BRIGHT BY THREE (BB3) EFFECTIVENESS TRIAL

1. SPECIFIC AIMS & HYPOTHESES

We propose to conduct a pragmatic randomized controlled trial of 200 parents of children ages one to four years old and their 200 children (secondary subjects) to study the effectiveness of 1) the Bright By Three (BB3) intervention for promoting children's language and socio-emotional development and 2) a Text for Child Safety (TCS) intervention for reducing safety hazards and injuries. The TCS intervention will serve as a control for the BB3 group and vice versa so that all study participants will receive a clinically meaningful intervention. In collaboration with primary care clinics that serve low-income and minority children, we will recruit and randomize 200 parents of children ages twelve to fifteen month old and their 200 children (secondary subjects) to one of the two intervention arms and deliver the interventions over a 2 year period.

Bright By Three (BB3):

- **Specific Aim 1**: Compare the effectiveness of the BB3 intervention with a control group (TCS) for the following outcomes: parental attitudes toward Talking, Reading, Playing and Praising (TRPP), actual TRPP behaviors, and children's social-emotional and language development at baseline and ages 2, 3, and 4 years.

  Hypothesis 1*: Compared to the TCS injury prevention group, the BB3 intervention will result in increased parental TRPP behaviors and improved language development at 3 and 4 years.*

- **Specific Aim 2:** Describe the implementation costs of the BB3 intervention.

  Hypothesis 2*: Because the cost of mobile technology interventions can be distributed across many different users, we anticipate that the cost per family enrolled in the BB3 program will not be significantly greater than the cost per family enrolled in the injury prevention program.*

- **Specific Aim 3**: Identify barriers and facilitators to successful BB3 program implementation and parental satisfaction with and use of different aspects of the BB3 mobile app.

  Hypothesis 3*: We will identify changes that could improve program implementation and key elements that are necessary for consistent implementation in preparation for a broader dissemination and implementation study.*

Text for Child Safety (TCS):

- **Specific Aim 4 (TCS Primary Aim):** To determine the efficacy of a child safety intervention (TCS) in reducing the presence of child safety hazards in the home and car environments. Specifically, we will:

a. compare the number and type of safety hazards between groups - TCS arm and BB3 arm - at baseline and follow-up
b. examine the number and type of safety hazards pre-/post- the TCS intervention within the TCS arm

Hypothesis 4.1*: Families who receive the TCS intervention (TCS) will have fewer safety hazards at follow-up compared with families who receive the BB3 intervention.*

Hypothesis 4.2*: At each follow-up point, families who receive the TCS intervention (TCS) will have a decreased number of safety hazards than at baseline or at the time of the prior follow-up..*

- **Specific Aim 5 (TCS Secondary Aim 1**): To determine the efficacy of a tailored child safety intervention (TCS) at decreasing the number of self-reported and medically-attended injuries.

Hypothesis 5.1*: Families who receive the TCS intervention will have fewer self-reported and medically-attended injuries compared with families who receive the BB3 intervention.*

Hypothesis 5.2*: Families who receive the TCS intervention will have a decreased number of self-reported and medically-attended injuries at follow-up compared to baseline.*

- **Specific Aim 6 (TCS Secondary Aim 2):** To compare safety knowledge attitudes/beliefs and self-reported efficacy of families who receive a tailored child safety intervention (TCS) as compared to children who receive the BB3 intervention.

Hypothesis 6: *Families who receive the TCS intervention have more safety knowledge, more favorable attitudes/beliefs about safety enhancement and increased self-efficacy as compared to families who receive the BB3 intervention.*

2. PURPOSE: BB3:

The purpose of the BB3 intervention (annual home visit, written materials, and BB3 mobile application 'app') is to increase parental talking, reading, playing, and praise (TRPP) behaviors and improves children's social-emotional and language development at ages 2, 3, and 4 years.

TCS:

The purpose of the injury prevention arm is to reduce the prevalence of safety hazards in the home and car environments, decrease the number of self-reported and medically-attended injuries among children, and increase caregiver's self-reported safety behaviors and knowledge of child safety. We will compare the results of our child safety intervention (Texts for Child Safety [TCS]) among participants in the injury prevention arm with those randomized to the BB3 arm.

