Northern Canada. Ninety-one percent of confirmed cases were hospitalized and 53% required admission to an intensive care unit. Of the 220 confirmed cases, outcome data was not reported for 12% (27) of cases and another 12% (27) resulted in death. Of the remaining cases, at the time of hospital discharge, 55% (91) were reported as normal while 45% (75) had neurological sequelae ranging from mild to severe. Thirty percent of all cases (67) had been previously investigated by child welfare authorities.[5]

Typically, an infant with AHT will be brought to medical attention because of non-specific symptoms such as irritability or vomiting and after investigation is found to have physical, laboratory and imaging findings believed to have resulted from either shaking or impact injury or both. Victims of AHT typically present with unexplained or inadequately explained cerebral dysfunction, intracranial hemorrhage (usually subdural), retinal hemorrhages, and rib and /or other skeletal fractures. [2 ,3, 12-17] External evidence of trauma such as bruises may be absent when injury occurs without direct impact of the head and not all clinical features need to be present for a diagnosis of AHT to be made.

In a recent systematic review, Maguire and colleagues[18] studied clinical features of AHT and non-AHT cases in 14 high quality comparative studies. Original data was obtained for six studies and an individual-patient pooled-analysis (n=1053) was performed to relate combinations of six clinical features to diagnosis of AHT (n=348) or non-AHT (n= 705) (i.e. bruising, seizures, apnea, long bone fracture, retinal hemorrhages, rib fractures). In children less than three

years of age with intracranial injury and the presence of 3 or more specific clinical features, the positive predictive value of AHT was greater than 85% with an odds ratio of greater than 100. The presence of retinal hemorrhages and rib fractures were the most discriminating features between the AHT and non-AHT populations.[18]

Piteau and colleagues[19] also conducted a meta-analysis to determine clinical and radiographic characteristics associated with AHT and non-AHT. Data was not combined on an individual patient level and clinical features were not analyzed in combination. They included twenty-four high quality studies, four of which were also part of the Maguire review.[19] A number of clinical features, that individually were significantly associated with AHT were identified such as subdural hemorrhage, cerebral ischemia, retinal hemorrhages, long bone fracture, rib and metaphyseal fracture, seizures and apnea at presentation and lack of adequate history while epidural hemorrhage, scalp swelling and isolated skull fracture (s) were each significantly associated with non-AHT.[19]

Recognizing that AHT can present in multiple guises is an essential first step in making the diagnosis. Medical management at the time of presentation should focus on the differential diagnosis of the complaint for which the child was brought to medical attention. For example, an infant who is brought for medical care with a fever may require testing to rule out possible infection of the blood, urine or spinal fluid.

All infants and young children in whom AHT is suspected should undergo a multi-image skeletal survey, nuclear bone scintigraphy (if available), dilated ophthalmoscopy by an ophthalmologist and head imaging such as a Computed Tomography (CT) Scan or Magnetic Resonance Imaging (MRI). A careful physical exam for external signs of trauma should be performed and findings should be documented on a body diagram with appropriate descriptions and measurements. These findings should also be documented in photographs. When a diagnosis of AHT is likely, a multidisciplinary approach to the child and family should be adopted and might include local child welfare authorities, social workers, law enforcement and medical practitioners with expertise in the field of child abuse pediatrics.[17]

Infant, caregiver and environmental characteristics are all important factors when considering the level of risk for AHT.[5, 11, 20-22] In keeping with this, the Centre for Disease Control (CDC) uses an ecological framework in their approach to violence as a public health issue including AHT prevention.[23] A four level socio-ecological model that incorporates

individual, relationship, community, and societal factors and how they interact is used to understand factors that contribute to violence and then to inform prevention efforts (Heads up, CDC) (Figure 1-1). AHT prevention programs typically target multiple "levels" of the model either uniquely or in combination. Using a multi-level approach is thought to be important for ensuring sustainability of prevention efforts. [24] For example, caregiver's knowledge or skills (e.g. how to soothe a crying infant), how people interact (e.g. walking away from a crying infant when frustrated) and protective factors (e.g. having a predefined action plan) are addressed by existing SBS prevention programs. [25-28]

Programs targeting those most at risk of becoming perpetrators is one possible approach to AHT prevention. Some have reported a preponderance of male caregivers as perpetrators of AHT with fathers and step-fathers more often identified as perpetrators. [1, 29, 30] Others have reported an equal distribution of perpetrators between both genders but with male perpetrators being more likely to confess, be convicted and cause greater harm to their victims. [21]

It has been suggested that the most salient infant characteristic contributing to AHT risk is inconsolable crying. [31, 32] Crying, because it is a predictable and potentially frustrating behavior, has become a critical target of prevention efforts. In a recent review of twenty-nine AHT cases in which there was a perpetrator confession, ten perpetrators reported shaking that was repeated because it stopped the infant's crying and the child would "go to sleep after the shaking".[1] Qualitative text from this series illustrates how a caregiver might be triggered into reacting violently because of crying; "He was crying; it drove me crazy, I shook him … maybe 10 times, and threw him on the sofa".[1] The evidence that supports crying as a specific trigger for AHT has helped shape the development of prevention programs that focus on education about infant crying by providing anticipatory guidance to caregivers.

1.2 STATEMENT OF THE PROBLEM

While less common than most other forms of child abuse such as neglect, witnessing family violence and less significant forms of physical injury, AHT results in more severe outcomes: death occurs in 12–36% of cases, and 13–60% of survivors have persistent motor, visual, cognitive and behavioral difficulties. [4, 5, 11, 33, 34] In hospital medical care and long-term care costs for survivors are significant. [20, 35-37] Costs incurred after identification of a case are

shared among the many sectors involved including medical management, investigation and prosecution. Estimates of long-term costs vary widely and have been estimated to be anywhere from eight hundred thousand up to 20 million USD per child over a lifetime.[37, 38]

Given the serious developmental, social and economic consequences of AHT, prevention is an important undertaking. Importantly, two recent systematic reviews of child maltreatment prevention initiatives identified AHT as an area showing promising results.[39, 40]

Return on investment for prevention of AHT is also significant. It has been argued that if implementation of an AHT prevention intervention prevents even one AHT event per year, the costs of implementation may be fully recoverable. [36] More importantly, negative short and long term outcomes for infants, their families, and society may be avoided.[36] Given the serious negative consequences of AHT, if prevention programs are effective "there is likely to be a strong economic argument for their implementation".[38]

The 'public health approach' to prevention has four steps: (1) define and quantify the problem, (2) identify risk and protective factors, (3) develop and test prevention strategies, and (4) assure widespread adoption of prevention principles and strategies. Challenges exist with each of these steps.

With respect to AHT prevention, the first challenge is how best to define and quantify the problem. It has been argued that consistent nomenclature and standardized data capture procedures are essential to more fully understand the scope of this problem.[41, 42,] Defining risk factors for AHT have been addressed primarily by review of retrospective data sets and also by prospective case collection methods. [1, 5 , 11, 21-22] These are described more fully below.

Step three, the development and testing of AHT prevention strategies remains an area of ongoing study and evaluation. Through the development and testing of prevention strategies, information can be gathered about their effectiveness, and areas of strength and weakness. Evaluation of strategies is critical prior to their widespread implementation. In the area of AHT prevention, program evaluation and dissemination are still in their infancy.

Primary prevention aims to prevent AHT and is targeted at those who are 'asymptomatic'. Examples included educational initiatives about SBS and its consequences or messages about how to cope with a crying infant. Secondary prevention initiatives are also important and constitute an immediate response after AHT has occurred. Tertiary prevention strategies aim to minimize the long term consequences of violence.

Prevention strategies can also be classified by the group for whom the intervention is intended or delivered. Selected interventions are aimed at those who are thought to be at risk for AHT, for example male care providers. Universal interventions are aimed at the general population regardless of level of risk. Examples of universal AHT prevention initiatives include prenatal or postpartum delivery of anticipatory guidance about infant crying to all parents and caregivers.

In the evaluation of AHT prevention initiatives, because the actual outcome of interest is a relatively rare occurrence, many have chosen to evaluate upstream or proxy measures such as change in knowledge, attitude or behavior. A change in knowledge may be the initial step required to effect a change in behavior and ultimately reduce the number of cases of AHT.

1.3 THESIS PROJECT

The *Period of PURPLE Crying* (*PURPLE*) is a crying education program for caregivers reported to improve knowledge about early infant crying and facilitate appropriate behavioral responses to infant crying. It is a universally delivered primary prevention program. Since February 2012, all families who give birth at the IWK Health Centre in Halifax receive the program as part of standard newborn care and postpartum discharge planning.

The primary purpose of this research was to determine whether there is a statistically significant change in the knowledge of first time mothers about infant crying and infant shaking after receiving the *Period of PURPLE Crying* program materials and to identify predictors of change. Additionally, we evaluated the uptake and perceived utility of *PURPLE* among a population of first time mothers.

A sample of first time mothers was recruited during their birth admission at the IWK Health Centre. Prior to their exposure to the *PURPLE* materials, a pre-intervention questionnaire was delivered during an in-person interview. Participants then received the *Period of PURPLE Crying* program. A follow-up post-intervention questionnaire was administered in a telephone call approximately 4-6 weeks after discharge from hospital.

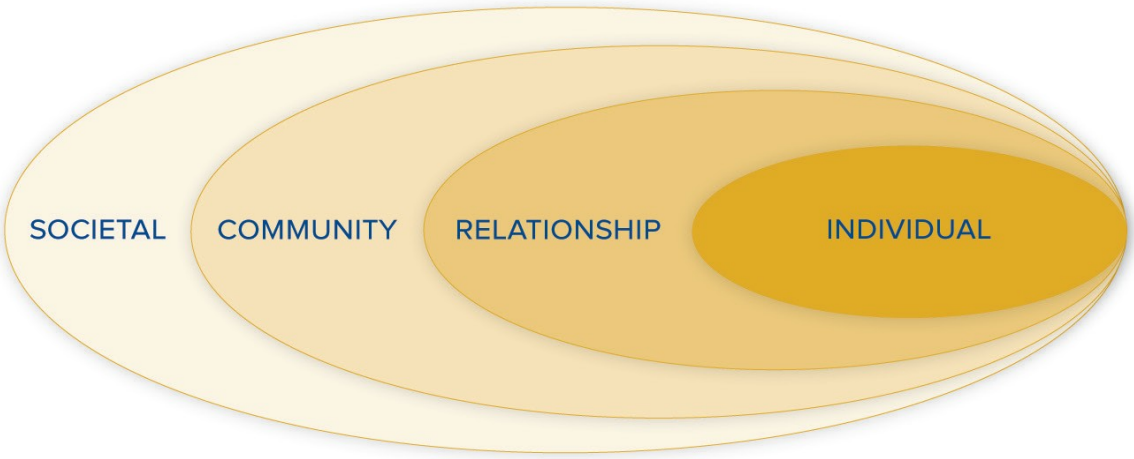

Figure 1-1 Four-level ecologic framework for prevention initiative [23] (reproduced with permission; Appendix A)

CHAPTER 2 REVIEW OF LITERATURE

2.1 Risk of AHT and Infant Crying

In an effort to prevent AHT, the identification of infants "most at risk" has been attempted. The perpetrator of AHT is more likely to be a live-in male caregiver such as a biological father, a mother's boyfriend, or a stepfather, and to be less than 24 years of age [11,29] Single parent status, drug addiction, and domestic violence have also been associated with increased risk. [11] Social and environmental factors including low income, lack of social support, poor prenatal care, diminished marital satisfaction, and poor family functioning [11,22,43] are also associated with AHT. Infant characteristics including male gender, history of prematurity, excessive crying, developmental delay, and feeding difficulties have also been reported as risk factors.[5,43] Young age is also a significant risk factor especially in those under one year of age with the peak incidence of AHT cases reported at two months of age. [8,32,44,45] This is shown in Figure 2-1.

Although caregiver characteristics are associated with the level of risk for AHT, crying is thought to be a specific trigger for AHT.[1, 32 ,44] Early infant crying can be a frustrating behavior for caregivers to manage. Both the length of crying bouts and unsoothable characteristics of the crying have been significantly associated with caregiver self-rating of frustration.[46] The convergence of multiple lines of evidence has led to AHT prevention efforts which focus on the predictable period of increased crying behavior in infancy.

The first study of early infant crying emerged in the 1960's with the work of Dr. T Berry Brazelton who studied crying behavior patterns in normal healthy babies. He found that all infants went through a stage in their development of increased crying beginning at about 2 weeks of age, peaking at six weeks of age and then decreasing around 3-4 months of age. [47] These findings were reproduced by Barr and colleagues who found a similar pattern of onset, peak and time to resolution of increased early infant crying.[31, 48, 49]

A common explanation provided to caregivers is that their baby has colic which is often perceived as meaning there is something wrong with the baby.[50] The study of development

across cultures, care giving milieus and species has led to a reframing of "colic" as a normal part of infant development. Based on reproducible features, such as the pattern (i.e. increasing, peaking then decreasing), similar distribution of crying bouts and lack of predictability for onset and ending of crying irrespective of parenting style, there is evidence that all babies will transition through a period of increased crying in infancy. The actual amount that a baby will cry can vary with some crying for up to five hours a day and for others as little as thirty minutes. Barr explains that this evidence "…has contributed to the reconceptualization of the early increases and decreases in infant crying as a manifestation of the development of normal infants".[50]

Crying itself is a reflection of the infant's current behavioral state. The transition out of this state is driven by the infant and is essentially independent of the caregiver's action. The uncertainty for caregivers that is created by this paradigm can itself be a source of frustration because "the very same soothing efforts …may be effective some of the time but not at others".[50] It also helps to explain why at times a baby's crying is described as "unsoothable" because despite the best efforts of the caregiver, it is the baby alone who transitions from its behavioral state to a non-crying one.

Several researchers have demonstrated in their work that when superimposed, the incidence curve for AHT and the peak of the early infant crying curve overlap to an impressive extent and suggested an association between these two observations.[32,44,51] By highlighting the overlap of the age-specific incidence curve of AHT hospitalizations and the normal early infant crying curve [30,42,49], frustration with a child's crying is believed to be a trigger for violence by a caregiver potentially resulting in physical harm.[32, 44, 51] This is supported by findings from select perpetrator confessions in which getting the baby to stop crying was cited as an explanation for why an infant was shaken[1]. This means that there is potentially a unique opportunity to prevent AHT. By promoting a greater understanding of the properties of crying, why it can be frustrating for caregivers and the appropriate responses to take when faced with a crying infant, caregivers may be better equipped to handle this foreseeable normal behavior.

Knowing that all babies will move through a period of heightened early infant crying and that this period can be a source of frustration for caregivers is critical for those responsible for providing care. Caregivers may interpret their inability to soothe their baby as a lack of parenting skill or failure while others may take it personally and believe that their baby does not love them

or is crying to purposefully upset them. Clinical experience supports that these feelings may result in frustration with the infant and trigger a violent response towards them.

As such, crying education and learning how to cope with a crying infant are core components of many AHT prevention programs. [25-28] Recent studies have demonstrated greater knowledge about the dangers of shaking and the 'physiological results of shaking' [25, 52] when compared to knowledge about infant crying. For example, while 98% of mothers knew of the dangers of shaking, only 25% of parents were aware that infants may 'cry for no reason'.[52] This trend, of parents having greater knowledge about the harms of shaking than about normal infant crying, was also observed in two recent large randomized controlled trials. [27, 28] However, recognizing the inter-relationship and importance of sound knowledge about the dangers of shaking and infant crying, most AHT programs continue to educate about both the danger of shaking and early infant crying.

2.2 The *Period of PURPLE Crying*

In response to research about normal infant crying as a trigger for shaking, Dr. Ron Barr and others at the National Center on Shaken Baby Syndrome (NCSBS) developed an AHT/SBS and infant abuse prevention program. [53] This program, called the *Period of PURPLE Crying* was developed based on knowledge about normal infant crying and its association with AHT. [53] In the development of the program, close to forty focus groups with parents in two countries were conducted. The *Period of PURPLE Crying* is an educational program which highlights the features of normal infant crying. The program materials also teach that babies should never be shaken, and highlights the importance of sharing program information with all of the infant's caregivers. Each of the letters in the word *PURPLE* refers to a characteristic of infant crying:

P for **Peak of Crying**-Crying peaks during the second month, decreasing after that;

U for **Unexpected**-Crying comes and goes unexpectedly, for no apparent reason;

R for **Resists Soothing**-Crying continues despite all soothing efforts by caregivers;

P for **Pain-like Face**-Infants look like they are in pain, even when they are not;

L for **Long Lasting**-Crying for 30-40 min and as much as 5 hours or longer;

E for **Evening Crying**-Crying occurs more in the late afternoon and evening.

Program materials consist of a 10-minute DVD and an 11-page full color booklet which are available in 10 languages and close captioned. The cost of purchasing the program ranges from $2.12 to $3.70 per package depending on the number purchased.[53]

The *Period of PURPLE Crying* program has been implemented to differing extents in parts of Canada, the United States, Australia and Japan. Jurisdiction wide implementation has been accomplished in two Canadian provinces and one territory; British Columbia, Prince Edward Island and the Yukon. While in the US, five states deliver *PURPLE* jurisdiction wide and for many others, jurisdiction wide implementation is in progress. [53]

The behavioral component of the program describes three action steps that guide caregivers on how to respond to crying to prevent shaking and abuse. These action steps are: (1) "Comfort, carry, walk and talk" behaviors, (2) It is "OK to walk away" and (3) It is "Never OK to shake or hurt" your baby to stop its crying under any circumstances. [51] By providing the information, that even in infants who cry many hours a day, it will come to an end at about 4-5 months of age, parents can become more aware and equipped to cope with their crying infant during this period. In 2012 the program package was expanded to include a 17-minute video called *Crying, Soothing, and Coping: Doing What Comes Naturally.* This video is considered supplementary to the core program and to date has not been extensively evaluated.

The *Period of PURPLE Crying* adopts a three-dose approach to deliver, reinforce and maximize the reach of its messages. Delivery of the DVD and booklet are considered Dose One. Universal delivery of the program commonly occurs during the birth admission as part of newborn care and discharge planning. [53] The materials are delivered in a standardized manner by a health care professional and then are given to each family to take home. Dose Two occurs when program messages are reinforced by others including public health, physicians and home visitors. Dose Three is a public education campaign which aims to create awareness and change within the general public about the normalcy of early infant crying and the dangers of shaking or hurting a baby.

