

CHILLIWACK SAFEBABY PROGRAM: A RANDOMIZED CONTROL TRIAL

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Introduction

Injuries represent the leading cause of death for children and youth under the age of 20 and account for approximately one-half of all deaths among 1-14 year olds in Canada and the United States (Souhbi, et al., 1999). Among infants less than one year, unintentional injuries are the fourth leading cause of death following perinatal mortality, congenital anomalies, and SIDS. The majority of unintentional injuries occur in the home (Health Canada, 1997). Injuries among infants are closely tied with their physical and cognitive development, their high degree of dependence on adult supervision and the need for protection from harm. Recent analysis of emergency department data shows that most falls among infants were due to falling down stairs, and falls off of various other surfaces. The other leading cause of unintentional injury among infants resulted from inappropriate placement of infants that resulted in exposure to hazardous circumstances (British Columbia Injury Research and Prevention Unit, 2000). The results of this analysis exemplifies the significance between adult behavior, infant dependence and occurrence of injury. Surveys have shown parents to have low levels of safety practices in the home. Studies on interventions which provide parents with safety devices and counselling to reduce home injuries among children have shown mixed findings. There have been few randomized trials in this area, and those which have been done have addressed a wide range in age often ignoring the developmental heterogeneity that can effect the success or failure of an intervention.

Project Aims

- This project seeks to assess the effectiveness of developmentally targeted interventions aimed at reducing the risk of injuries among new infants by assisting parents to:
 - 1) identify risks in their home
 - 2) plan actions to reduce risks
 - 3) take action to create safer home environments including the use of safety devices

Purpose

- evaluate the effectiveness of interventions designed to reduce the occurrence of home injuries to infants aged 12 months and younger using a prospective community-based randomized control study
- Interventions:
 - 1) distribution of free-of-charge home safety guide and equipment
 - 2) distribution of free-of-charge home safety guide, equipment and an in home consultation from a public health nurse.

Study Rationale

The proposed intervention targets new parents at a time when they are amenable to change as a result of adjusting to caring for a new baby. The intervention also targets infants who are at risk for home injuries and suffer proportionately more head injuries and concussions than other age groups. This project will supply and evaluate Safe Baby Kits with devices and educational materials that are designed to reduce injury among infants and promote actions to reduce risks in the home environment. The added home visit will test the benefits of nurse consultation to assist parents with risk assessment and taking action to reduce risks in the home environment.

Methods

Research Design

- prospective community-based randomized controlled trial to assess the effectiveness of the proposed interventions.
- randomly assign parents and infants to one of three experimental groups.
- subjects in each group will be followed for a period of 10 months
- data collection will occur at 2, 6 and 12 months old immunization visits to the Health Unit.

Inclusion Criteria

- Parent(s) presents infant for 2 month old immunization
- Parent(s) with a Fraser Valley address.

Research Setting

- The district of Chilliwack .

Sample and Sample Size

- The sample for this study will be the entire population of parents and new infants born during one year in Chilliwack. Between 775 and 850 babies are born each year and over 95% of these parents return with their new infants to the health unit for each of their immunizations at ages 2, 6 and 12 months.

Instrumentation and Measurement of Outcomes

- A self reported survey will be completed by parents
- Major variables include:
 - 1) Parental risk perceptions
 - 2) Parental safety practices
 - 3) Injury incidents
 - 4) Use of safety devices
 - 5) Demographics (age, gender, etc.)



Intervention

Group 1

- Parent(s) will receive a free-of-charge Safe Baby Kit from a nurse at the time of their baby's 2 month immunization health unit visit.
- Infant home safety guide - contains a step by step approach to assist parent(s) to:
 - 1) complete the Safe Home Assessment Tool to identify infant injury risks in the home
 - 2) make an action plan to modify risks identified
 - 3) take actions to reduce environmental risks for infant home injuries.

Group 2

- Parent(s) will receive free-of-charge the Baby Safe Kit from a nurse at the time of their baby's 2 month immunization health unit visit.
- Parent(s) will also receive a 40 minute home visit from a community health nurse within 3 weeks of their 2 month health unit visit. The nurse will:
 - 1) assist the parent(s) to identify risks in the home
 - 2) plan actions to modify identified risks
 - 3) discuss the benefits, use and installation of each of the safety kit devices

Group 3 (Control Group)

- Parent(s) will receive the standard services and education provided by health nurses at the Chilliwack Health Unit to parents of infants of this age.

Data Analysis

Subjects will be described in terms of age, gender, household income, number of children in the household, marital status, occupation, education, injury occurrence, use or installation of safety devices. The comparability of subjects in each of the three groups will be assessed. Even though randomization is used as a means of ensuring comparable groups at the onset of the trial, events after randomization may have rendered study groups non equivalent on characteristics known to effect outcome. The direction and impact of any differences or biases on the results will be highlighted.

Differences in groups' will be assessed using descriptive analyses (chi-square tests and/or Mantel-Haenszel chi-square for categorical and proportions). All the analyses will be considered significant at $p < 0.05$. Multiple logistic regression (dichotomous outcomes) will be done to test each one of the hypotheses. These analyses will examine the impact of the intervention on each of the outcomes after adjusting for demographic variables and variables assessing the underlying belief system, specifically perception of risk, awareness, and knowledge of injury prevention at baseline. Separate analysis will be done for each follow-up period. Secondary analysis will assess the interactions between interventions and cognitive constructs related to behavior change on each of the proposed outcomes.

Anticipated Significance of the Work (outcome indicators) and Impact on the Field

This prevention project will help to determine how community health professionals can most effectively aid parents of new babies make their home environments safer for their infants. Anticipated outcomes include increased safe-proofing practices in the home and the reduction of infant injuries among one or both intervention groups compared with the group receiving no intervention. We will also determine if in-home consultation makes a significant impact on the adoption of home safety practices. The literature to date regarding the effectiveness of home safety equipment giveaway programs has been conflicting. This project will add to this field by testing an intervention which is focussed on a more defined developmental level and in which high levels of follow-up are anticipated.