3. BACKGROUND AND SIGNIFICANCE

BB3/Early Childhood Development:

Children living in poverty are at risk for stunted language and social-emotional development. A large body of data has established that early life experiences are critical determinants of how a person's brain develops and how that person functions in society over time.[4] Before children enter Kindergarten, striking disparities in their knowledge and skills can

be identified that are strongly associated with parental income, education, and other life circumstances.[5] Parents with higher income and education engage in activities supporting their children's brain development such as talking, reading, playing, and praise.[5] In a seminal study, Hart and Risley found that by 3 years old children from low income families had significantly smaller vocabularies and added words more slowly than children from higher income families.[1] A subset of these children who were followed into elementary school showed persistent disparities. The size of a child's vocabulary at age 3 was strongly predictive of verbal and reading skills at age 10.[6] Children from low socioeconomic status families are also more likely to have behavior problems and poor social skills.[7]

Disparities in early childhood development lead to decreased academic achievement and poor economic and health outcomes as adults. By the time they enter Kindergarten, children with lower incomes have lower reading, math, and general knowledge scores and poorer social skills compared to higher income children. In fact, a dose-response relationship exists—the lower the income, the less prepared a child is when he or she enters Kindergarten.[8,9] This leads to ongoing academic struggle with increased dropout rates, and less college and graduate training.[10-12] Adults with less education and lower income have a shorter life expectancy and increased likelihood of having poor health and suffering from chronic illness.[13,14]

Fortunately, interventions to increase children's exposure to talking, reading, playing, and praise can improve development and reduce disparities. The Carolina Abecedarian Project, Perry Preschool Project, and Chicago Child-Parent Center Program rigorously studied the effect of center-based programs that emphasized language-promoting activities and parent engagement on child development for at-risk young children. Children participating in these programs had higher IQ scores, achievement test scores, and years of completed schooling compared to similar children who did not participate.[2] The Nurse-Family Partnership, a nurse home-visiting program for first-time, low-income mothers, provides a variety of interventions to support children's language and social development. Randomized, controlled trials conducted over 30 years have shown this program to be effective at improving at-risk children's cognitive and language development and school achievement.[15-18] While such high intensity programs are cost effective[19,20], they have been focused on the highest risk children and, because of cost, aren't accessible to all children who would benefit.

Therefore, effective, low-cost and high reach interventions to support early childhood development are needed. The Reach Out and Read (ROR) program is the nationally recognized model for low-cost, high-reach interventions.[21,22] The BB3 (formerly Bright Beginnings) program is complementary to ROR. Similarly, families are usually identified and referred from primary care clinics. BB3 families receive a picture book and written materials including *Learning Games* and *Language Power* that describe activities to promote language and social development based on strong evidence from studies of the Abecedarian project, Hart and Risley, and dialogic reading.[23-26] The BB3 intervention includes two sets of written materials for families of children ages 12 to 24 months and 24 to 36 months. These materials are intended to be accompanied by a demonstration of how they can be used, often by a trained community volunteer, in clinic, at a group visit in a community center, or at a home visit. The major limitation of the BB3 intervention is that families are usually actively engaged only once per year. The

availability of mobile technology offers an opportunity to engage families more frequently at a place and time that is convenient for them without significantly increasing cost.