The results of two large-scale randomized controlled trials to date have shown some promising results. Mothers who received the program materials scored higher on crying

knowledge scales and were more likely than controls to share advice and information with other caregivers about walking away if frustrated by inconsolable crying. They were also more aware of the dangers of shaking. [27, 28] The improvement in mean crying knowledge scores, measured on a scale ranging from 0-100, between intervention and control groups was statistically significant in both studies but small in absolute terms. For example, in one study the mean crying knowledge score in the *PURPLE* intervention group, was 69.5 vs 63.3 in the control group (on a 100 point scale); similar changes were observed in the second trial. [27, 28] Similar improvements in knowledge about the dangers of shaking an infant were not observed, most likely because the parents' scores were already high, leaving little room for improvement. Changes in parents' handling of their babies during crying (e.g. walking away if frustrated) were not consistently demonstrated by the studies. [27,28] Recently, the results of these studies have been replicated in a randomized controlled trial of 201 parents in Japan.[54] Scores for crying knowledge were higher in the intervention group, who received the *PURPLE* materials than control group (56.1 vs.53.1; $P < 0.005$). Sharing of advice to walk away and walk away behaviors were also higher in the intervention group.

How the implementation of the *Period of PURPLE Crying* program will ultimately affect the incidence of SBS/AHT is currently under study. Several longitudinal studies, including active surveillance of both AHT and physical abuse of infants, are currently underway in the United States and Canada [55-57] and results are eagerly anticipated.

2.3 AHT Prevention Efforts in Nova Scotia

In the first phase of a planned research program about AHT prevention at the IWK Health Centre, Ornstein, Abeysekera and O'Connell [58] examined caregiver preparation for and confidence in their ability to manage early infant crying (IC). Participant knowledge about patterns of IC, dangers of shaking an infant, and caregiver behaviors were also assessed. One hundred and ten first-time mothers were surveyed about their prenatal preparation and perceived level of confidence for managing infant crying compared with their preparation for labor and delivery, feeding and nutrition. The mean preparation score (max=7) for IC (4.68) was significantly lower than the mean scores for labor and delivery (LD) (5.55) and feeding and

nutrition (FN) (5.10) ($P < 0.02$). Conversely, mean confidence level (max=4) for management of IC (3.55) was significantly higher than for LD (2.59) and FN (3.36) ($P < 0.002$).

Although participants were knowledgeable of the consequences of shaking, they were less knowledgeable of normal infant crying. A full one-third of respondents did not demonstrate knowledge of safe walk away behaviors such as placing the infant in a safe place which suggests that first time mothers are less prepared for managing crying when compared with other domains of infant care. They nevertheless were confident in their management abilities. These findings are supported elsewhere in the infant crying literature [24,26,27,50] and demonstrate a need for enhanced education in Nova Scotia about patterns of infant crying and appropriate caregiver responses.

In a second phase of AHT prevention research at the IWK Health Centre, the *Period of PURPLE Crying* program materials were delivered in the Emergency Department (ED), a novel and practical setting for delivery of this information.[59] All caregivers of infants under the age of six months who presented to the ED and consented to participate completed a pre intervention questionnaire assessing knowledge, attitude and behaviors with respect to infant crying. The *Period of PURPLE Crying* program materials were then delivered with each participant viewing the DVD in a quiet, private location and having the opportunity to review the booklet. A follow-up telephone interview using a structured questionnaire occurred 4-6 weeks post intervention to assess participant knowledge of infant crying and behaviors in response to infant crying in the post intervention period. Caregiver satisfaction with having received the *Period of PURPLE Crying* program materials in the ED was also assessed. Eighty participants were enrolled and pre and post intervention data was available for 72 participants.

A statistically significant change in the mean scores was not demonstrated; however, a trend towards increased knowledge in each category (i.e. crying knowledge, shaking knowledge) was demonstrated. For example, the minimum pre score for knowledge of shaking was 22.4 and the minimum post score was 60.74 on a 100 point scale. This trend towards increased minimum knowledge across categories suggests that receiving the *Period of PURPLE Crying* program is effective in fostering an increase in knowledge for some.

This study demonstrated widespread acceptability for the program to be delivered in the ED and parent/caregivers' desire to have access to the program.[59] Caregivers' satisfaction with the pediatric ED as an appropriate location for delivery of the program was overwhelmingly

positive with over 90% (n=67) in agreement that it was appropriate to receive the *Period of PURPLE Crying* Program during their child's visit to the ED and just under 90 % (n=63) in agreement that all families with young infants should receive the program materials. At follow-up, nearly three-quarters of participants (N=53) had reviewed the *PURPLE* booklet at home and nearly half (n=32) had reviewed the *PURPLE* DVD. This overwhelmingly positive acceptance suggests that the ED could potentially be an acceptable setting for delivery of Dose Two reinforcement messaging.

Given, the promising results of *PURPLE* in other jurisdictions and because of the identified gap in prenatal education about infant crying, provision of the *Period of PURPLE Crying* program has been incorporated into standard newborn and post partum care at the IWK since February of 2012. An implementation committee with hospital, government and community organization representation is responsible for ongoing management, education and evaluation of the program. Other DHAs have expressed an interest in the program while others have begun delivery. A provincial frame work for post partum delivery of Dose One has not yet been adopted.

2.4 Summary

Although a rare form of physical abuse, AHT in infants can result in chronic negative physical and developmental outcomes for survivors. The cost to society after identification of a case, both in the short and long term is significant, and existing prevention programs are not expensive to implement. Given the empirical evidence that suggests a window for intervention in the lives of infants; effective prevention programs may have a role in reducing morbidity and mortality from inflicted injury in the pediatric population. Rigorous evaluation of prevention initiatives including specific and proxy measures of their effectiveness is critical and will likely require the study of broad outcome measures in different populations in both the short and long term.

The *Period of PURPLE Crying* has shown promising results as a tool to improve caregiver knowledge about early infant crying, a known source of caregiver frustration and

specific trigger for AHT. Improving knowledge through anticipatory guidance may be the first step towards prevention of AHT and other forms of physical abuse in young children. Due to the rarity of the outcome event, long term and population based evaluation will be required to document effectiveness of AHT prevention programs like the *Period of PURPLE Crying*.

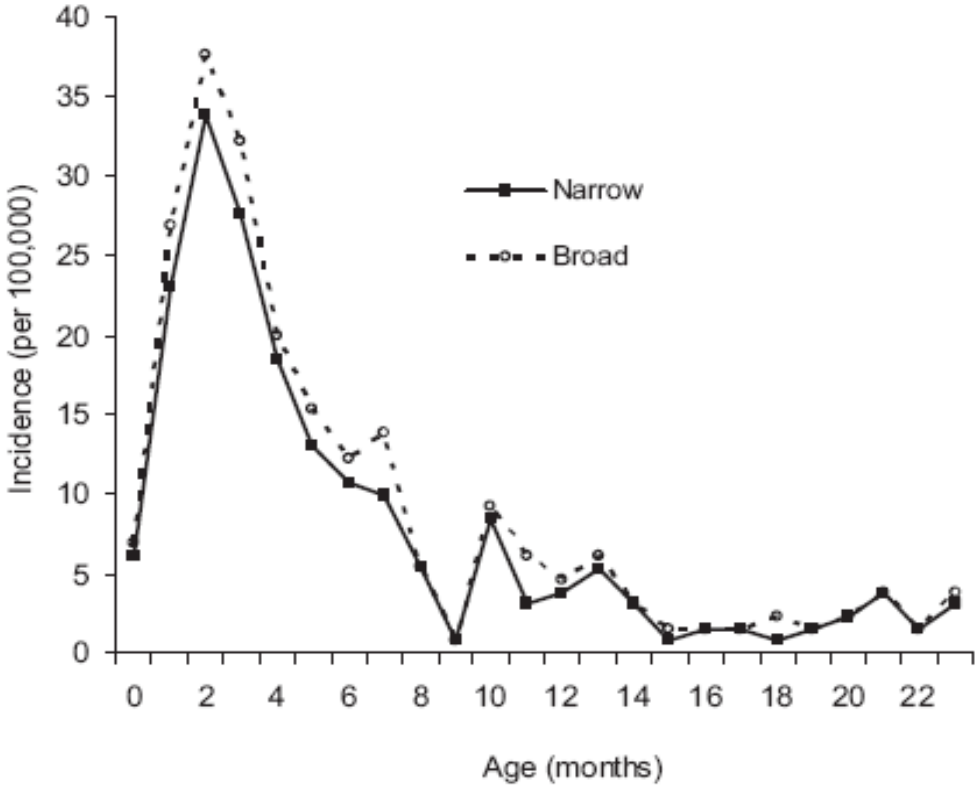

Figure 1. Incidence of abusive head trauma by month of life, narrow and broad probable cases

Note: Incidences are averaged for fiscal years 2002/2003–2007/2008.

Figure 2-1 Incidence of AHT by month of life, narrow and broad probable cases [8] (reproduced with permission; Appendix B)

CHAPTER 3 METHODS

3.1 RESEARCH OBJECTIVES

The proposed research evaluated outcomes following exposure to the *Period of PURPLE Crying* program to all first mothers who received the program on the IWK Family Newborn Adult Surgery Unit (FNASU) and consented to participate. The purpose of the proposed research was to quantify the change in new mothers' knowledge about infant crying and infant shaking and to assess the behavioral responses employed by caregivers when faced with a crying infant. In addition, the uptake and perceived utility of the program was measured among a population of first time mothers who gave birth at the IWK Health Centre. Specific research objectives were:

Primary:

To quantify the change in knowledge of first-time mothers about infant crying and infant shaking after receiving the *Period of PURPLE Crying* program materials.

Secondary:

1. To identify factors associated with a change in knowledge of first-time mothers about infant crying and infant shaking.
2. To determine how often mothers have employed appropriate behavioral responses and self-talk strategies in response to infant crying since discharge from hospital and after receiving the *Period of PURPLE Crying* program materials.
3. To identify factors associated with utilization of appropriate behavioral responses in response to infant crying.
4. To determine whether first time mothers perceive that the *Period of PURPLE Crying* program materials are useful and to determine if they have shared program information with others since discharge from hospital.

3.2 STUDY OVERVIEW

This research project took place at the IWK Health Centre (Halifax, Nova Scotia) on the Family Newborn/ Adult Surgery Unit (FNASU). The study design was a single-group pretest-posttest design to evaluate a group of first time mothers before and 4-6 weeks after the delivery of the *Period of PURPLE Crying* program materials. The study was conducted over 5 months (July-October 2012).

As part of discharge teaching on the FNASU, all mothers receive the *Period of PURPLE Crying* materials and are then given a copy of the program materials to keep. Program materials include a 10 minute DVD and an 11-page information booklet. Recipients are encouraged to watch the DVD in hospital on a portable DVD player and read the program booklet.

Using a convenience sample during the study time period, first time mothers were recruited during their IWK birth admission. A research assistant approached eligible mothers, explained the purpose of the study and obtained informed consent. Each participant was provided with written information about the study (Appendix C). While in hospital, prior to receiving the *PURPLE* program materials, a pre-intervention questionnaire was administered with an in-person interview. Approximately 4-6 weeks after delivery and discharge a post-intervention questionnaire was administered by telephone.

For the duration of the study period, each day a research assistant with the assistance of the clinical leader or designate identified first time mothers who would not be appropriate to approach for participation; all others were approached. Once identified, the research assistant introduced themselves to the new mother, explained the study, provided an information form and sought consent to participate. This process took approximately 5 minutes. After obtaining consent, the research assistant administered the pre-intervention questionnaire. The structured survey took approximately 10 minutes to complete. Total participation time required did not exceed 15 minutes.

A *PURPLE* face sheet (Appendix D) was incorporated into the newborn admission chart and was stamped with the patient addressograph, a notation of the woman's parity and an additional notation was made once they received the *PURPLE* program materials from nursing staff. The face sheet was completed by a member of the postpartum care team and placed in a secure folder by the ward clerk when the chart was disassembled. The *PURPLE* face sheets were

collected by a member of the research team at the end of every week. All first time mothers had a face sheet completed and were assigned a participant number.

Approximately 4-6 weeks post-intervention, a research assistant, trained in telephone interviewing, contacted the new mothers by phone. The participant was reminded about their prior enrollment in the study and ongoing consent for participation was ensured. After consent was reaffirmed, the *Period of PURPLE Crying* Post-Questionnaire was administered. This telephone survey took approximately 10 minutes to complete.

This study was reviewed and approved by the Research Ethics Board of the IWK Health Centre (July 9th, 2012) (Appendix E). The IWK Health Centre provided funding for this project with a Category A grant.

3.3 Study Population

Mothers who gave birth at the IWK Health Centre between July 2012 and October 2012 were invited to participate in the study. Inclusion criteria were: first time mothers with a term newborn being discharged from Family Newborn/ Adult Surgery Unit (FNASU). Exclusion criteria were: inability to converse in English, no telephone for follow-up call and admission of baby to the Neonatal Intensive Care Unit (NICU).

3.4 Study Measures

The questionnaires were designed to collect demographic information, pregnancy and obstetric factors, knowledge regarding infant crying and shaking, behaviors employed in response to infant crying and evaluation of the *Period of PURPLE Crying* Program. Certain measures were only conducted at the initial recruitment point of contact (i.e. pre intervention) or only in follow-up (i.e. post intervention), and others were collected at both points of contact (i.e. pre intervention and 4-6 weeks post intervention).

Pre-Intervention Measures:

Demographic information (Appendix F) was collected for all participants and included; maternal age, paternal age, highest level of maternal education obtained and annual household income. Information about each of these items was requested in categories, some of which were combined prior to analysis because of small cell numbers in individual categories.

Pregnancy and obstetric factors (Appendix G) were collected for all participants and included: maternal past medical and pregnancy history, planned pregnancy, features of the delivery such as the nature of onset of labor, mode of delivery and infant characteristics such as gender and birth weight. Information about these items was either dichotomous or requested in categories.

The Preparation for Infant Crying Scale, shown in Appendix H, was created to capture the amount, type and quality of preparation first time mothers received about infant crying prior to delivery. This scale has been used in prior research about this topic.[58] It was reviewed for face validity and ease of use by experts in the field prior to its original use. The scale consists of five questions including: number of hours spent learning about infant crying before delivery, perceived amount of learning about infant crying before delivery, sources of information about infant crying, utility of information sources and perceived utility of information about infant crying. Responses to perceived amount of learning and utility of information were captured on a Likert response scale, of 4 and 3 points respectively, and with responses ranging from "none at all" to "large amount" and "not helpful at all" to "very helpful".

Information about perceived confidence and future concern about infant crying was collected in a scale created to capture how confident first time mothers feel about managing infant crying (Appendix I). Five questions had been used in prior research about this topic [58] with an additional question added for this study about the participant's prior knowledge of the *Period of PURPLE Crying*. The scale measured the degree of confidence for dealing with a crying infant and degree of concern that crying will be an issue on a 4 point Likert scale with response ranges from "not confident" to "very confident" and "not at all" to "very likely". Which resources participants would consult should they require assistance with infant crying was captured as well as plans for dealing with crying, fussing, and unsoothable crying. Participant's prior knowledge of the *Period of PURPLE Crying* Program was measured with dichotomous response options of yes and no.

Pre and Post-Intervention Measures:

Knowledge of infant crying and knowledge of infant shaking were each measured using previously published sets of questions that were created for research about this topic [27, 28] The scales were designed by experts in the field and pilot tested with subjects prior to use. The Knowledge of Infant Crying (K-IC) Scale is shown in Appendix J and the Knowledge of Infant Shaking (K-S) Scale is shown in Appendix K.

The K-IC scale consists of eight items that included statements about the characteristics of normal infant crying such frequency, onset and duration and how to safely respond to this behavior. Responses were measured on a 4-point (0-3) Likert scale, with participants indicating their degree of agreement with statements about infant crying from strongly disagree to strongly agree. Five items were true statements about crying and stronger agreement with these statements indicated greater knowledge. Three of the eight items were incorrect statements about crying and stronger disagreement with these statements indicated greater knowledge. These three items were reverse scored such that a response of "strongly disagree" was assigned 3 points. The K-IC score was computed by totaling the raw scores for each of the eight items on the crying knowledge scale. The maximum score possible for the K-IC was 24 which was then transformed to a 100 point scale for ease of interpretation.

The K-S scale consists of five items and included statements about the consequences of shaking a baby and responsibility of caregivers for sharing this information with all other caregivers. Responses were measured on a 4-point (0-3) Likert scale, with participants indicating their degree of agreement with statements about shaking an infant. The scale response range was "strongly disagree", "disagree", "agree" and "strongly agree". Four items were true statements about shaking and stronger agreement with these statements indicated greater knowledge. One of the five items was an incorrect statement about shaking and stronger disagreement with this statements indicated greater knowledge. This item was reverse scored such that a response of "strongly disagree" was assigned 3 points. The K-S- score was computed by totaling the raw scores for each of the five items on the shaking knowledge scale. The maximum score possible for the infant shaking knowledge scale was 15. The total score was then transformed to a 100 point range scale (0-100) for ease of interpretation.

A general knowledge score (K-G) was calculated as the mean of the K-IC and K-S. Higher scores indicated greater knowledge about infant crying and shaking. The total score was

then transformed to a 100 point range scale (0-100) for ease of interpretation.

Post-Intervention Measures:

The Response to Crying Generally Scale (Appendix L), Response to Unsoothable Crying Scale (Appendix M) and Self-talk Responses to Unsoothable Crying Scale (Appendix N) are previously published sets of questions that were created for research about this topic. [27, 28] The scales were designed by experts in the field and pilot tested with subjects prior to their use.

The original Response to Crying Generally Scale contained five items, whereas in our research, only four were included because of an omission in the design of the questionnaire itself. The four questions were about specific behaviors in response to crying generally. Responses options were ordinal categories and consisted of increasing frequency of use in the past month: 0=Did not do it; 1=Once or twice; 2=3-5 times; 3= 6-10 times and 4=11 times to almost every day. Two questions in this scale reflect how often information was shared with others about infant crying and how to respond to it. A maximum possible score, which would indicate the highest level of use, was equal to 16.

The Response to Unsoothable Crying scale contained four items about response to unsoothable infant crying referred to as "walk-away behaviors", which are considered to be appropriate behavioral responses and are promoted in the *PURPLE* materials. Response options were ordinal categories and consisted of increasing frequency of use in the past month; 0 = Did not do it; 1=Once or twice; 2= 3-5 times; 3= 6-10 times and 4 = 11 times to almost every day. A maximum possible score, which would indicate the highest level of use, was equal to 16.

The Self-talk Responses to Unsoothable Crying Scale contained four items about specific self-talk behaviors in response to unsoothable crying. Response options were ordinal categories and consisted of increasing frequency of use in the past month: 0= Did not do it; 1= Once or twice; 2= 3-5 times; 3= 6-10 times and 4=11 times to almost every day. A maximum possible score, which would indicate the highest level of use, was equal to 16.