Mobile devices and mobile applications (apps) have proliferated. Mobile device use has proliferated among minority and low income communities in the US, with over 60% of African Americans and Latinos aged 18 and older using web enabled or "smart" cell phones and/or tablets.[27] With these mobile devices come a plethora of apps, including apps to address child development[28,29], and the "Parenting Ages and Stages App"[30] providing targeted information on developmental milestones. We know of no evidence, however, that use of these apps leads to improvements in parental behaviors that support increased achievement of developmental milestones. Also, apps marketed directly to consumers are not widely downloaded-- about 30% of cell and tablet users have downloaded any app and, once downloaded, they are rarely used.[31] With such widespread dissemination of mobile devices, apps may represent an innovative strategy to reach vast numbers of parents and engage them to interact effectively with their children. However**, we know little about "what works" in mobile apps to improve parent engagement and child development**. While the app industry has little evidence demonstrating efficacy of apps, a growing body of data shows other technology-based programs can deliver improvements in health. Technology-based health promotion programs can work to increase physical activity, improve nutrition, reduce smoking, and decrease risky sexual behavior. Meta-analyses of Internet and cellphone text messaging programs indicates their efficacy for facilitating improvements in knowledge and behavior change.[32,33] Dr. Bull, a Co-Investigator on this project, has demonstrated the promise of using text messages and the efficacy of using tailored messages via the Internet and social media to increase healthy sexual behaviors in the short term.[34-37] A recent meta-analysis of health promotion using text messaging identified some key elements common to programs that work.[38] Text message programs that have a clear theoretical framework have larger effect sizes than others; those that target specific audiences have greater effects, and those that tailor information based on algorithms employed with user data increase program effects. Cell phone text messaging offers the opportunity to take advantage of the "ecological moment" to communicate with individuals, their networks, and care providers using mobile media.[39,40] **BB3 will capitalize on the proliferation of mobile devices and potential advantages of mobile apps to create a low-cost, high reach, evidence-based intervention to increase parental behaviors that support children's language and social development.**

To our knowledge, we propose to conduct the first study that links parents of children at-risk for developmental delay to child development information and skills building activities using low-cost, easy to use written materials and a mobile app. By targeting the project to a population with many low income, low educational level, and primarily Spanish-speaking parents, we will overcome a critical barrier to delivery of child development skills building programs and reach those communities most in need. In addition, **ours will be the first study to document whether engagement with a child development app results in changes in parental engagement with their children and improvements in child development. This proposal offers an opportunity to study the types of messages and features of a child development app that are most engaging for parents.** As described below, our study will document the activities that parents most often engage in and respond to,

allowing us to better understand the features of the BB3 app that are most effective. By using mobile technology to increase the number of contacts with parents, BB3 has the potential to reach a large audience without significantly increasing the cost of the existing BB3 program. If we can realize the promise of using an effective app to reach many parents whose children are at risk for poor development, we can increase the impact of the BB3 intervention.

Finally, our study is innovative in its use of trained, local community members to implement an intervention to support early childhood development following a community health worker (CHW) health educator and outreach agent model.[41] Since CHWs are usually members of the communities they serve, they are able to build trusting relationships and provide culturally-competent services to their clients. The CHWs' positive connection with their clients can increase the efficacy of an intervention. CHWs are frequently used in low-income countries and in high-income countries among low-income and minority populations. Data support their effectiveness in improving immunization uptake, breastfeeding initiation and continuation, tuberculosis cure rates, and maternal and child health[42]; however a Cochrane review identified only 5 studies (2 in the US) that studied CHW interventions to promote parent-child interaction.[43]

TCS/Unintentional Injury in Children:

Unintentional injury is the leading cause of child death the United States. Each year, nearly 9,000 children die as a result of these injuries and over 9 million are treated in the nation's emergency departments (ED).[44] Injuries suffered within the home are commonplace and account for over 13 million outpatient visits, 74,000 hospitalizations, and 2,800 deaths each year.[45,46] Motor vehicle-related injuries are another major cause of child injury, representing nearly 9 million ED visits and 6,700 child fatalities annually.[44] Children ages 12 to 36 months are significantly burdened by unintentional injury. The top causes of fatalities from unintentional injury in this age group are: drowning, motor vehicle-related, suffocation and burns. The leading cause of non-fatal unintentional injury is falls.[47]

The American Academy of Pediatrics and Centers for Disease Control and Prevention and other nationally recognized health organizations promote prevention recommendations for child unintentional injury. These evidence- based/expert-guided recommendations are aimed at parents of children, and are categorized by child age or by the injury cause/mechanism.[48]

4. PRELIMINARY STUDIES

4a. Randomized controlled trial of original Bright Beginnings program (name now changed to Bright by Three)