Information about the *Period of PURPLE Crying* Program was collected using a scale designed specifically for this research to evaluate program delivery and perceived utility of the materials including the DVD and booklet. Questions were asked about receipt of the information,

location of review of materials, sharing of the material with others and six items about perceived utility of the program materials (Appendix O).

3.5 DATA ANALYSIS

All analyses were performed using IBM-SPSS® statistical analysis software (version 20). Analytic strategies for each objective are discussed below.

3.5.1 Analysis plan for Primary Objective

To quantify the change in knowledge of first-time mothers about infant crying and infant shaking after receiving the Period of PURPLE Crying program materials.

The difference between pre and post scores was calculated for K-IC, K-S and K-G. A paired t-test was used to assess change in crying knowledge, shaking knowledge and general knowledge from pre to post intervention. Change in knowledge was also assessed within strata of baseline knowledge (i.e. high or low) using a paired t-test. Low baseline K-IC was defined as a score of 62.5 or below and low K-S was defined as a score of 80 or below. These cut-off scores were established by inspection of the distribution of scores for the entire sample on each scale, and were determined based on approximating that 70 percent of the sample to be in the low knowledge group and 30 percent in the high knowledge group. This approach ensured that there were an adequate number of participants in each group and that the knowledge scores in each group were sufficiently distinct.

3.5.2 Analysis plan for Secondary Objective 1

To identify factors associated with a change in knowledge of first-time mothers about infant crying and infant shaking.

Scores for knowledge of infant crying and knowledge of infant shaking were dichotomized into positive change (increased knowledge score) and neutral outcome (no change or decrease in knowledge score) post intervention. In univariate analyses using Fisher exact test, potential predictors of change in knowledge were tested including maternal age, maternal education, household income, infant gender, planned pregnancy, time spent learning about crying, amount learned about crying, confidence about managing a crying infant, anticipation of crying as an issue, prior knowledge of the *Period of PURPLE Crying* baseline crying and shaking knowledge and location the book was read and DVD was watched.

Following univariate analyses, variables with a $P \leq 0.5$ were entered in a backwards stepwise logistic regression model to identify the factors which independently influenced change in crying and shaking knowledge from baseline. The probability for removal of a variable was set at 0.1 and for re-entry of a variable was set at 0.05. An odds ratio with 95% confidence interval was calculated for variables that remained within the final model.

3.5.3 Analysis plan for Secondary Objective 2

To determine how often mothers have employed appropriate behavioral responses and self-talk strategies in response to infant crying since discharge from hospital and after receiving the Period of PURPLE Crying program materials.

How often mothers employed appropriate behavioral responses and self-talk strategies in response to infant crying since discharge from hospital and after receiving the *Period of PURPLE Crying* program materials was evaluated. Frequency of use of individual behaviors in response to crying and unsoothable crying are reported.

Using the frequency responses as measured by a 5 point Likert scale (i.e. “Did not do it =0” to “11 times- almost every day=4)”, a total score was created for each of three scales: response to crying generally, response to unsoothable crying and self-talk behaviors.

Each behavioral scale had a maximum possible response score of 16 and scores were dichotomized into “high frequency users” (top 30%) and “low frequency users” (bottom 70%).

The cut point for the Response to Crying Generally Scale was < 7 versus ≥ 7. The cut point for the response to Unsoothable Crying, < 6 versus ≥ 6. In the Self-talk scale the cut point was < 11 versus ≥ 11. The proportions in each of these categories were reported.

3.5.4 Analysis plan for Secondary Objective 3

To identify factors associated with utilization of appropriate behavioral responses in response to infant crying.

The factors associated with utilization of appropriate behavioral responses in response to infant crying were identified. Participants were classified as either high or low frequency users for each of the three behavioral scales as described above: responses to crying generally, response to unsoothable crying and self-talk behaviors. In univariate analyses using Fisher exact test, potential predictors of significant of utility (i.e. high or low users) for each scale were tested including maternal age, maternal education, household income, infant gender, planned pregnancy, time spent learning about crying, amount learned about crying, confidence about managing a crying infant, anticipation of crying as an issue, prior knowledge of the *Period of PURPLE Crying*, knowledge of crying at 4-6 weeks and location the book was read and DVD was watched.

Following univariate analyses, variables with a $P \leq 0.5$ were entered in a backwards stepwise logistic regression model to estimate the factors which influence independently utilization of the three behavioral response scales. The probability for removal of a variable was set at 0.1 and for re-entry of a variable was set at 0.05. An odds ratio with 95% confidence interval was calculated for variables that remained within the final model.

3.5.5 Analysis plan for Secondary Objective 4

To determine whether first time mothers perceive that the Period of PURPLE Crying program materials are useful and to determine if they have shared program information with others since discharge from hospital.

The perceived utility of the *Period of PURPLE Crying* program material and sharing of information with others since discharge from hospital was explored by using descriptive statistics including frequency counts and percentages.

3.6 POWER

A formula provided by Cohen[60] for the sample size calculation, with power set at 0.80 and α set at 0.05, a sample size of 91 was determined sufficient to detect a medium effect size when employing the most complex analyses (i.e. multiple regression analysis with approximately 5 variables).

CHAPTER 4 RESULTS

During the study period from July 9th to October 25th, there were 302 (IWK, decision support) births to first time mothers at the IWK Health Centre. The majority, but not all, of these women were approached for participation during their hospital birth admission. Reasons for mothers not being approached were primarily logistical such as short length of stay following a birth, birth and discharge over weekends or at other times when the research assistant may not have been available. Study recruitment only occurred during the daytime hours and as a result a number of mothers were discharged prior to the research assistant having an opportunity to recruit them. Also, a number of families had privacy signage posted on their door and were therefore not approached. Other families had already seen the *PURPLE* materials when the research assistant approached them and so they were no longer eligible to participate. Based on the number of births to potentially eligible first time mothers during the study period (n=302) we recruited 125 participants or 41.4% of the eligible cohort.

Figure 4-1 shows the number of participants at each phase of the study and the exclusions. One hundred and twenty five participants consented to participate and completed a questionnaire prior to exposure to the *Period of PURPLE Crying* Program materials. Of these, 97 participants (77.6%) also completed the post questionnaire approximately four to six weeks after discharge from hospital. One participant, who completed the pre-intervention questionnaire, consented to complete the post-questionnaire but a high proportion of data were missing in the questionnaire, so this participant was excluded. Three participants did not receive the *Period of PURPLE Crying* Program materials and were therefore excluded from the analysis. Twenty-eight mothers (22%), of the original 125 were lost to follow-up and did not complete the post questionnaire because we were not able to contact them in follow-up. Included for analysis was data on 93 participants who completed both the pre and post questionnaires. The average number of weeks for completion of the post questionnaire was 5.7 weeks (range: 4.7-9.6 weeks).

Demographic information of the study sample is shown in Table 4-1. Of the 93 participants, most were between the ages of 20-39 (n=88). Over one-half of the mothers had an undergraduate or college degree and reported annual household income of greater than $ 60,000. Thirty-five (37.6%) identified themselves as the primary caregiver of their infant while 62.4% (n=58) reported that care would be shared equally between parents. For 61.3% of participants

(n=57) this was a planned pregnancy and one-quarter of the infants were delivered by caesarian section. Additional pregnancy and obstetric characteristics of participants are shown in Table 4-2.

Primary Objective:

To quantify the change in knowledge of first-time mothers about infant crying and infant shaking after receiving the Period of PURPLE Crying program materials.

The responses of five participants on the pre questionnaire had one question that was not answered in the infant crying knowledge scale. The answer to this question was assigned based on the most frequent response given by that participant to other questions in this scale and was used to calculate the pre K-IC score. Data for pre-intervention shaking knowledge was complete. The responses of nine participants on the post test questionnaire had one question that was not answered, in the infant crying knowledge scale. The answer to this question was assigned based on the most frequent response given by that participant to other questions in this scale and was used to calculate the post K-IC score. Data for post-intervention shaking knowledge was complete.

The mean pre K-IC score was 62.0 (SD = 10.6) and the mean post K-IC score was 65.5 (SD = 10.7). The mean pre K-S score was 84.0 (SD = 7.7) and the mean post K-S score was 83.3 (SD = 10.5).

A paired T-test was used to compare pre and post knowledge score for knowledge of infant crying, shaking and total knowledge. The mean change in knowledge of infant crying was 3.5 (95 % CI: 1.5-5.5; $P = 0.001$) while the mean change in knowledge of shaking was -0.7 (95 % CI: -2.8-1.3; $P = 0.5$). The difference in total knowledge between pre and post scales was 1.4 (95 % CI : 0.3-3.0; $P = 0.1$) (Table 4-3).

For women with low baseline knowledge of infant crying (n=57), the mean difference in knowledge was greatest (6.2, 95 % CI: 3.4-8.4; $P < 0.01$). Participants with low baseline shaking knowledge (n=45) demonstrated a smaller and non significant increase in knowledge scores (1.6, 95 % CI: -1.4-4.7; $P = 0.29$) (Table 4-4). Overall participants with lower baseline knowledge for

both crying and shaking, showed greatest knowledge gains post intervention with Pearson correlations (R^2) of 0.20 and 0.10 respectively (Figures 4-2, 4-3).

Secondary Objective 1:

To identify factors associated with a change in knowledge of first-time mothers about infant crying and infant shaking.

Scores for change in knowledge of infant crying and change in knowledge of infant shaking were dichotomized into positive change (increased knowledge score) and neutral outcome (no change or decrease in knowledge score) post intervention. Univariate analysis of thirteen potential predictors of change in crying and shaking knowledge was conducted.

Seven candidate variables were identified as factors that might influence the change in knowledge of crying (Table 4-5) and were entered in a backwards stepwise logistic regression. These were maternal age years, time spent learning about crying prior to baseline, amount learned about crying prior to baseline, anticipation of crying as an issue, low baseline crying knowledge, watched DVD in hospital, read book in hospital. In the final model, only baseline level of crying knowledge contributed significantly to change in knowledge of crying ($P < 0.01$). Mothers with low baseline knowledge were at significantly greater odds for a knowledge increase than mothers with high baseline knowledge (OR: 5.1, 95% CI: 2.1-12.6, $P \leq 0.01$) (Table 4-6).

In a similar analysis for change in shaking knowledge, seven factors had a $P \leq 0.5$ in the univariate analysis (Table 4-7). These factors included planned pregnancy, time spent learning about crying prior to baseline, perceived confidence level prior to baseline, prior knowledge of *PURPLE*, anticipation of crying as an issue, low baseline shaking knowledge and watched DVD in hospital. In the final logistic regression model, planned pregnancy status, amount of time learning about infant crying prior to baseline, perceived level of confidence for dealing with a crying infant at baseline and prior knowledge of the *Period of PURPLE Crying* all contributed to a significant change in shaking knowledge (Table 4-8)

Mothers whose pregnancy was unplanned were at nearly four times the odds of an increase in shaking knowledge than mothers with a planned pregnancy (OR: 3.98, 95% CI: 1.36-11.59, $P = 0.01$) and mothers who had heard of *PURPLE* at baseline had nearly three times the odds for an increase in shaking knowledge than mothers who had not (OR: 2.71, 95% CI: 0.92-7.95, $P = 0.07$). Mothers who had spent little time (i.e. < 1 hour) or significant amount of time (i.e. > 10 hours) learning about infant crying were at lower odds than mothers who had spent between one and nine hours, for an increase in shaking knowledge ($P = 0.04$). For each increase in the category of confidence for dealing with a crying infant, the odds of an increase in shaking knowledge increased (OR: 1.86, 95% CI: 0.90-3.84, $P = 0.09$) as well (Table 4-8).

Secondary Objective 2:

> *To determine how often mothers have employed appropriate behavioral responses and self-talk strategies in response to infant crying since discharge from hospital and after receiving the Period of PURPLE Crying program materials.*

Participants for which there was significant missing (i.e. ≥ 75%) data were excluded from these analyses. The data for these participants were excluded because the scales captured behavioral responses and answers on one question would not necessarily be predictive of the response to other questions. Of the 93 participants, 8 participants were excluded from the analysis in response to crying generally (n=85), 3 participants were excluded from the analysis in response to unsoothable crying (n= 90) and 7 participants were excluded from the analysis for utilization of self-talk behaviors (n=86). Each behavioral scale had a maximum possible response score of 16 and scores were dichotomized into "high frequency users" (top 30%), and "low frequency users" (bottom 70%).

The cut point for the Response to Crying Generally Scale was < 7, for low frequency user versus ≥ 7 high frequency user. In response to crying generally in the last month, nearly 50% of participants (n = 42) did not report ever putting their infant down in a safe place and walking away and just under one third (n= 25) reported using this response only "once or twice". Eighty percent of mothers (n= 68) reported walking around with their infant when they cried or fussed "11 times to almost every day" (Table 4-9). Fifty-four mothers (63.5%) had low scores for the response to crying generally scale (Figure 4-6).

The cut point for the response to Unsoothable Crying, < 6 for low frequency users versus > 6 for high frequency users. The frequency of behavioral responses to unsoothable crying are shown in Table 4-9. Only 10 participants (11.1%) had never passed the baby to someone else, with all others trying this at least once or twice. When baby's crying was unsoothable, 41.1% of mothers did not report putting their baby down in a safe place and nearly 50% of mothers had not "taken a break" from the crying. Fifty-seven mothers (63.3%) had low scores for the response to unsoothable crying scale (Figure 4-7).

In the Self-talk scale the cut point was < 11 for low frequency users versus ≥ 11. Participants reported employing self-talk strategies when their infant's crying was unsoothable with over 45% of participants (n=40) endorsing daily use of "told yourself the crying will end" and "told yourself your baby is ok" (n=36). Telling oneself "there is nothing I can do" and it is not my fault, two additional self-talk strategies, were employed less frequently with close to 40% of mothers not ever having used either strategy (Table 4-10). Fifty-nine mothers (68.6%) had low scores for the utility of self-talk behaviors in response to unsoothable crying (Figure 4-8).

Secondary Objective 3:

To identify factors associated with utilization of appropriate behavioral responses in response to infant crying.

Univariate analysis of thirteen variables as possibly predictive of the utility of behaviors for the three response scales; response to crying generally, response to unsoothable crying and self-talk in response to unsoothable crying, was conducted. Variables included were: maternal age, maternal education, annual household income, planned pregnancy, infant gender, time spent learning about infant crying before baseline, amount learned about infant crying prior to baseline, perceived confidence level prior to baseline, prior knowledge of *PURPLE,* anticipation of crying issue, knowledge of crying at 4-6 weeks, watched DVD in hospital and read book in hospital.

Eight candidate variables were identified as factors that might influence the high or low use of safe responses to crying generally including with $P \leq 0.5$; maternal age, maternal education, annual household income, planned pregnancy, infant gender, perceived confidence

level prior to baseline, anticipation of crying as an issue and knowledge of crying at 6-8 weeks (Table 4-11).

These eight variables were entered in a backwards stepwise logistic regression. In the final model, planned pregnancy, maternal education and anticipation of crying as an issue all contributed to a high score, (i.e. top 30%), on the response to crying generally scale (Table 4-12). Mothers whose pregnancy was unplanned had nearly three times the odds for high scoring than mothers with planned pregnancy (OR: 2.89, 95% CI: 1.04-8.08, $P = 0.04$). Mothers who had a grade twelve education or less were at greatest odds for high scores when compared with mothers, with undergraduate, college or postgraduate education (OR: 1.72, 95 % CI: 0.53-5.60, $P = 0.07$). For each increase in category of anticipation of the likelihood that crying would be an issue, an increase odds for a high utility score in response to crying generally was observed (OR: 2.22, 95% CI: 1.11-4.35, $P = 0.02$)

Following univariate analysis, seven candidate variables were found to be associated with high use of behaviors in response to unsoothable crying including: maternal education, annual household income, time spent learning about infant crying prior to baseline, perceived confidence level prior to baseline, anticipation of crying as an issue, watched DVD in hospital and read book in hospital (Tables 4-13).

These seven variables were entered in a backwards stepwise logistic regression. In the final model, annual household income, viewing of the DVD in hospital and anticipation of crying as an issue all contributed to a high score on the response to unsoothable crying scale (Table 4-14). Mothers whose annual income was reported to be < $20,000 had nearly 6 times greater odds for high scoring than mothers with higher incomes (OR: 5.75, 95% CI: 1.18-27.94, $P = 0.06$). Mothers who had not watched the DVD in hospital were at 5 time the odds for high scores when compared with mothers who had watched it in hospital (OR: 4.81, 95% CI: 1.57-14.74), $P = 0.01$). As mothers' reported level of anticipation of crying as an issue increased, their odds of scoring highly on the behavior scale increased by over 2 times per incremental increase in Likert scale unit; those that had anticipated that crying would very likely be an issue for them were more likely to score highly on this scale ($P = 0.01$).

Following univariate analysis, four candidate variables were identified as factors that might influence use of self-talk in response to unsoothable crying (Table 4-15) including; time

spent learning about infant crying before baseline, amount learned about infant crying before baseline, perceived confidence level prior to baseline and anticipation of crying as an issue.

These four variables were entered in a backwards stepwise logistic regression model. In the final logistic model, only "anticipation of crying as an issue" remained in the model. As mothers' reported level of anticipation of crying as an issue increased, their odds of scoring highly on the use of self-talk behavior scale increased by over 1.5 times per incremental increase in Likert scale unit; those anticipating that crying would very likely be an issue for them, were more likely to score highly on this scale (OR: 1.67, CI 95%: 0.93-2.94, $P = 0.09$). (Table 4-16).

Secondary Objective 4:

To determine whether first time mothers perceive that the Period of PURPLE Crying program materials are useful and to determine if they have shared program information with others since discharge from hospital.

Of the 93 participants, all indicated receipt of the *Period of PURPLE Crying* program while in hospital. Seventy-six percent (n=71) of mothers indicated that they watched the DVD in hospital and 61% (n=57) read the book in hospital prior to discharge (Table 4-17).

After discharge form hospital, 17% of participants (n= 16) viewed the DVD and over thirty-four percent (n=32) shared the DVD with other caregivers. Just over 10% (n=11) read the booklet after discharge and just under 20% (n=18) shared the booklet with other caregivers. Nearly 60% of participants (n=55) reported that they had shared information about the *Period of PURPLE Crying* program with others and seventy-six percent of participants (n=70) reported having used strategies from the DVD (Table 4-17).

Over 95% of participants either agreed or strongly agreed that the *Period of PURPLE Crying* program is useful and informative and nearly 85% (n=78) indicated that they understood infant crying because of the program. Eighty percent of participants (n=78) either agreed or strongly agreed that the *PURPLE* program had helped them cope with their infant's crying and 95% (n=88) would recommend the *Period of PURPLE Crying* program DVD to friends with infants (Table 4-18).