Between October 2002 and August 2003, 324 children aged 10-24 months were enrolled in a RCT to determine the efficacy of delivering the BB1.0 intervention during well child visits. Children were randomized to receive either the Bright Beginnings intervention (n=164) or an injury prevention intervention (n=160). Six months after enrollment 55% of families (n= 179) were followed up by telephone. At enrollment and 6 month follow-up, families were administered the MacArthur Communicative Development Inventory to measure children's vocabulary and STIMQ to measure parental behaviors to promote development. 44 Children's vocabulary did not significantly differ between the Bright Beginnings and control groups. However, families who received the Bright Beginnings intervention were more likely to report

shared reading 6-7 nights per week at 6 month follow-up (30% vs 18%, p = 0.06), and, among those families, children's vocabulary percentiles were higher. A subset of parent-child dyads (n= 31) were also videotaped during a shared book reading activity. Videotapes were analyzed and scored by trained speech-language pathologists. Mothers who had received the Bright Beginnings intervention were significantly more likely than control mothers to ask questions, give positive comments, and take turns during shared reading.

A second, telephone follow-up was conducted 7 to 9 years after enrollment to determine if Bright Beginnings had an effect on self-reported school performance among 68 children from the original 324 families (n=32 control, n= 36 intervention). The individual measures of school performance of children from families who had received BB1.0 were not significantly different than children from control families as shown in the table.

Description	BB1.0	Control	p-value
Attention Problems	28%	34%	0.56
Medication for ADHD	8%	9%	0.99
Below Grade Level	28%	41%	0.32
Receives Special Help	35%	41%	0.67
IEP	19%	22%	0.80
Seldom Enjoys School	44%	53%	0.36
Does not Read Daily	56%	59%	0.78

However, when taken together, children from families who had received the Bright Beginnings intervention had better overall performance. The RCT and subsequent follow-up had a number of problems including high attrition rates and low power. While the results of this study of Bright Beginnings are promising, they also indicate the need for more rigorous study of Bright Beginnings and suggest that an intervention with more frequent contact with families may result in less attrition and more effectiveness.

4b. Survey of parents exposed to Bright Beginnings

A computer-assisted telephone interview was conducted from October to November 2011 among English and Spanish-speaking parents who had received BB materials in the previous 1 to 4 months. The response rate was 26% (402/1526). About 46% of respondents were Latino, 22% spoke only Spanish, 48% had a high school diploma or less, and about 70% of their children had Medicaid/SCHIP or no insurance. Most respondents remembered receiving the Bright Beginnings materials and rated these materials as 'very useful' with information about reading and games to stimulate development ranked most highly. Sixty-five percent of parents reported that they read more to their children because of what they learned from the Bright Beginnings materials. The table below shows the frequency that parents reported doing different TRPP behaviors with their children in a typical week.

	Not at all	1-2 times	3-5 times	More often	Don't
Play make-believe with child	24%	16%	27%	31%	2%
Point out or introduce new words	17%	9%	17%	56%	1%
In picture books, point to pictures and describe them to child	14%	11%	22%	52%	1%
Point to things, name them, and talk with child	12%	8%	18%	61%	1%

This survey study indicates that parents see value in the Bright Beginnings materials and suggests that parents may change their behaviors based on information from the Bright Beginnings materials. It also shows that there is room for improvement, since more than 25% of parents engage in development promoting behaviors fewer than 3 times per week.

4c. Development and pilot test of Bright Beginnings mobile app (BB app)

In July 2013, we held 3 focus groups with a total of 14 parents of 12-18 month old children to gauge their reaction to, anticipate use of, and develop attractive features for a BB app. All participants used smart phones and 5 used tablets. Most used cell phones for several activities including texting, and posting pictures, comments, and "likes" on social media. Parents reacted positively to the concept of having an app to facilitate engagement with their children and requested that the app have a moderate number of postings, opportunities to share pictures and comments, and opportunities to find information to improve their child's development.

We then developed a prototype of our BB app with two main features: text messages and social media. The BB2.0 app was designed to allow users a single place to access information, link to videos, photos and other resources, and social support from other parents with children of similar ages. We created Spanish and English versions of the app and populated it with one month's worth of content, including 26 text messages and 63 Facebook posts.