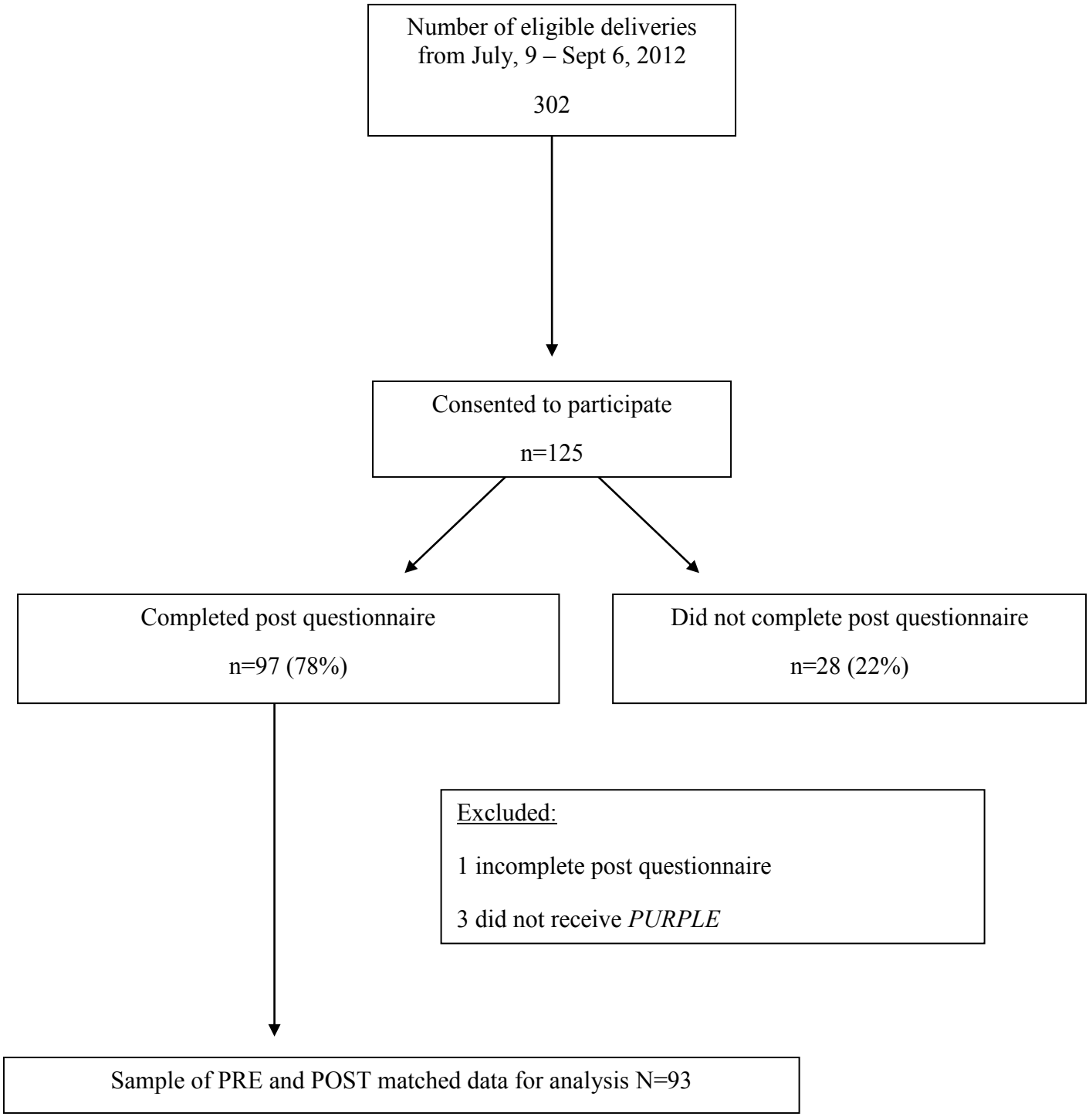

Figure 4-1 Recruitment and retention of sample

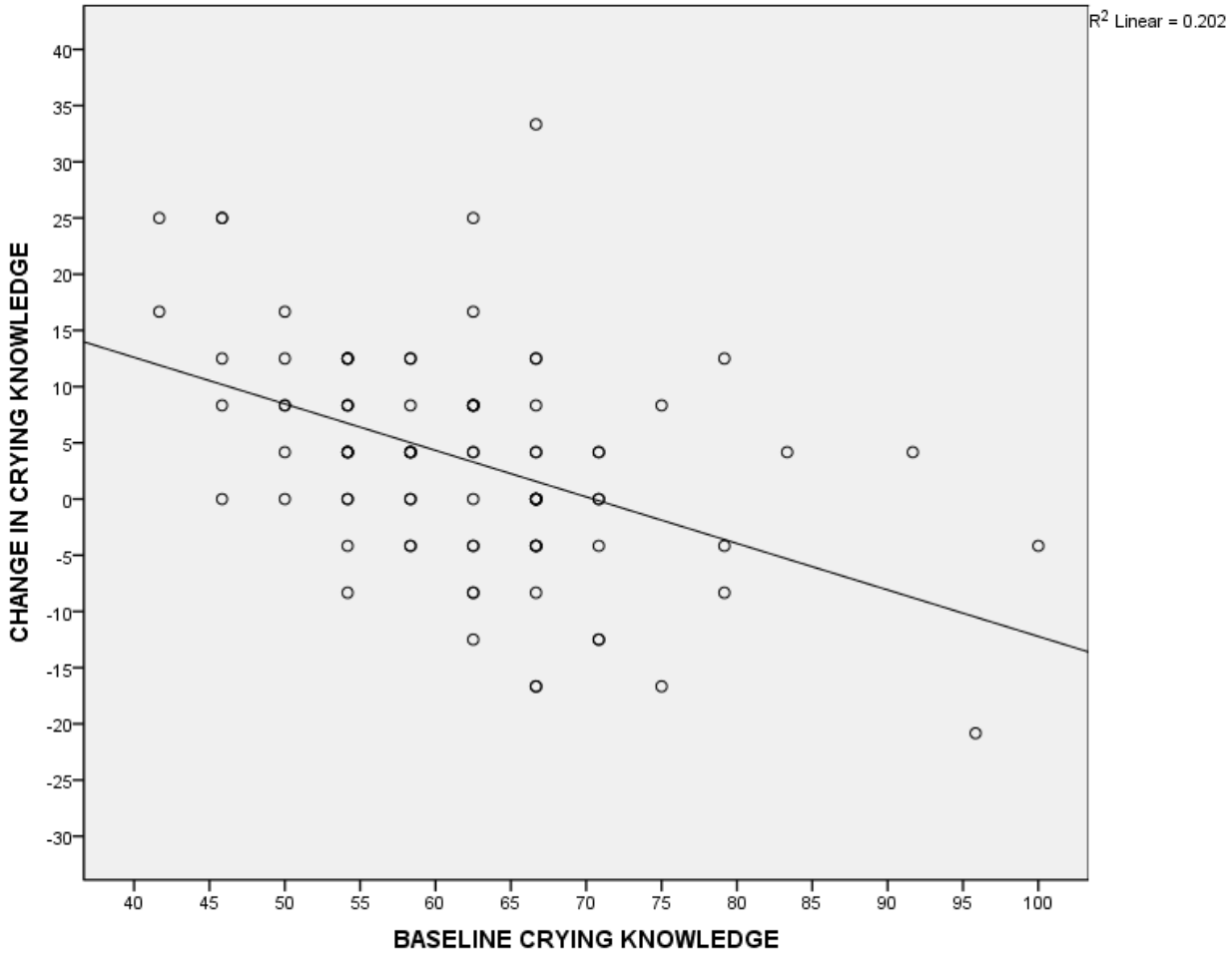

Figure 4-2 Relationship between baseline crying knowledge and change in crying knowledge

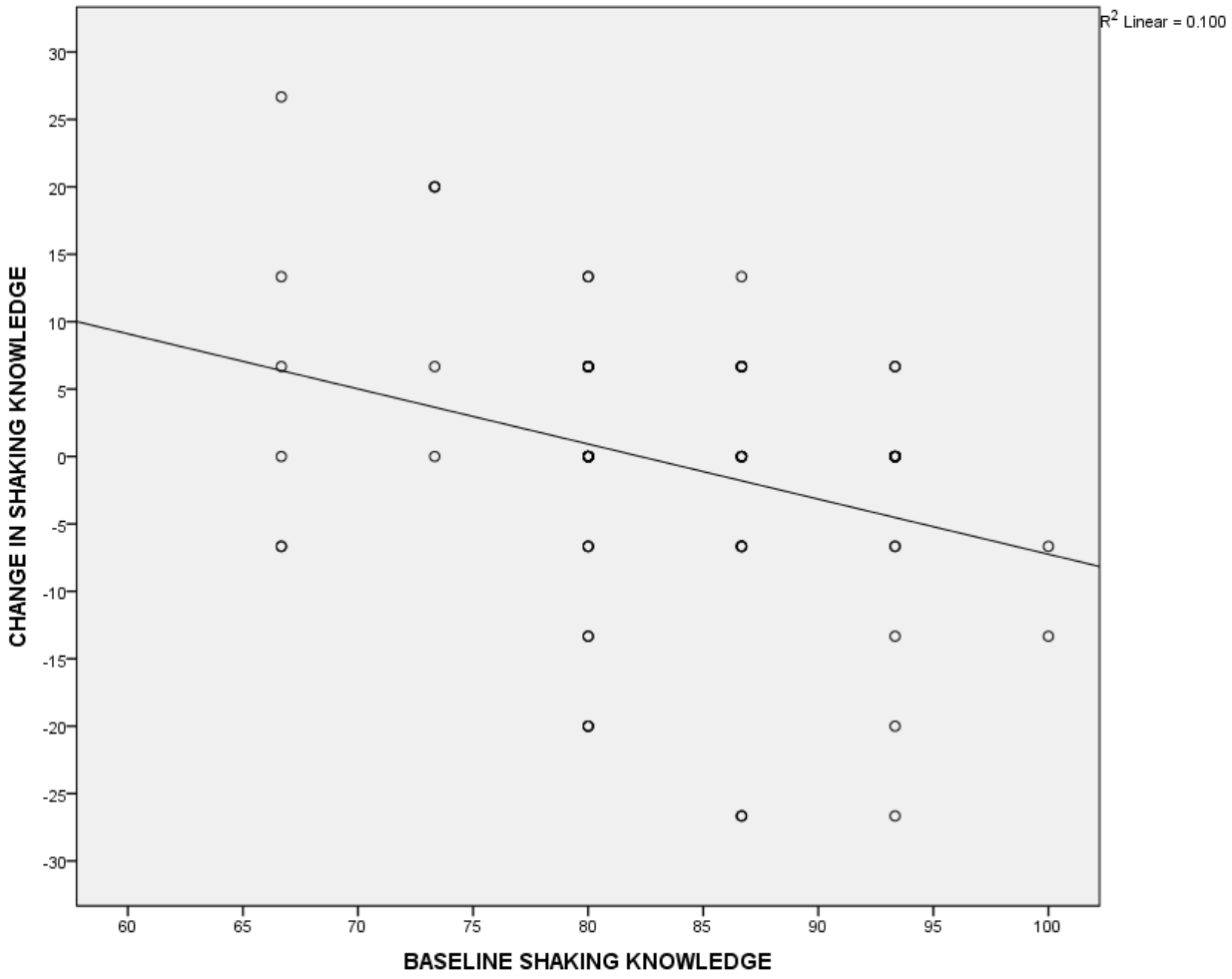

Figure 4-3 Relationship between baseline shaking knowledge and change in shaking knowledge

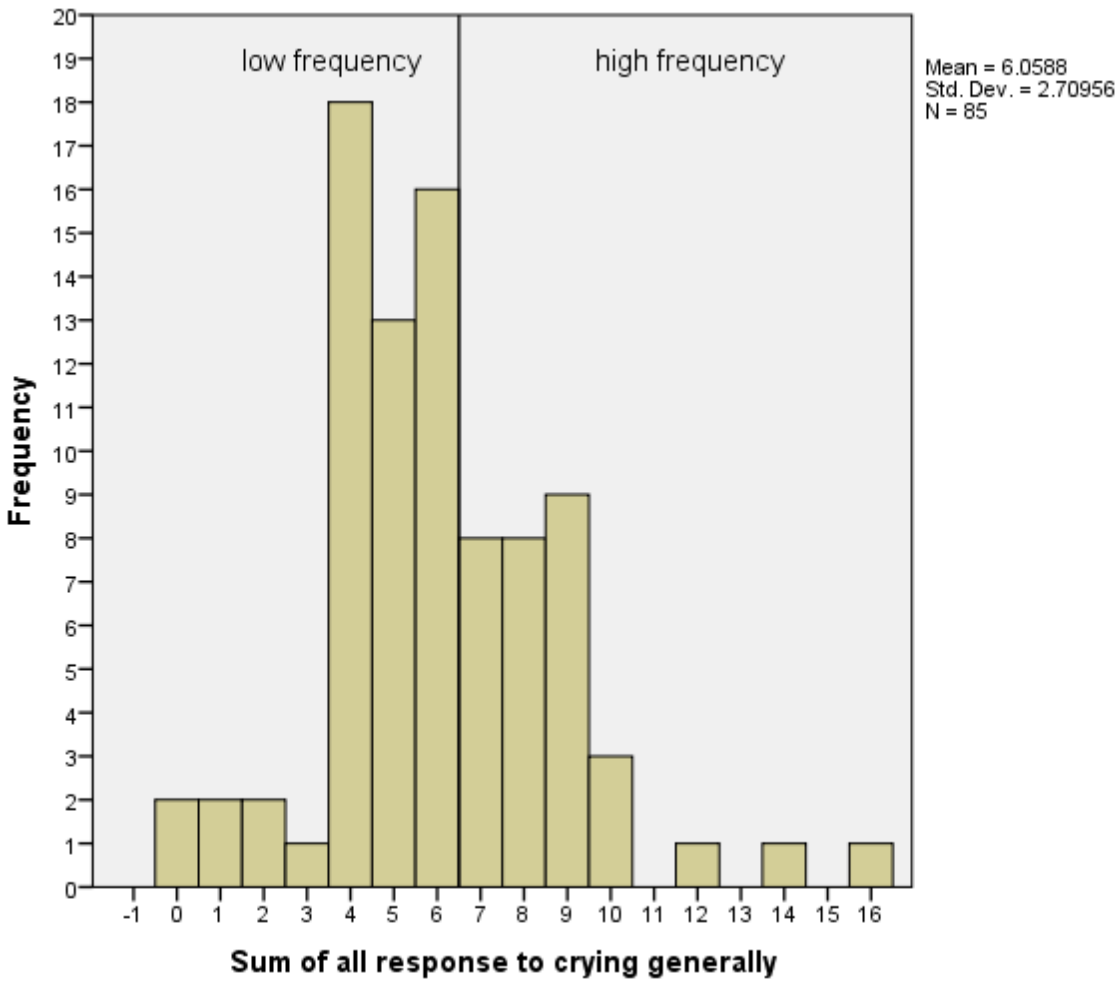

Figure 4-4 Use of response to crying generally scores by frequency

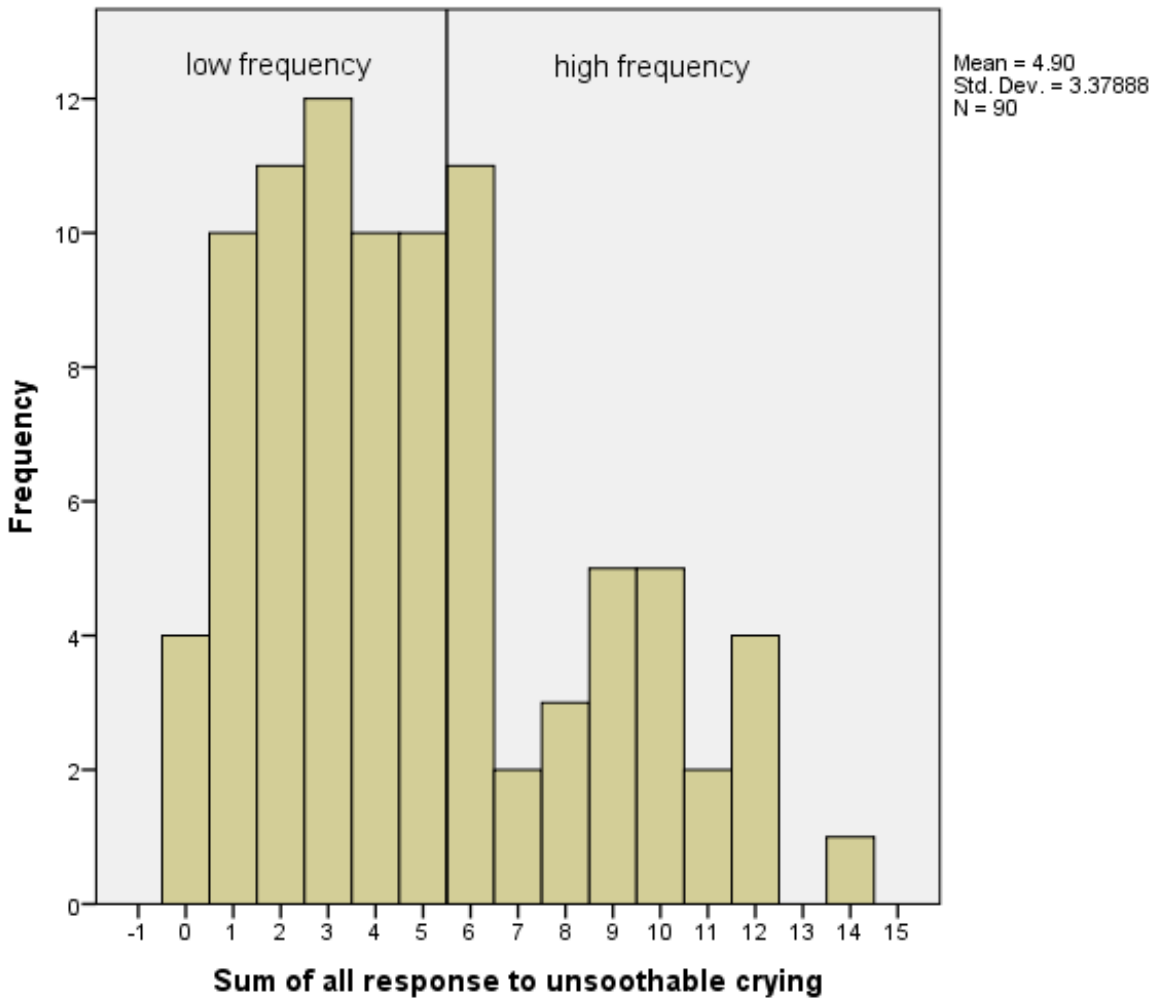

Figure 4-5 Use of response to unsoothable crying scores by frequency

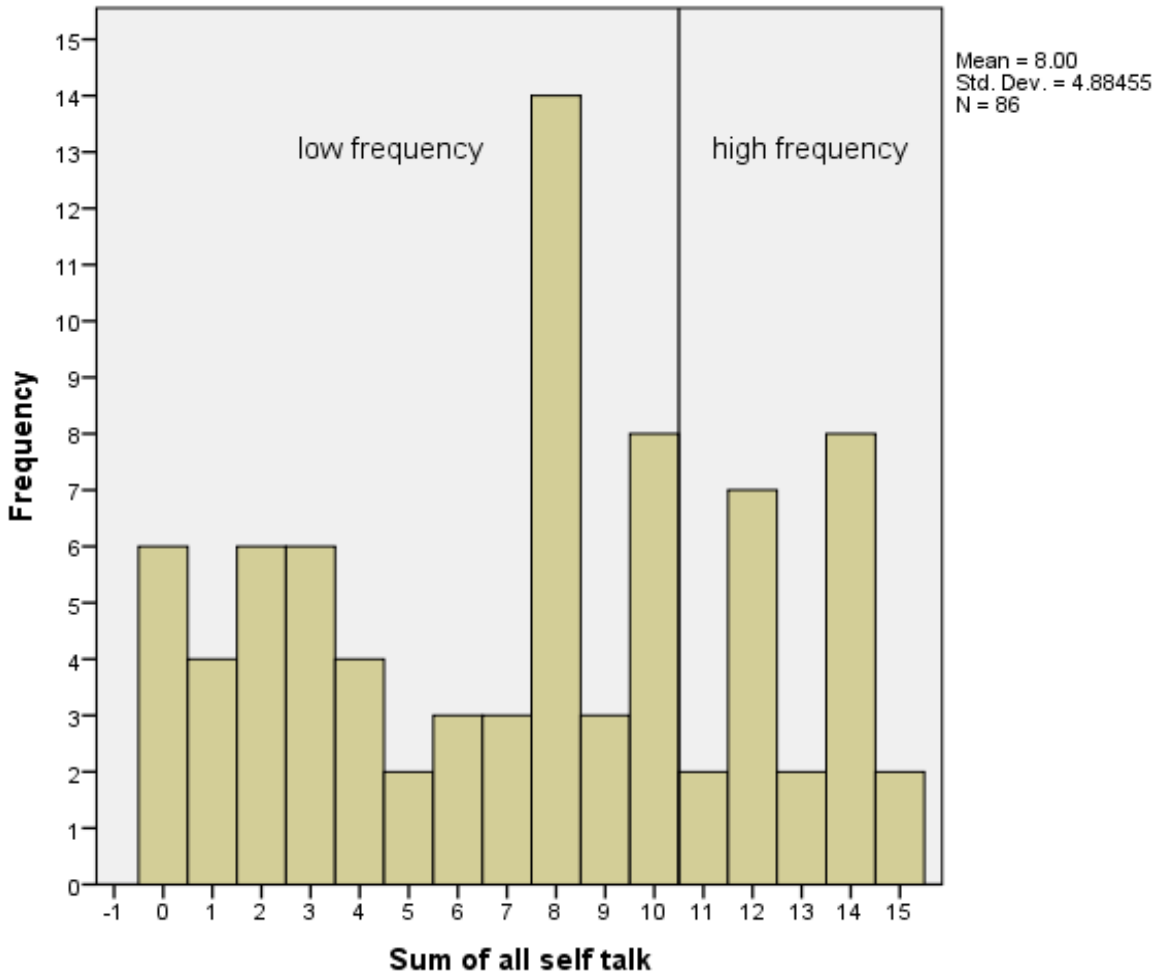

Figure 4-6 Use of self-talk response to unsoothable crying scores by frequency

Table 4-1 Characteristics of participants, N=93

CHARACTERISTIC	NUMBER (%)
Age years	
< 20	3 (3.2)
20-29	44 (47.3)
30-39	44 (47.3)
≥ 40	2 (2.2)
Primary caregiver	
Yes	35 (37.6)
Equal	58 (62.4)
Highest education	
< Grade 12	5 (5.4)
Grade 12	15 (16.1)
College degree	21 (22.6)
Undergraduate degree	36 (38.7)
Post-graduate degree	16 (17.2)
Annual household income	
< $ 20,000	10 (10.8)
$ 20,000-59,999	28 (30.1)
≥ $ 60,000	55 (59.1)
Planned pregnancy	
Yes	57 (61.3)
No	36 (38.7)
Smoking during pregnancy	9 (9.7)
Alcohol use during pregnancy	1 (1.1)

Table 4-2 Pregnancy and obstetric characteristics of participants, N=93

CHARACTERISTIC	NUMBER (%)
Labor onset[#]	
Spontaneous	59 (63.4)
Induced	33 (35.5)
Delivery mode	
Vaginal	70 (75.3)
Cesarean	23 (24.7)
Assisted	
Vacuum	6 (6.5)
Forceps	5 (5.4)
None	82 (88.2)
Male infant	47 (50.5)
Pre-existing medical condition	12 (12.9)
Gestational diabetes	5 (5.4)
Medication use	8 (8.6)

[#] n=92, one missing data point

Table 4-3 Mean change in knowledge from pre to post intervention

	N	Mean change 95% CI	SD	*P*
Crying knowledge	93	3.5 (1.5-5.5)	9.7	< 0.01
Shaking knowledge	93	-0.7 (-2.8-1.3)	10.0	0.5
Total knowledge	93	1.4 (-0.3-3.0)	8.0	0.1

Table 4-4 Mean change in knowledge from pre to post intervention stratified by baseline knowledge

Knowledge on 100 point scale		N	Mean change crying knowledge (95% CI)	SD	*P*
Baseline crying knowledge	Low ≤ 62.5	57	6.2 (3.4-8.4)	8.4	< 0.01
	High > 62.5	36	-0.8 (-4.3-2.6)	10.2	0.64
Knowledge on 100 point scale		N	Mean change shaking knowledge (95% CI)	SD	*P*
Baseline shaking knowledge	Low ≤ 80.0	45	1.6 (-1.4-4.7)	10.2	0.29
	High > 80.0	48	-3.0 (-5.6- -0.2)	9.3	0.04

Table 4-5 Variables predictive of change in crying knowledge from pre to post intervention

Variable	Improved knowledge n=53 (row %)	No change or decrease n=40 (row %)	P^*
Maternal age years [I]			
≥30	22 (48)	24 (52)	0.10
≤29	31 (66)	16 (34)	
Maternal education			
Post graduate degree	10 (63)	6 (37)	0.91
Undergraduate / College	32 (56)	25 (44)	
Grade 12 or less	11 (55)	9 (45)	
Annual household income			
≥ $ 60,000	31 (56)	24 (44)	0.71
$ 20,000-59,999	15 (54)	13 (46)	
< $ 20,000	7 (70)	3 (30)	
Planned pregnancy			
Yes	32 (56)	25 (44)	1.00
No	21 (58)	15 (42)	
Infant gender			
Male	28 (60)	19 (40)	0.68
Female	25 (54)	21 (44)	
Time spent learning about crying prior to baseline [I]			
No time - <1 hour	15 (68)	7 (32)	0.16
1-9 hours	23 (62)	14 (38)	
≥ 10 hours	15 (44)	19 (66)	
Amount learned about crying prior to baseline [I]			
None at all	3 (43)	4 (57)	
Very little	17 (65)	9 (35)	0.25
Fair amount	27 (61)	17 (39)	
Large amount	6 (38)	10 (62)	
Perceived confidence level prior to baseline			
Not confident	1 (100)	0 (0)	
Somewhat	12 (60)	8 (40)	0.63
Adequately	20 (50)	20 (50)	
Very	20 (62)	12 (38)	
Prior knowledge of *PURPLE*			
Yes	31 (57)	23 (43)	1.00
No	22 (56)	17 (44)	
Anticipation crying issue [I]			
Very likely	1 (100)	0 (0)	
Likely	11 (58)	8 (42)	0.36
Maybe	16 (47)	18 (53)	
Not at all	25 (64)	14 (36)	
Baseline crying knowledge [I]			
Low	41 (72)	16 (28)	< 0.01
High	12 (33)	24 (67)	
Watched DVD in hospital [I]			
Yes	43 (61)	28 (39)	0.23
No	10 (45)	12 (55)	
Read book in hospital [I]			
Yes	30 (53)	27 (47)	0.39
No	23 (64)	13 (36)	

*P from Fisher's exact test (2-sided)

[I] Indicates inclusion in logistic regression if $P \leq 0.5$

TABLE 4-6 Factors predictive of improvement in crying knowledge from baseline in 93 participants

Factor	Level	OR (95% CI)	*P*
Baseline level of crying knowledge	Low	5.13 (2.1-12.6)	$\leq$ 0.01
	High*	1.00	

*referent category

Table 4-7 Variables predictive of change in shaking knowledge from pre to post intervention

Variable	Improved knowledge n=26 (row %)	No change or decrease n=67 (row %)	P^*
Maternal age years			
≥30	12 (26)	34 (74)	0.82
<29	14 (30)	33 (70)	
Maternal education			
Post graduate degree	4 (25)	12 (75)	0.95
Undergraduate / College	17 (30)	40 (70)	
Grade 12 or less	5 (25)	15 (75)	
Annual household income			
≥ $60,000	17 (31)	38 (69)	0.70
$20,000-59,999	6 (21)	22 (79)	
< $20,000	3 (30)	7 (70)	
Planned pregnancy [ɪ]			
Yes	12 (21)	45 (79)	0.10
No	14 (39)	22 (61)	
Infant gender			
Male	14 (30)	33 (70)	0.82
Female	12 (26)	34 (74)	
Time spent learning about crying prior to baseline [ɪ]			
No time-<1 hour	3 (14)	19 (86)	0.14
1-9 hours	14 (38)	23 (62)	
>10 hours	9 (26)	25 (74)	
Amount learned about crying prior to baseline			
None at all	2 (29)	5 (71)	
Very little	6 (23)	20 (77)	0.94
Fair amount	13 (30)	31 (70)	
Large amount	5 (31)	11 (69)	
Perceived confidence level prior to baseline [ɪ]			
Not confident	1 (100)	0 (0)	
Somewhat	4 (20)	16 (80)	0.16
Adequately	9 (22)	31 (78)	
Very	12 (37)	20 (63)	
Prior knowledge of *PURPLE* [ɪ]			
Yes	18 (33)	36 (67)	0.24
No	8 (21)	31 (79)	
Anticipation of crying issue [ɪ]			
Very likely	1 (100)	0 (0)	
Likely	3 (16)	16 (84)	0.23
Maybe	9 (26)	25 (74)	
Not at all	13 (33)	26 (67)	
Baseline shaking knowledge [ɪ]			
Low	17 (38)	28 (62)	0.06
High	9 (19)	39 (81)	
Watched DVD in hospital [ɪ]			
Yes	18 (25)	53 (75)	0.42
No	8 (36)	14 (64)	
Read book in hospital			
Yes	15 (26)	42 (74)	0.81
No	11 (31)	25 (69)	

*P from Fisher's exact test (2-sided)

[ɪ] Indicates inclusion in logistic regression if $P \leq 0.5$

TABLE 4-8 Factors predictive of improvement in shaking knowledge from baseline in 93 participants

Factor	Level	OR (95% CI)	*P*
Planned pregnancy	Yes*	1.00	0.01
	No	3.98 (1.36-11.59)	
Time spent learning about infant crying prior to baseline	No time-< 1 hour	0.18 (0.04-0.80)	0.04
	1-9 hours*	1.00	
	> 10 hours	0.27 (0.08-0.95)	
Perceived confidence for dealing with a crying infant at baseline	Per increase in Likert unit	1.86 (0.90-3.84)	0.09
Prior knowledge of *PURPLE*	No*	1.00	0.07
	Yes	2.71 (0.92-7.95)	

*referent category

Table 4-9 Frequency of response to crying generally and unsoothable crying in the last month

	Didn't do it n (%)	1-2 times n (%)	3-5 times n (%)	6-10 times n (%)	11 times-almost every day n (%)
Crying generally (n=85)					
Put baby down and walk away	42 (49.4)	25 (29.4)	14 (16.5)	1 (1.2)	3 (3.5)
Walked around with baby	2 (2.4)	6 (7.1)	4 (4.7)	5 (5.9)	68 (80)
Unsoothable crying (n=90)					
Pass baby to someone else	10 (11.1)	30 (33.3)	26 (28.9)	10 (11.1)	14 (15.6)
Put baby down in a safe place	37 (41.1)	31 (34.4)	18 (20)	2 (2.2)	2 (2.2)
Took a break from crying	43 (47.8)	26 (28.9)	13 (14.4)	4 (4.4)	4 (4.4)
Took baby for walk / drive	41 (45.6)	16 (17.8)	14 (15.6)	8 (8.9)	11 (12.2)

Table 4-10 Frequency of self-talk use in response to unsoothable crying in the last month (n=86)

When crying was unsoothable, how often did tell yourself…	Didn't do it n (%)	1-2 times n (%)	3-5 times n (%)	6-10 times n (%)	11 times- almost every day n (%)
The crying will end	17 (19.8)	9 (10.5)	12 (14)	8 (9.3)	40 (46.5)
Your baby is okay	13 (15.1)	11 (12.8)	29 (22.1)	7 (8.1)	36 (41.9)
There is nothing you can do	38 (44.2)	17 (19.8)	12 (14)	5 (5.8)	14 (16.3)
It is not your fault	34 (39.5)	10 (11.6)	14 (16.3)	5 (5.8)	23 (26.7)

Table 4-11 Potential predictors of use of response to crying generally (n=85)

Variable	High score n=31 (row %)	Low score n=54 (row %)	P^*
Maternal age years [ɪ]			
≥30	12 (30)	28 (70)	0.27
<29	19 (42.2)	26 (57.8)	
Maternal education [ɪ]			
Post graduate degree	2 (14.3)	12 (85.7)	0.06
Undergraduate or college	19 (35.8)	34 (64.2)	
Grade 12 or less	10 (55.6)	8 (44.4)	
Annual household income [ɪ]			
≥ $ 60,000	15 (31.3)	33 (68.7)	0.47
$ 20,000-59,999	12 (44.4)	15 (55.6)	
< $ 20,000	4 (40)	6 (60)	
Planned pregnancy [ɪ]			
Yes	13 (26)	37 (74)	0.02
No	18 (51)	17 (49)	
Infant gender [ɪ]			
Male	18 (41)	26 (59)	0.50
Female	13 (32)	28 (68)	
Time spent learning about infant crying before baseline			
No time- <1 hour	6 (30)	14 (70)	0.81
1-9 hours	13 (38.2)	21 (61.8)	
≥10 hours	12 (38.7)	19 (61.3)	
Amount learned about infant crying prior to baseline			
None at all	1 (14.3)	6 (85.7)	
Very little	8 (34.8)	15 (65.2)	0.67
Fair amount	16 (30)	25 (70)	
Large amount	6 (42.9)	8 (57.1)	
Perceived confidence level prior to baseline [ɪ]			
Not confident	1 (100)	0 (0)	
Somewhat	8 (47.1)	9 (52.9)	0.43
Adequately	13 (32.5)	27 (67.5)	
Very	9 (33.3)	18 (66.7)	
Prior knowledge of *PURPLE*			
Yes	18 (36.7)	31 (63.3)	1.00
No	13 (36)	23 (64)	
Anticipation of crying issue [ɪ]			
Very likely	1 (100)	0 (0)	
Likely	5 (31.2)	1 (68.8)	0.06
Maybe	17 (50)	17 (50)	
Not at all	8 (23.5)	26 (76.5)	
Knowledge of crying at 4-6 weeks [ɪ]			
Low knowledge	18 (40.9)	26 (59.1)	0.50
High knowledge	13 (31.7)	28 (68.3)	
Watched DVD in hospital			
Yes	24 (36.4)	42 (63.6)	1.00
No	7 (37)	12 (63)	
Read Book in hospital			
Yes	21 (38.9)	33 (61.1)	0.64
No	10 (32)	21 (68)	

*P is from Fisher's exact test (2-sided)

[ɪ] Indicates inclusion in logistic regression if $P \leq 0.5$

TABLE 4-12 Factors predictive of being a high user in response to crying generally in 85 participants

Factor	Level	OR (95% CI)	*P*
Planned pregnancy	Yes*	1.00	0.04
	No	2.89 (1.04-8.08)	
Maternal education	Grade 12 or less	1.72 (0.53-5.60)	0.07
	Undergraduate or college*	1.00	
	Postgraduate	0.18 (0.03-1.01)	
Anticipation of crying as an issue	Per increase in Likert unit	2.22 (1.11-4.35)	0.02

* referent category

Table 4-13 Potential predictors of use of response to unsoothable crying (n=90)

Variable	High score n=33 (row %)	Low score n=57 (row %)	P^*
Maternal age range			
≥30	16 (35.6)	29 (64.4)	1.00
<29	17 (37.8)	28 (62.2)	
Maternal education [I]			
Post graduate degree	8 (53.3)	7 (46.7)	0.29
Undergraduate / College	20 (35.8)	36 (64.2)	
Grade 12 or less	5 (26.3)	14 (73.7)	
Annual household income [I]			
≥ $ 60,000	19 (35.8)	34 (64.2)	0.44
$ 20,000-59,999	9 (32.1)	19 (67.9)	
< $20,000	5 (55.6)	4 (44.4)	
Planned pregnancy			
Yes	19 (33.9)	37 (66.1)	0.51
No	14 (41)	20 (59)	
Infant gender			
Male	17 (37)	29 (63)	1.00
Female	16 (36)	28 (64)	
Time spent learning about infant crying before baseline [I]			
No time-<1 hour	5 (23.8)	16 (76.2)	0.27
1-9 hours	13 (36.1)	23 (63.9)	
≥10 hours	15 (45.5)	18 (54.5)	
Amount learned about infant crying prior to baseline			
None at all	2 (28.6)	5 (71.4)	
Very little	7 (29.2)	17 (70.8)	0.59
Fair amount	16 (37.2)	27 (62.8)	
Large amount	8 (50)	8 (50)	
Perceived confidence level prior to baseline [I]			
Not confident	1 (100)	0 (0)	
Somewhat	11 (61.1)	8 (38.9)	0.05
Adequately	13 (33.3)	26 (66.7)	
Very	8 (25.8)	23 (74.2)	
Prior knowledge of *PURPLE*			
Yes	19 (35.8)	34 (64.2)	1.00
No	14 (38)	23 (62)	
Anticipation of crying issue [I]			
Very likely	1 (100)	0 (0)	
Likely	8 (44.4)	10 (55.6)	0.03
Maybe	16 (48.5)	17 (51.5)	
Not at all	8 (21.1)	30 (78.9)	
Knowledge of crying at 4-6 weeks			
Low knowledge	16 (35.6)	29 (64.4)	1.00
High knowledge	17 (37.8)	28 (62.2)	
Watched DVD in hospital [I]			
Yes	20 (29.4)	48 (70.6)	0.02
No	13 (59)	9 (41)	
Read book in hospital [I]			
Yes	18 (32.1)	38 (67.9)	0.27
No	15 (44)	19 (56)	

*P from Fisher's exact test (2-sided)

[I] Indicates inclusion in logistic regression if $P \leq 0.5$

TABLE 4-14 Factors predictive of being a high user in response to unsoothable crying in 90 participants

Factor	Level	OR (95% CI)	*P*
Annual household income	< $20,000	5.74 (1.18-27.94)	0.06
	$ 20,000-59,999	0.80 (0.27-2.34)	
	≥ $ 60,000*	1.00	
Viewing of the DVD in hospital	Yes*	1.00	0.01
	No	4.81 (1.57-14.74)	
Anticipation of crying as an issue	Per increase in Likert unit	2.33 (1.22-4.35)	0.01

*referent category

Table 4-15 Potential predictors of use of self-talk in response to unsoothable crying (n=86)

Variable	High score n=27 (row %)	Low score n=59 (row %)	P^*
Maternal age range			
≥30	13 (31.8)	28 (68.2)	1.00
<29	14 (31.1)	31 (68.9)	
Maternal education			
Post graduate degree	5 (38.5)	8 (61.5)	0.75
Undergraduate / College	17 (31.5)	37 (68.5)	
Grade 12 or less	5 (26.3)	14 (73.7)	
Annual household income			
≥ $ 60,000	17 (34.7)	32 (65.3)	0.80
$ 20,000-59,999	7 (25.9)	20 (74.1)	
< $ 20,000	3 (30)	7 (70)	
Planned pregnancy			
Yes	17 (31.5)	37 (68.5)	1.00
No	10 (31)	22 (69)	
Infant gender			
Male	14 (31.8)	30 (68.2)	1.00
Female	13 (31)	29 (69)	
Time spent learning about infant crying before baseline [I]			
No time-<1 hour	7 (36.8)	12 (63.2)	0.40
1-9 hours	13 (36.1)	23 (63.9)	
≥10 hours	7 (22.6)	24 (77.4)	
Amount learned about infant crying before baseline [I]			
None at all	1 (14.3)	6 (85.7)	
Very little	12 (50)	12 (50)	0.15
Fair amount	10 (25.6)	29 (74.4)	
Large amount	4 (25)	12 (75)	
Perceived confidence level prior to baseline [I]			
Not confident	1 (100)	0 (0)	
Somewhat	9 (45)	11 (55)	0.19
Adequately	9 (25.7)	26 (74.3)	
Very	8 (26.7)	22 (73.3)	
Prior knowledge of *PURPLE*			
Yes	16 (31.4)	35 (68.6)	1.00
No	11 (31)	24 (69)	
Anticipation of crying issue [I]			
Very likely	1 (100)	0 (0)	
Likely	8 (44.4)	10 (55.6)	0.21
Maybe	9 (29)	22 (71)	
Not at all	9 (25)	27 (75)	
Knowledge of crying at 4-6 weeks			
Low knowledge	12 (29.3)	29 (70.7)	0.82
High knowledge	15 (33.3)	30 (66.7)	
Watched DVD in hospital			
Yes	21 (32.3)	44 (67.7)	1.00
No	6 (29)	15 (71)	
Read Book in hospital			
Yes	17 (32.1)	36 (67.9)	1.00
No	10 (30)	23 (70)	

*P from Fisher's exact test (2-sided)

[I] Indicates inclusion in logistic regression if $P \leq 0.5$

TABLE 4-16 Factors predictive of being a high user of self-talk in response to unsoothable crying in 86 participants

Factor	Level	OR (95% CI)	*P*
Anticipation of crying as an issue	Per increase in Likert unit	1.67 (0.93-2.94)	0.09

Table 4-17 Assessment of the *Period of PURPLE Crying* Program (N=93)

	Strongly agree n (%)	Agree n (%)	Disagree n (%)	Missing n (%)
PURPLE is informative	45 (48.4)	44 (47.3)	------	4 (4.3)
PURPLE is useful	44 (47.3)	46 (49.5)	------	3 (3.2)
PURPLE has helped me cope with my baby's crying	7 (7.5)	71 (76.3)	8 (8.6)	7 (7.5)
I have used strategies from the DVD	7 (7.5)	63 (67.7)	15 (16.1)	8 (8.6)
I would recommend the *PURPLE* program DVD	37 (39.8)	51 (54.8)	1 (1.1)	4 (4.3)

Table 4-18 Assessment of the *Period of PURPLE Crying* Program materials (N=93)

CHARACTERISTIC	Yes (%)
DVD	
Watched in hospital	71 (76.3)
Watched at home	16 (17.2)
Shared with other caregivers	32 (34.4)
Booklet	
Read in hospital	57 (61.3)
Read at home	11 (11.8)
Shared with other caregivers	18 (19.4)
General	
Shared information about *PURPLE*	55 (59.1)
I understand crying because of *PURPLE*	78[#] (83.9)

[#] n = 89, with 4 missing answers

CHAPTER 5 DISCUSSION

5.1 SIGNIFICANCE OF FINDINGS

AHT is a rare form of physical abuse which can result in significant morbidity and mortality. Emotional costs for AHT survivors and their families, as is in other forms of child abuse, are high both short and long-term. The economic costs as a result of a case of AHT are significant and impact multiple sectors including: health care, child protection authorities, the legal and penal systems as well as education. As with other forms of child maltreatment, there is a need for effective prevention strategies to reduce the incidence of AHT cases.

Educating caregivers about crying, a predictable behavior of infants and certainly one that can be a source of frustration may be an upstream intervention that can prevent the occurrence of AHT and physical abuse in infancy. In the context of the ecologic framework for violence and AHT prevention (Figure1-2), improving knowledge is an intervention at the first or 'innermost' (i.e. individual) level.

Understanding how education might, as a first step, help to modify behavior, is critical. By examining another Canadian hospital's SBS prevention program, we can begin to understand how the process of knowledge influencing behavior might occur. As part of a Montreal hospital's four pronged approach to reduce the incidence of SBS, The Perinatal Shaken Baby Syndrome Prevention Program (PSBSPP) is an educational anticipatory intervention about infant crying and the dangers of shaking, similar to the *Period of PURPLE Crying*. Goulet et al. [26] in their development of the PSBSPP employed the stress theory of Lazarus and Folkman which emphasizes the interplay between individual characteristics, their environment, a stressful event and the coping response.[61] The PSBSPP, which promotes awareness of infant crying and dangers of shaking, is similar to *PURPLE* in that there are both cognitive (knowledge) and adaptive (coping strategies) theoretical underpinnings. Based on their program logic model, Goulet and colleagues [26] theorize that "if knowledge can be increased about infant crying (stressor), the triggered reaction (anger) and its progression to violence and SBS, while working on practical strategies to cope with anger …could decrease stress and ensuing violence".[26]

Similar to the ecologic framework for understanding violence and approaching AHT prevention adopted by the CDC, Goulet and colleagues also stress the importance of social support in reducing violence. With *PURPLE*, this level in the ecologic model is achieved by encouraging caregivers to share the materials with all of their baby's caregivers (i.e. community, relationships) and by implementing Dose Three, the public education campaign, which is designed to effect social change about how crying is generally perceived (i.e. society).

The *Period of PURPLE Crying* is an educational program that teaches caregivers about normal early infant crying, how they can best respond to a crying infant and about the dangers of shaking a baby. In our study evaluating post partum delivery of the *Period of PURLPLE crying*, we demonstrated a statistically significant improvement in knowledge of participants about early infant crying. For change in crying knowledge, the calculated Cohen's effect size of the intervention was 0.33, which is similar to that reported in prior evaluations. [27, 28, 54] There was also improvement in the shaking knowledge scores of those with low baseline knowledge levels about infant shaking following the intervention, although the change was not statistically significant. The greatest improvement in knowledge was observed in those who had low baseline levels of knowledge for both crying and shaking and suggests that those who were in the greatest need of education became more knowledgeable after exposure to the program materials.

Knowledge scores for both crying and shaking decreased for some participants from before to after intervention. This "decrease" in knowledge may not represent an actual drop in knowledge, but may more accurately reflect the mother's parenting experience of her new baby. For example, in response to that statement "Infant's cry more often in the late afternoon and evening", a mother whose baby only cries in the early morning, may have disagreed and her post K-IC score may have dropped as a result. Similarly, a mother may have initially agreed with the statement "Sometimes healthy infants can cry for 5 or more hours a day" however, at the time of follow-up, this same participant may have disagreed with the statement, if this had not been their lived experience with their baby. For those participants whose post intervention knowledge scores decreased, an analysis of which items contributed to the apparent "decrease" in knowledge might support the need to re-word or structure certain statements to ensure that they are measuring the same construct both before and after intervention. Knowledge certainly can be informed by personal experience however, for the purpose of program evaluation, understanding how the parenting experience might cofound any change in knowledge is important.

In the future, targeted delivery to those identified as most in need of education may be an alternate strategy for delivery if universal delivery is not possible. In our study, increase in shaking knowledge was predicted by having an unplanned pregnancy, spending an intermediate (i.e.1-9 hours) amount of time learning about infant crying prior to baseline and prior knowledge of the *PURPLE* program. Also, as participant's baseline confidence about their ability to manage a crying infant increased so did their odds of an increase in shaking knowledge. These associations suggest that participant's with some understanding of early infant crying, perhaps anticipating that it might be an issue for them in the first few months post-partum, were open to receiving the messages of *PURPLE* and subsequently demonstrated increased knowledge in follow-up. However, prior to targeted delivery of the program a number of factors would need to be carefully considered including: evaluation of the validity of identified predictors of increased knowledge, how feasible their a priori measurement would be, how predictive they are of AHT occurrence and the risk of false negative prediction for both knowledge gain and AHT.

We observed that the average baseline knowledge scores for infant shaking were greater than those for infant crying, a finding that is consistent with the work of others and is likely a result of educational campaigns about SBS over the last decade.[25,52] This trend towards greater knowledge about the harms of shaking than about normal infant crying suggests that those who already have significant knowledge about a topic (i.e. high baseline knowledge) do not have the same room for improvement in their knowledge scores and may explain why we did not observe a statistically significant change in shaking knowledge post intervention.

Given the importance of knowledge and information about shaking and its dangers, maintenance of education about the topic is important; however, alternative strategies for effective messaging through varied approaches may be required to affect a further increase in knowledge about the topic. In Nova Scotia, a gap in prenatal education about early infant crying was identified [58] and universal delivery of the *PURPLE* program would fill this void.

As AHT prevention programs are being established, it is important that evaluation of program content and individual materials occur to ensure their usefulness. The *Period of PURPLE Crying* Program espouses an educational approach to messaging about the dangers of shaking an infant and the importance of not responding to an infant's crying with violence. Existing programs vary in their messaging style with some adopting positive messages for parents rather than negative warnings about shaking.[57] In a small study, Russell[62] examined

whether the type of educational material affected information retention. Three types of interventions were studied: (1) teaching video that included information about soothing and coping techniques, and brochure, (2) testimonial video that included statements from parents of AHT victims and brochure and (3) brochure only. They found that participants who viewed the teaching video, similar to the *PURPLE* DVD, were most likely to demonstrate a positive change in awareness, followed by the testimonial video and finally the brochure alone. In a recent systematic review, Johnson and colleagues also found that parents discharged with both written and verbal instructions for follow-up care had a better understanding of what was required.[63] These results suggest that both the modality and messaging strategy can be important in creating awareness about AHT [62, 63]

In our study, participant perception of the utility of the *PURPLE* program materials was excellent with over 95% of participants in agreement that the program was useful and informative, nearly 85% of participants indicating that they understood infant crying because of it and 80% of participants agreeing that the program had helped them cope with their infant's crying. These results are compelling and given that they were accompanied by a significant change in crying knowledge, suggest that satisfaction with the program and acquisition of new knowledge may be related; participants may have been satisfied with the program because they learned something from it. Although no control or alternate education program arm was studied alongside this work, the overwhelmingly positive ratings for participant satisfaction with and perceived utility of the *PURPLE* program are encouraging.

In our study, in response to crying generally nearly 50% of participants did not report ever putting their infant down in a safe place and walking away, while 80% of mothers reported walking around with their infant when they cried or fussed almost every day. In response to unsoothable crying, a similar trend was observed with over forty percent of mothers reporting that they did not put their baby down in a safe place and almost half of mothers had not "taken a break" from the crying.

These results suggest that most new mothers in our study felt comfortable keeping their crying baby close to them and is in keeping with an "attachment-style" parenting. A caregiver who is able to tolerate the sound of a crying baby and not become overwhelmed, tired or frustrated, may be able to adequately manage daily crying behavior. Also, it is possible that, in our sample, walk-away behaviors were not highly endorsed because these mothers may not have

reached the point at which putting their infant down or taking a break was perceived as a useful or necessary option. Participants did report employing frequent use of self-talk strategies when their infant's crying was unsoothable with over 45% of participants endorsing daily use of "told yourself the crying will end" and "told yourself your baby is ok". Those who more highly anticipated that crying would be an issue for them, were at greater odds of using of self-talk strategies in response to unsoothable crying. These self-talk strategies are examples of "positive self-talk" which participants may have employed to become empowered to cope with their infant's crying.

The term attachment parenting was first coined by pediatrician Dr. William Sears [64] and "babywearing" features prominently as a recommendation in this approach to child-rearing. Babywearing is accomplished by holding or carrying one's infant in a sling or other type of carrier.[65] Reported benefits of babywearing include; enhanced parent-child attachment, increased parent satisfaction, reduction in the daily number of hours of infant crying, reduction of post-partum depression and facilitation of breastfeeding [66-68] Babywearing is also promoted among many baby and family retail merchants who supply different models of baby carriers tailored to different lifestyles.

Our study did not capture information about parenting style espoused or the innate temperament of participants, such as whether they were highly anxious or calm, which would affect how they might respond to a crying baby and their ability to tolerate frustration. Personality traits have been linked to coping strategies employed when faced with interpersonal stress and are often moderated by other variables such as age and severity of stressor.[69, 70] Additional study focused on the interaction personality of caregivers, their need for prescribed coping strategies to mange infant crying and their ability to tolerate daily crying may have allowed for identification of variables associated with high or low use of actions recommended in *PURPLE*. It is possible the individual factors about participants, which were not explored, such as personality type and parenting style influenced their level of utility of strategies suggested in the *Period of PURPLE Crying* program.

The *Period of PURPLE Crying* program has been delivered and evaluated in a limited number of settings. In British Columbia, all new parents receive the program materials, either in hospital prior to discharge from the birth admission, at an early infant public health clinic visit or as part of a home nurse visitor partnership visit. In Nova Scotia, program delivery was evaluated

in the emergency department setting.[59] It has been suggested that delivery in prenatal classes may be another option for program delivery, although given that many expectant parents do not attend prenatal classes this would likely lead to 'un-exposed individuals'. The NCSBS recommends program messages can be introduced during prenatal classes and messages are delivered in a similar fashion as Dose Two; the re-enforcement /re-exposure phase of the program. If introduced in prenatal classes, expectant parents are not provided with the actual program materials (i.e. book and DVD) which are only provided postnatally. Given that prior knowledge of *PURPLE* was associated with an improvement in shaking knowledge, the introduction of the materials at any point prior to delivery may be important as a means to maximize gain in knowledge of participants.

The NCSBS, in their program agreement with centers who are delivering *PURPLE*, stress the importance of program delivery by a health care professional or health care worker who has authority and suggest in-hospital delivery to ensure that there is maximum capture of caregivers eligible for the program. In our study, over three-quarters of mothers indicated that they watched the DVD in hospital and 61% (n=57) read the book in hospital prior to discharge. This study was conducted during the first six months of implementation of program delivery on the FNASU and suggests that program objectives for universal delivery were reasonably well met, although there continues to be room for improvement. Ideally all new mothers should watch the DVD and read the booklet in hospital as a means to ensure initial exposure to the program messages. Importantly, three-quarters of participants (n=70) reported having used strategies from the DVD in the weeks following discharge from hospital.

In our study, location of DVD viewing and booklet reading were not identified as factors associated with a change in knowledge about infant crying or infant shaking. Similarly, no association was identified between locale for DVD viewing and booklet reading for being a high endorser of responses to crying generally and use of self-talk. However, mothers who did not watch the DVD in hospital had nearly five times greater odds for being a high endorser of responses to unsoothable crying than mothers who did. This was the only outcome variable for which a relationship to location the DVD was viewed was observed and may have resulted by chance.

Re-watching of the DVD, and re-reading of the booklet once at home are stressed, as is sharing of program messages with other caregivers. Both may have an additional effect on

caregiver knowledge. After discharge from hospital, less than twenty percent of participants viewed the DVD and just over 10% read the booklet which suggests that once home, revisiting of program messages, by review of the materials, did not frequently occur. This may have been observed for a number of reasons including: some babies' crying was not unmanageable for their caregiver or follow-up occurred before the peak of early infant crying occurred for others. These caregivers may not have felt compelled to review the information. Also, participants who were exposed to the materials in hospital may have felt comfortable enough with their understanding and uptake of the program information. Finally, participants may have chosen not to review the materials because they did not find them helpful initially.

Importantly, more mothers than had re-reviewed program materials reported sharing of information once at home, with nearly one-quarter of mothers having shared the booklet with others and over one-third having shared the DVD with others. When asked about sharing of information about the program, sixty percent of mothers reported that they had shared information about *PURPLE*. These higher levels of sharing may have constituted "review" of program materials for some participants once at home and suggests that, although they did not report personally re-watching or re-reading the materials, re-exposure may have in fact occurred as mothers shared information with others.

The *Period of PURPLE Crying* is designed as a universal intervention, appropriate in style and content for delivery to anyone involved in caring for an infant. Although the information was applicable to all caregivers, we observed different effects of the intervention based on recipient characteristics. For example, in those with lower levels of knowledge, we observed a large change in knowledge following program delivery. We also observed that mothers who had an annual income of less than $ 20,000 are at a five times greater odds for being high users of behaviors in response to unsoothable crying as compared with those of mid or upper annual income ranges. The need for use of these strategies may have been greatest in this group.

5.2 Policy and Practice Implications

Sound policy decisions are designed to "influence systems development, organizational change, social norms, and individual behavior to promote improvement in the health of a

population".[24] There are different types of policy, some of which involve the law and others of which may be implemented at an organizational or system level such as at a hospital or daycare centre.

In regard to AHT prevention, multiple states in the USA have legislation that requires provision of SBS education, although to date no single policy initiative has been evaluated for effectiveness in AHT prevention.[24] In California, information and instructional materials about AHT must be provided to parents or guardians of newborns.[24] In New York State, there are similar requirements for education of new parents and mandatory training for child care providers on the identification, diagnosis, and prevention of AHT.[24]

In Prince Edward Island (PEI), Canada, the *Period of PURPLE Crying* program is being delivered to each family that has a new baby as of November 26th, 2012. The program is being sponsored by PEI Reproductive Care (Department of Health &Wellness) partnered with Health PEI and the Department of Community Services & Seniors.[71] Dose Two of the program will be accomplished when families are given an opportunity to talk about the program during at-home visits with Public Health Nursing. A longitudinal evaluation of the program and its delivery is ongoing with results anticipated over the next five to ten years.[72]

The results of this study are similar to those of Barr and Fujiwara [27, 28, 54] and suggest that provision of the *Period of PURPLE Crying* materials increases knowledge about early infant crying. Given that policy change is dependent on a number of factors such as available financial resources and competing priorities for public health interventions, and that the evidence for policy level initiatives on prevention of SBS are limited, a first step in Nova Scotia would be to advocate for province wide delivery of the *PURPLE* program. This might be accomplished through leadership at the level of each district health authority (DHA) or by adoption of a provincial strategy.

Given the small number of birth hospitals in Nova Scotia and equally, the relatively small number of births per year, a province led approach may be wise and create opportunities for cost-effective program delivery. In Nova Scotia, if delivered to all first time mothers and caregivers, the annual estimated cost for purchase of program materials based on 4082 births per year (RCP NS database 2009-2010) would be $8,164.00. If delivered to all new parents, regardless of parity, the annual cost would be $17,632 based on 8816 births per year (RCP NS database 2009-2010). With the average cost of the acute hospital admission for one AHT case averaging

approximately $13,000, adopting either of these approaches would be a sound upstream and easily recouped investment of health care dollars.[36] In addition, given the reported estimated lifetime costs of even one SBS survivor of between eight hundred thousand and 20 million USD over a lifetime [37, 38] the potential return on investment is significant. The PEI experience and results from their planned multi-year evaluation may help to inform the next steps that are taken here in Nova Scotia.

5.3 Strengths and Limitations

This study had a number of strengths and also certain limitations. Prospective data collection and repeated measures for data collection were strengths of the project. The pre /post-intervention design allowed for consideration of the effect of our intervention, the *Period of PURPLE Crying* program materials, and permitted examination of factors predictive of change in knowledge. To date, the educational effect of *PURPLE* has been evaluated in several randomized controlled trials [27,28,54] but the effect of baseline characteristics, including knowledge on program effectiveness, had not yet been described.

The knowledge and response scales we employed are based on previously published measurement tools [27, 28] designed for the purpose of studying and evaluating the program. They were designed by experts in the field and although not formally evaluated, likely have face validity. The data from these response scales had some limitations, likely because they were solely focused on measuring knowledge and self-reported behaviors. They did not capture attitudes of the mothers or other caregivers about infant crying and how these may have been affected by prolonged bouts of crying. Nor did they measure perception of parenting self-efficacy and how this may have been affected by their baby's crying.

Some studies [27,28,54] have used The Baby's Day Diary© [49] as a method to collect additional information about infant behavioral states, caregiver behavioral states (i.e. body contact such as carrying or holding) and the daily level of frustration experienced by caregivers in response to their infant's crying. These diaries have been used to cross examine and validate results such as use of actions recommended in *PURPLE* in response to infant crying. This type of tool may have captured additional information about caregiver need for use of strategies from *PURPLE* and whether or not they had experienced significant frustration as a result of infant

crying or not, a dimension which our study did not explore. Capturing data about behavior from two sources would have increased validity of information obtained. Qualitative data about the experience of participants may have helped our understanding of the motivations underlying their behaviors. However, inclusion of the diary in the study may have been onerous for participants and could have lead to a high dropout rate, and possible bias of the final sample.

Information about parenting style and personality traits of caregivers may have been helpful in the interpretation of our results. Personality traits have been linked to coping strategies employed when faced with interpersonal stress and are often moderated by other variables such as age and severity of stressor. [69,70] Additional study focused on the interaction between personality of caregivers, their need for prescribed coping strategies to mange infant crying and their ability to tolerate daily crying may have allowed for identification of variables associated with high or low use of actions recommended in *PURPLE*.

The study sample was large and diverse enough that it allowed for generalizability of results across a population of first time mothers. Within a relatively short period of time, the program was being delivered in an effective way with all participants having received the program in hospital and the vast majority having watched the DVD and read the booklet. This facilitated recruitment of an appropriate sample of first time mothers who were eligible for study.

Limitations of our study include a relatively short time frame for the study and adoption of a convenience sample. This time frame was selected due to funding availability for the project. Repeated follow-up, perhaps at 3 months post partum and then again at one year, could have offered a perspective on longer term knowledge retention of participants and use of appropriate responses to infant crying. The study may have had an element of selection bias. Research assistants approached most first time mothers with 41.4% of eligible mothers during the study period recruited to participate. It is possible that there were differences between those who were not approached, those who did not consent to participate and our participants. Data about eligible first time mothers who were not enrolled in the study was not systematically captured in a way that would allow comparisons to be made. Therefore, the changes that we observed may have occurred because of other factors to which these mothers were exposed.

The lack of a control group who were not exposed to the *PURPLE* materials was another limitation. Given the universal delivery of the program, beginning in the winter of 2012, to all families delivering at the IWK, recruitment of this type of sample would have required a multi-

institutional study. The lack of a control group did not allow for comparisons in level of knowledge and behaviors utilized between those who had received the *PURPLE* materials and those who had not.

Another limitation in the study was the inadvertent omission of one of the items on the response to the crying generally scale, which affected the total possible score a participant could obtain on this measure. The original scale contained five items whereas in this study it only contained four. The omitted item was how often the participant "… picked up your infant when she or he fussed or cried." While this may not have affected the final results, it is important to note that the measure in our study was not the same as has been previously used and the results should be considered in the context of possible instrument bias.

Finally, in regard to our evaluation of the utility and acceptability of the *Period of PURPLE Crying* program materials, there may have been an element of response bias with new mothers wanting to please the interviewer and not wanting to speak unfavorably about a hospital driven initiative shortly after the birth of their child.

5.4 FUTURE DIRECTIONS

This study evaluated the effect of Dose One of a three pronged approach to education about early infant crying. Favorable outcomes were demonstrated with a measured change in the knowledge of participants about early infant crying, positive endorsement of the program in terms of utility, and acceptability and utility of a number of safe behaviors in response to infant crying. The information taught in Dose One was also shared by a high proportion of participants with others who care for their infant. The delivery of the program was initiated after a gap in prenatal education about infant crying was identified and our results of have helped to determine that this gap is being addressed.

Additional areas for study may include the evaluation of caregivers other than mothers (e.g. male caregivers) following exposure to program materials. Since in some studies men are reported to more likely be perpetrators of AHT,[1, 29] targeted study of this population is critical. Program delivery and messaging strategies may require modification for maximum effectiveness among different groups. A better understanding of the need for modification, if any, in the

content and delivery of the program can be achieved through additional evaluation in novel settings and to novel recipients.

Differences among families accessing services in different health care centers may necessitate some modification of how *PURPLE* is delivered. For example, in rural communities the provision of post-partum and early infant care may be delivered in a different way than in urban settings. More effective and efficient ways of universal delivery may be achieved differently depending on the resources and number of births that occur in a given region.

The timing of delivery of AHT prevention programs in this and other published studies have focused primarily on the immediate post-partum period and in the first few months of life. Evaluation of the intervention in the prenatal context would also be important. Reinforcement of the messages may yield greater changes in knowledge and larger behavioral changes. For example, introduction of the program in prenatal classes and the standard program after birth with new caregivers being given the program materials (i.e. DVD and booklet) could occur. This early and repeated exposure may allow for even greater changes in knowledge. Strategies to enhance review of the materials at home and sharing of materials with others, which may more firmly entrench knowledge about infant crying, would also be of value.

This study assessed change in knowledge and use of behaviors in response to infant crying as outcomes believed to be related to the more critical and desired outcome which is a reduction in the number of AHT cases. At present large scale longitudinal population studies are underway to study this question in both British Columbia and North Carolina. Results of these studies should be generalizable to the Maritime region. In these regions under study, all three doses of the program have been implemented and the components are being evaluated individually and in totality for their effects. The number of Doses adopted in our region may impact the ability to generalize the results of population based studies regionally.

Following more widespread delivery of the program, perhaps on a regional Maritime level, local evaluation projects with different populations which explore different dimensions of the program may be possible. Given the relative rarity of this event, proxy measures may suggest that over time, a reduction in AHT cases is possible. The study of other important outcomes related to infant crying might include ED visits, calls to health help lines or hospital admissions for crying and incidence of other forms of infant abuse such as bruising or fractures without associated brain injury. These outcomes may provide proxy evidence of program success.

Increasing knowledge about infant crying, why it can be frustrating and how best for caregivers to respond may result in a decrease in the incidence of infant physical maltreatment.

CHAPTER 6 CONCLUSIONS

All babies normally will transition through a period of early increased crying. Although this *Period of PURPLE Crying* is predictable, many new parents are unaware of this developmentally common, and normal, phenomenon. This often misunderstood *Period of PURPLE Crying* can lead to anxiety and frustration in many new parents. In some cases crying had been identified as a specific trigger for AHT, as the caregiver reacts violently to the infant's crying behavior.

There appears to be a high level of awareness of the dangers of shaking a baby and its potential consequences among caregivers. The *Period of PURPLE Crying* program is an AHT prevention program that highlights education about normal crying and provides anticipatory guidance about this normal early infant behavior. It also provides messaging about the dangers of shaking a baby; however, at its core it is an educational intervention about crying. The underpinning of the messages is that, if caregivers are aware of the normality of this crying behavior and are prepared for it, they will be less likely to respond with violence to a crying infant.

The *Period of PURPLE Crying* program was recently incorporated into standard post partum care on the FNASU at the IWK after a gap in prenatal education about infant crying was identified and as an AHT prevention initiative. Other birth hospitals in Nova Scotia have also begun to deliver the program and the Department of Community Services has provided training to all those working in family resource centers across the province.

This study was the first to evaluate the *Period of PURPLE Crying* program after its adoption at the IWK in February of 2012 and is the first study to have used a pre and post intervention study design. In a sample of 93 first time mothers, we demonstrated that after exposure to the program materials, a significant increase in knowledge about infant crying occurred. This increase in crying knowledge was especially noticed in those with low baseline knowledge about crying. These results support the program as an effective tool to improve knowledge about infant crying and especially in those with low baseline knowledge. If a caregiver is prepared with strategies for coping with early infant crying and understands that it is a normal phase of infant development, they may be less inclined to interpret their infant's persistent crying negatively, such as a reflection of their parenting efficacy or that the baby is

being difficult on purpose or doesn't like them. These findings are significant because of the reported association between infant crying as a trigger for infant abuse and specifically shaking injury.

Likely due to high baseline knowledge levels about infant shaking, the same change in shaking knowledge was not demonstrated in the entire sample. However, in mothers with low baseline shaking knowledge there was a non-significant increase in knowledge about shaking. A planned pregnancy, prior knowledge of *PURPLE*, having spent between 1-9 hours learning about infant crying at baseline and increased confidence for managing a crying infant resulted in greater odds of a positive change in shaking knowledge post intervention. These characteristics might describe a caregiver who is more motivated and receptive to learning about their new infant.

This study also demonstrated widespread positive endorsement of program materials by first time mothers as informative, useful, and helpful in coping with infant crying and as something to be recommended to other caregivers. Over eighty percent of participants reported that they understood crying because of *PURPLE.* Most participants were exposed to program materials in hospital, as is now part of standard newborn care on the FNASU. Only a small percentage of participants re-watched or re-read the booklet at home whereas nearly sixty percent of mothers reported having shared information about *PURPLE*. This suggests that for many, a review of information did occur once at home but it may not have been through re-exposure to the materials themselves.

If change in knowledge and behavior are outcomes of interest, and re-exposure to messages is related to these outcomes, perhaps promoting review of information and messages may be more valuable than promoting review of the actual program materials. Implementation of Dose Two (reinforcement of program messages by public health, physicians, and others) and Dose Three (a public education campaign to create awareness and change within the general public) may be critical in ensuring that re-exposure to the messages of the program occurs given that the reported rates of re-watching the DVD and re-reading of the book are low. Reminder postcards, print media, television and radio campaigns and anticipatory guidance about *PURPLE* crying at primary care visits are other ways in which re-exposure to program messages might occur. Consideration should be given as to how these strategies might enhance a provincial framework for dissemination of *PURPLE*.

In response to both crying and unsoothable crying, 70-80% of participants infrequently or did not ever put their baby down in a safe place and walk away. Walking around with the baby was the most commonly reported response to infant crying and when the crying became unsoothable, passing the baby to someone else was the behavior most frequently used. Self-talk strategies, including telling oneself that the crying would end and that the baby is okay, were used by nearly half of all participants on a daily basis.

The trend of not putting the baby down may reflect an attachment based parenting style that promotes keeping the infant in arms. Walking around with the baby and passing the baby to someone else are safe ways in which to respond to a crying infant; however, there may be situations in which their use would be limited. For example, if a caregiver was alone, they could not pass the baby to someone else. In this study, the reported use of self-talk strategies was promising while ways in which to reinforce and promote the safety of program "walk-away" behaviors may be required.

Anticipation of crying as an issue was the only factor that was consistently associated with each of the three behavioral responses (i.e. response to crying generally, response to unsoothable crying, self-talk in response to unsoothable crying). As anticipation that crying would be an issue for caregivers increased, their odds of being a high user on each of the response scales increased. There likely is a complex relationship between the level of anxiety of a caregiver and how they respond to and perceive to their infant's crying behavior. Level of parental anxiety about infant crying may be an important characteristic to be considered when delivering program materials or in the subsequent reinforcement of program messages.

Additional research on the rates of AHT and other proxy measures of program effectiveness are still required. Fortunately, this work is already underway in several jurisdictions in large scale population studies. Given that AHT is a rare outcome, these types of studies are required and will be important in strengthening the evidence base for prevention programs. In the interim, positive results from this and other evaluations of the *Period of PURPLE Crying* program favor its universal adoption in Nova Scotia. By delivering program materials to all new parents and caregivers, we can work towards enhancing knowledge about early infant crying and how to safely respond and the dangers of shaking an infant.

A provincial strategy to ensure universal provision of Dose One materials to all new caregivers is important. This will ensure that all caregivers in Nova Scotia will have access to a

timely and effective educational intervention about early infant crying and will support the creation of an evaluation framework. In addition to the incidence of AHT, proxy outcomes such as rates of infant physical abuse, ED visits for crying and the study of parental self-efficacy are examples of areas in which additional research is required. Provision of Dose Two and Three province wide may help create a Nova Scotia in which there is a culture of acceptance of crying as a normal newborn behavior that requires knowledge and anticipatory guidance to be managed in the most effective and safe way possible.

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APPENDIX C Information form In-Hospital Participants

Delivering the *Period of PURPLE Crying* Program in the Post Partum Period: A Step towards Child Abuse Prevention

Researchers:
Amy Ornstein, MD, FRCP(C), Child Protection Team Director, IWK Health Centre and Dalhousie University and MSc candidate in Clinical Epidemiology, Dalhousie University
Linda Dodds, PhD, Director of the Perinatal Epidemiology Research Unit
Eleanor Fitzpatrick, RN, MN, Coordinator Research IWK Emergency Department
Jill Hatchette, PhD, Clinician Scientist, IWK Health Centre
Jayani Abeysekera MD, Pediatrics Resident, IWK Health Centre
Christy Woolcott, PhD, Perinatal Epidemiology Research Unit

Funding Source: IWK Category A Grant

Introduction and Purpose:

You are being invited to take part in a research study. This research will evaluate first-time mothers' knowledge, attitudes, and behaviour in response to infant crying, and the acceptability and utility of the *Period of PURPLE Crying* delivered on the Family and Newborn Unit. The *Period of PURPLE Crying* is a crying education program that teaches about normal early infant crying and how best to manage this.

This study is being conducted in two steps. The first step involves a brief interview to be conducted with you about the preparation you received about infant crying and your knowledge and attitudes about infant crying. The second step is a brief follow-up telephone interview with you when your baby is between 4-6 weeks old. Prior to discharge from the IWK you will watch a DVD called the *Period of PURPLE Crying* and receive a booklet with similar information.

This form is part of the process to inform you about the research study. It is important that you understand the purpose of the study, the risks and benefits of taking part and what you will be asked to do, before you decide if you want to take part. Taking part in this study is entirely voluntary; it is your choice. Informed consent starts with the first contact about the study and continues until the study is complete. If you have any questions that this form does not answer, the study staff will be able to provide you with further information. The care you or your family receives at the IWK will not be affected by this study.

How will the researchers do the study?

This study is only being done at the IWK and involves the mothers of newly born babies. If you agree, you will complete will complete a short face to face interview before discharge and before receiving the *Period of PURPLE Crying* program. You will complete a short telephone questionnaire approximately 4-6 weeks after you have been discharged from the IWK. A research assistant will contact you by phone to complete the second questionnaire. We anticipate enrolling 100 participants in total for the pre-questionnaire and a total of 300 for the post-questionnaire

What will I be asked to do?

Once you have agreed to participate in this study you will be asked to complete the questionnaire with the research assistant while in hospital. This should take no more than 10 minutes to complete. In about 4-6 weeks time, you will be asked to complete a second questionnaire on the phone with the research assistant. This should take no more than 10 minutes to complete.

Potential Harms and Burdens

There are no foreseen risks to participating in this study apart from the inconvenience of answering questions**.**

Potential Benefits

You may not directly benefit from this study, although you may benefit from the information learned. It is hoped that what is learned from this study will be of future benefit to others.

Can I withdraw from the study?

Participation in this study is entirely voluntary (your choice). You are free to withdraw at any time including the withdrawal of data already collected. Withdrawing from the study will not affect you or your family's care at the IWK Health Centre.

Costs and reimbursements

Participation in this study will not result in any expense to you. Participants who complete the questionnaires will be entered to win one of two $50 gift certificates to a local children's retailer.

How will my privacy be protected?

Any information that is learned about you or your child will be kept private. None of your identifying information will be transcribed to the data files. Study data will only be linked to you by code. The linking codes will be stored separately from the data. Only study staff will have access to the study records. In addition, the records may be shown to personnel of the Research Services Office of the IWK Health Centre and the regulatory authorities in Canada. If the results of the study are published in the medical literature, the publication will not contain any information that may identify you or your child. Study records will be stored in a locked area and will be kept for 5 years post-publication as required by the IWK Research Ethics Board. Any individual who has information pertaining to the protection of a child is mandated to report this information to Child Welfare Authorities regardless of any pre-existing claims to confidentiality.

What if I have study questions or problems?

If you have questions about this study, you can contact Dr. Amy Ornstein at 470-8222 (amy.ornstein@iwk.nshealth.ca) or Dr. Jayani Abeysekera at 470-8888 and ask for her to be paged.

What are my Research Rights?

Signing this consent indicates that you have agreed to take part in this research and for your responses to be used. In no way does this waive your legal rights nor release the investigator(s), sponsors, or involved institution(s) from their legal and professional responsibilities. If you have any questions at any time during or after the study about research in general you may contact the Research Office of the IWK Health Centre at (902) 470-8520, Monday to Friday between 9a.m. and 5p.m.

How will I be informed of study results?

The grouped results of this survey will be available in approximately 12 months. If you would like to receive a summary of the study results we will collect your name and address/email address and send them to you.

Delivering the *Period of PURPLE Crying* Program in the Post Partum Period: A Step towards Child Abuse Prevention

Consent:

I have read or had read to me this information and consent form and have had the chance to ask questions which have been answered to my satisfaction before signing my name. I understand the nature of the study and I understand the potential risks of participating. I understand that I have the right to withdraw from the study at any time without affecting my child's care in any way. I have received a copy of the Information Form for future reference.

Participants Name: _____Date:_____

(print name) Time:_____

Participant's Signature _____

Participant's preferred phone number for contact: _____

I wish to receive the group results of this study: □ yes □ no

Address:

_____
_____
_____
_____

OR

E-mail Address: _____

I wish to be entered into the incentive draw for one of two 50$ gift cards to a local supplier of baby supplies/toys: □ yes □ no

STATEMENT BY PERSON PROVIDING INFORMATION ON STUDY

I have explained the nature and demands of the research study and judge that the participant named above understands the nature and demands of the study.

Name:_____ (print name)

Position:_____

Signature: _____Date:_____ Time:_____

STATEMENT BY PERSON OBTAINING CONSENT

I have explained the nature of the consent process to the parents of the participant and judge that they understand that participation is voluntary and that they may withdraw at any time from participating.

Name:_____ (print name)

Position:_____

Signature: _____Date:_____ Time:_____

.

APPENDIX D *PURPLE* Face Sheet Study Intake

Addressograph or Sticker

Is this a FIRST time mother?	**YES**		**NO**	**(exclude)**
Was the baby in the NICU?	**YES**	**(exclude)**	**NO**	
Is there a telephone for follow-up?	**YES**		**NO**	**(exclude)**

Was the *Period of PURPLE Crying* Program Delivered?

YES ☐ NO ☐

For research use only:

Participant number assigned 1 __ __ __

Date of 4-6 week phone contact

_____

*When patient is discharged and chart disassembled, please place this sheet in the *PURPLE* box

THANK YOU

APPENDIX E Research Ethics Board Approval Letter

IWK Health Centre
Research

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Approval - Delegated Review
July 03, 2012

Principal Investigator: Dr Amy Ornstein
Co-Principal Investigator: Dr Linda Dodds
Title: Delivering the Period of Purple Crying Program in the Post Partum Period: A Step Towards Child Abuse Prevention
Project #:1011401

On behalf of the IWK Research Ethics Board (IWK-REB) I have reviewed the documents included in this study. I am pleased to confirm the Board's full approval for this research study, effective today. This includes approval for the following study documents:

Document Name	Version Date
Protocol	2012/05/31
Research Summary	2012/05/31
Flowchart	2012/05/31
Script - Telephone Consent Group 2	2012/05/28
Script - Follow Up Telephone Interview Group 1	2012/05/28
Study Sticker For DVD	2012/05/31
Form - Intake	2012/05/31
Information Form - At Home	2012/06/21
Information Form - In Hospital	2012/06/21
Questionnaire - Pre Group 1	2012/06/21
Questionnaire - Post Group 1	2012/06/21
Questionnaire - Group 2	2012/06/21

The Board's approval for this study will expire one year from the date of this letter (July 03, 2013). To ensure continuing approval, submit a Request for Continuing Review to the Board 2 - 4 weeks prior to the renewal date. If approval is not renewed prior to the anniversary date, the Board will close your file and you must cease all study activities immediately. To reactivate a study, you must submit a new Initial Submission (together with the usual fee, if applicable) to the IWK-REB and await notice of re-approval.

IWK Health Centre
Research

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Approval - Amendment
July 09, 2012

Principal Investigator: Dr Amy Ornstein
Co-Principal Investigator: Dr Linda Dodds
Title: Delivering the Period of Purple Crying Program in the Post Partum Period: A Step Towards Child Abuse Prevention
Project #: 1011401

On behalf of the IWK Research Ethics Board (IWK-REB) I have examined the proposed amendment to this research study. I am pleased to confirm the Board's approval of the following amended documents, effective today:

Document Name	Version Date
Protocol	2012/07/06
Information Form - In Hospital	2012/07/06
Form - Intake	2012/07/06
Questionnaire - Pre Group 1	2012/07/06
Questionnaire - Post Group 1	2012/07/06
Questionnaire - Group 2	2012/07/06

[redacted]
Adam Huber
Co-Chair, Research Ethics Board

The following is a complete list of approved documents for use on this study:

Document Name	Version Date
Research Summary	2012/05/31
Flowchart	2012/05/31
Script - Telephone Consent Group 2	2012/05/28
Script - Follow Up Telephone Interview Group 1	2012/05/28
Study Sticker For DVD	2012/05/31

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Approval - Amendment
August 14, 2012

Principal Investigator: Dr Amy Ornstein
Co-Principal Investigator: Dr Linda Dodds
Title: Delivering the Period of Purple Crying Program in the Post Partum Period: A Step Towards Child Abuse Prevention
Project #: 1011401

On behalf of the IWK Research Ethics Board (IWK-REB) I have examined the proposed amendment to this research study. I am pleased to confirm the Board's approval of the following amended documents, effective today:

Document Name	Version Date
Amendment - Changes to Research Personnel, addition of Christy Woolcott	2012/07/27
Information Form - At Home	2012/07/30
Information Form - In Hospital	2012/07/30

[redacted]
Adam Huber
Co-Chair, Research Ethics Board

The following is a complete list of approved documents for use on this study:

Document Name	Version Date
Research Summary	2012/05/31
Flowchart	2012/05/31
Script - Telephone Consent Group 2	2012/05/28
Script - Follow Up Telephone Interview Group 1	2012/05/28
Study Sticker For DVD	2012/05/31
Protocol	2012/07/06
Form - Intake	2012/07/06

APPENDIX F Demographic Information

1. Maternal Age

☐ <20 ☐ 20-29 ☐ 30-39 ☐ >40

2. Paternal Age

☐ <20 ☐ 20-29 ☐ 30-39 ☐ >40

3. Maternal Education (highest level obtained) – *highest level of education you have?*

☐ Less than grade 12

☐ Grade 12 (high school)

☐ College degree

☐ Undergraduate degree

☐ Postgraduate degree

4. Household Income

☐ Less than 20,000 ☐ 20,000 – 59,999 ☐ 60,000 or greater

5. Maternal Past Medical History *(conditions)*

☐ Yes, Please describe._____.
☐ No

APPENDIX G Pregnancy and Obstetric Factors

1. Pregnancy History

☐ Gestational Diabetes ☐ Recreational Drugs ☐ Medication Use

☐ Hypertension ☐ Alcohol

☐ Smoking ☐ Bleeding ☐ None

2. Was this a planned pregnancy?

☐ Yes ☐ No

3. Infant gender

☐ Male ☐ Female

4. Infant Birth Weight (in lbs):_____.

5. Did you have a vaginal or cesarean delivery?

☐ Vaginal ☐ Cesarean

6. Did your labour begin naturally? – *or induced?*

☐ Yes ☐ No – Induced

7. Was the delivery of your baby assisted?

☐ None ☐ Forceps ☐ Vacuum

APPENDIX H Preparation for Infant Crying Scale

1. About how much time did you spend learning about infant crying before your delivery?

☐ 20 or more hrs
☐ 10-19 hrs
☐ 1-9 hrs
☐ <1 hr
☐ No time was spent at all

2. How much did you learn about infant crying before your delivery?

☐ Large Amount
☐ Fair Amount
☐ Very little
☐ None at all

3. Before your delivery, where did you get information about infant crying?

(Check all that apply)

☐ Prenatal Classes	☐ Friends	☐ Doula
☐ Family Doctor	☐ Books	☐ Experience with other babies
☐ Family	☐ Internet	☐ Public Health
☐ Obstetrician	☐ Midwife	

☐ Other. Please describe._____.

4. Which of these sources provided the best information about infant crying?

☐ Prenatal Classes	☐ Friends	☐ Doula
☐ Family Doctor	☐ Books	☐ Experience with other babies
☐ Family	☐ Internet	☐ Public Health
☐ Obstetrician	☐ Midwife	

☐ Other. Please describe._____.

5. How helpful do you think this information about infant crying will be?

☐ Very Helpful
☐ Somewhat Helpful
☐ Not helpful at all
☐ N/A

APPENDIX I Confidence and Future Concern Scale

1. How confident do you feel about dealing with a crying infant?

☐ Not confident
☐ Somewhat confident
☐ Adequately confident
☐ Very confident

2. Do you think that infant crying will be an issue for you?

☐ Not at all
☐ Maybe
☐ Likely
☐ Very likely

3. Which resources will you use if you require further assistance with infant crying? *–y/n (check all – not scored)*

☐ Friends	☐ Doula	☐ Internet
☐ Family Doctor	☐ Books	☐ Family
☐ Public Health	☐ Emergency room	☐ Obstetrician
☐ Midwife	☐ Other. Please describe._____.	

These are questions about what you will do when your infant cries, if you do not know or do not have an answer to these questions, that is ok, and you can simply not answer the question or you can answer the question to the best of your ability.

4. What will you do if [insert infant's name] starts to fuss or cry?

Answer: _____

☐ Don't know

5. What will you do if [insert infant's name]'s crying is unsoothable?

Answer:_____

☐ Don't know

6. Have you heard about The *Period of PURPLE Crying* Program?

☐ Yes ☐ No

APPENDIX J Knowledge of Infant Crying Scale (K-IC)

For each of the following, please answer as to how much you agree with each statement about an infant's behaviors and needs in the first few months of life? You may strongly agree, agree, disagree, or strongly disagree.

1. Infants cry more often in the late afternoon and evening

☐ Strongly agree
☐ Agree
☐ Disagree
☐ Strongly disagree

2. Infant crying increases in the first few weeks of life and reaches a peak in the first 2 or 3 months before getting less

☐ Strongly agree
☐ Agree
☐ Disagree
☐ Strongly disagree

3. If an infant is healthy, it should not cry unexpectedly or without a clear reason (reverse score)

☐ Strongly agree
☐ Agree
☐ Disagree
☐ Strongly disagree

4. When an infant cries, it is always a sign that something is wrong (reverse score)

☐ Strongly agree
☐ Agree
☐ Disagree
☐ Strongly disagree

5. Sometimes a crying infant can look like it is in pain, even when they are not.

☐ Strongly agree
☐ Agree
☐ Disagree
☐ Strongly disagree

6. Sometimes healthy infants can cry for 5 or more hours a day

☐ Strongly agree
☐ Agree
☐ Disagree
☐ Strongly disagree

7. A good parent should be able to soothe their crying infant (reverse score)

☐ Strongly agree
☐ Agree
☐ Disagree
☐ Strongly disagree

8. It is ok to walk away from a crying infant (after making sure they are in a safe place) when their crying becomes very frustrating

☐ Strongly agree
☐ Agree
☐ Disagree
☐ Strongly disagree

APPENDIX K Knowledge of Infant Shaking Scale (K-S)

1. Shaking a baby is a good way to help a baby stop crying (reverse score)

☐ Strongly agree
☐ Agree
☐ Disagree
☐ Strongly disagree

2. Sometimes infant crying can be so frustrating or upsetting that I can see how someone might shake or hurt an infant

☐ Strongly agree
☐ Agree
☐ Disagree
☐ Strongly disagree

3. Shaking a baby can be very dangerous and can cause serious injuries

☐ Strongly agree
☐ Agree
☐ Disagree
☐ Strongly disagree

4. Shaking an infant can cause serious health problems or even death.

☐ Strongly agree
☐ Agree
☐ Disagree
☐ Strongly disagree

5. One important role for parents is to protect their infant by making sure people who take care of their infant know about the dangers of shaking an infant.

☐ Strongly agree
☐ Agree
☐ Disagree
☐ Strongly disagree

APPENDIX L Response To Crying Generally Scale

How often did you do the following things with your infant in the PAST MONTH?

1. You put your infant down in a safe place and walked away when he or she fussed or cried to the point that you were frustrated.

   ☐ Did not do it
   ☐ Once or twice
   ☐ 3 – 5 times
   ☐ 6 – 10 times
   ☐ 11 times -almost every day
   ☐ Don't know

2. You told other people who take care of your infant about the characteristics of infant crying.

   ☐ Did not do it
   ☐ Once or twice
   ☐ 3 – 5 times
   ☐ 6 – 10 times
   ☐ 11 times -almost every day
   ☐ Don't know

3. You walked around with your infant when he or she fussed or cried.

   ☐ Did not do it
   ☐ Once or twice
   ☐ 3 – 5 times
   ☐ 6 – 10 times
   ☐ 11 times -almost every day
   ☐ Don't know

4. You told other people who take care of your infant what to do if they became frustrated with your infant's crying.

   ☐ Did not do it
   ☐ Once or twice
   ☐ 3 – 5 times
   ☐ 6 – 10 times
   ☐ 11 times -almost every day
   ☐ Don't know

APPENDIX M Response To Unsoothable Crying Scale

When your infant's crying was unsoothable, how often did you do the following things with your infant in the PAST MONTH"?

1. Pass the baby to someone else for a while.

- ☐ Did not do it
- ☐ Once or twice
- ☐ 3 – 5 times
- ☐ 6 – 10 times
- ☐ 11 times-almost every day
- ☐ Don't know

2. Put the baby down in a safe place for a while.

- ☐ Did not do it
- ☐ Once or twice
- ☐ 3 – 5 times
- ☐ 6 – 10 times
- ☐ 11 times -almost every day
- ☐ Don't know

3. Took a break from the sound of crying.

- ☐ Did not do it
- ☐ Once or twice
- ☐ 3 – 5 times
- ☐ 6 – 10 times
- ☐ 11 times- almost every day
- ☐ Don't know

4. Took the baby for a walk or drive.

- ☐ Did not do it
- ☐ Once or twice
- ☐ 3 – 5 times
- ☐ 6 – 10 times
- ☐ 11 times-almost every day
- ☐ Don't know

APPENDIX N Self-Talk Response to Unsoothable Crying

When your infant's crying was unsoothable, how often did you do the following things with your infant in the PAST MONTH?

1. Told yourself the crying would end.

- ☐ Did not do it
- ☐ Once or twice
- ☐ 3 – 5 times
- ☐ 6 – 10 times
- ☐ 11 times-almost every day
- ☐ Don't know

2. Told yourself your baby is ok.

- ☐ Did not do it
- ☐ Once or twice
- ☐ 3 – 5 times
- ☐ 6 – 10 times
- ☐ 11 times -almost every day
- ☐ Don't know

3. Told yourself there is nothing you can do

- ☐ Did not do it
- ☐ Once or twice
- ☐ 3 – 5 times
- ☐ 6 – 10 times
- ☐ 11 times- almost every day
- ☐ Don't know

4. Told yourself it was not your fault.

- ☐ Did not do it
- ☐ Once or twice
- ☐ 3 – 5 times
- ☐ 6 – 10 times
- ☐ 11 times-almost every day
- ☐ Don't know

APPENDIX O Perceived Utility of the *Period of PURPLE Crying*

1. Did you receive the *PURPLE* Program?

   ☐ Yes ☐ No ☐ Don't know

2. Did you view the *PURPLE* Program DVD at the hospital?

   ☐ Yes ☐ No ☐ Don't know

3. Have you viewed the *PURPLE* DVD at home?

   ☐ Yes ☐ No ☐ Don't know

4. Have you shared the *PURPLE* Program DVD with other caregivers?

   ☐ Yes ☐ No ☐ Don't know

5. Did you read the *PURPLE* booklet in the hospital?

   ☐ Yes ☐ No ☐ Don't know

6. Have you read the *PURPLE* booklet at home?

   ☐ Yes ☐ No ☐ Don't know

7. Have you shared the *PURPLE* booklet with other caregivers?

   ☐ Yes ☐ No ☐ Don't know

8. Have you shared information about the *PURPLE* program with others?

   ☐ Yes ☐ No ☐ Don't know

9. Do you think that infant crying is an issue for you?

- ☐ Not at all
- ☐ Maybe
- ☐ Likely
- ☐ Very likely

10. How confident do you feel about dealing with a crying infant?

- ☐ Not confident
- ☐ Somewhat confident
- ☐ Adequately confident
- ☐ Very confident

11. Which resources have you used for assistance with infant crying? *–y/n (check all, not scored)*

☐ Friends	☐ Doula	☐ Internet
☐ Family Doctor	☐ Books	☐ Family
☐ Public Health	☐ Emergency room	☐ Obstetrician
☐ Midwife	☐ *Period of PURPLE Crying* materials (book or DVD)	
☐ Other. Please describe._____	☐ None or not needed	

12. Please rate the extent to which you agree with the following statements

1. The *PURPLE* Program is informative

- ☐ Strongly agree
- ☐ Agree
- ☐ Disagree
- ☐ Strongly disagree

2. The *PURPLE* Program is useful

- ☐ Strongly agree
- ☐ Agree
- ☐ Disagree
- ☐ Strongly disagree

3. I understand infant crying because of the *PURPLE* Program

☐ Yes ☐ No ☐ Don't know

4. I have employed the strategies described in the *PURPLE* Program DVD

☐ Strongly agree
☐ Agree
☐ Disagree
☐ Strongly disagree

5. The *PURPLE* Program has helped me cope with my infant's crying

☐ Strongly agree
☐ Agree
☐ Disagree
☐ Strongly disagree

6. I would recommend the *PURPLE* Program DVD to friends with infants

☐ Strongly agree
☐ Agree
☐ Disagree
☐ Strongly disagree