In December 2013, we enrolled 78 parents of children aged 12-18 months in a pilot study to beta-test the BB prototype. The parents were recruited from the Child Health Clinic at Children's Hospital Colorado; 18% were African American, 8% multiracial, 63% Hispanic/Latino, and 24% white. Only 33% were high school graduates; 62% had children with Medicaid. Nearly two thirds (60%) spoke a language other than English at home and 38% were single parents. Eighty-six percent were "smart" cell phone users and 29% used a tablet. Those who used neither a phone nor tablet (n=3) viewed social media content only through a home computer.

Parents completed a baseline assessment of their engagement with their children, then downloaded the BB app prototype into their smartphones, and subsequently were able to review any content pushed to them through the app. Three-quarters downloaded the English version of the app and the remainder the Spanish app. With only 20 Spanish speakers utilizing the app, we couldn't document engagement with the social media elements for this group. However, use statistics for the users of the English app show that 48% of the posts got "likes" from the viewers and 12% of the posts generated comments from users.

At one-month post enrollment, parents were asked to complete the assessment of

engagement with their children a second time. We have complete data from 80% of those enrolled (n=62). We found increases in the frequency of daily reading (79% to 85%, p=0.05), sharing Nursery Rhymes (66% to 82%, p=0.07), and praising children (74% to 86%, p=0.002). In summary, our pilot work on BB2.0 to date reveals that **we can successfully recruit, enroll, and engage parents of children at risk for developmental delays**. We completed assessments of their parenting behaviors and documented changes in those behaviors with 80% of parents at one-month follow up. While we did not have a control group to address potential bias, we did observe improvements in some key behaviors linked to improvements in child development.

4d. The Text for Child Safety (TCS) Intervention

Several prior studies have evaluated the efficacy of anticipatory guidance interventions on child safety, with or without the provision/installation of safety devices.[49-55] The TCS intervention incorporates written child safety material from the AAP and other organizations such as SafeKids. Safety topics focus on the home and car environments, specific for children ages 1-4 years. Information provided helps families determine injury risks in these environments and promotes prevention practices to decrease these risks.[56-57] Multiple unintentional injury categories are covered in the TCS program – car safety, burn protection, falls, poisoning, suffocation and drowning – as these have a significant public health burden and have known countermeasures. Both English and Spanish versions of TCS are available.

4e. The Case for Mobile Technology Interventions for Injury Prevention

Mobile technology is a rapidly growing field, and use of this innovative approach is increasing within health care. Prevention interventions that utilize text messages to provide anticipatory guidance and reminders have been effective at increasing safety behaviors. Additionally, systematic reviews have found "strong evidence to supports the value of integrating text-messaging interventions into public health practice."[58] To date, however, there has been little incorporation of the use of text messages for child safety. Our TCS intervention will use a publically-available evidence-based injury prevention information and further expand application of this information by using mobile technology in the form of text messages. The population in the control arm will receive the TCS intervention in both written format and text messages which were derived from nationally espoused safety organizations and other safety programs. [55-57]

5.**PROJECT PARTNERS:**

Bright by Three (BB3) Nonprofit and Primary Care Clinics: **BB3** works directly with parents/caregivers to stimulate children's development during the critical first three years of life. Since BB3's inception, its programs have reached more than 200,000 families about 75% of whom are considered vulnerable. The program has evolved over nearly 20 years of implementation, guided by input from early childhood development experts and informed by experiences with parents/caregivers of young children. The **Child Health Clinic** at Children's Hospital Colorado and the three **Rocky Mountain Youth Clinics** are located in a large, urban area in and around Denver, Colorado and serve mainly low-income and minority families.

- *Any participant information will be collected only after consent has been obtained.*
- *The clinics' staff and administration will not be engaged in the research. All research activities will be performed solely by the UCD research team.*

6.METHODS:

6.1 Study Overview: Three Study Phases

The proposed study will be conducted in 2 phases over 3 years with most time spent on study implementation and data collection. We will recruit 10 to 20 parents of 1 to 4 year old children to serve on a parent advisory board (PAB) that will meet throughout the project. PAB terms will vary from 1 to 3 years to facilitate continuity and respond to variability in commitment. PAB members will receive $50 stipends to attend quarterly meetings. They will offer guidance on program development, implementation, and evaluation.

6.2 Phase 1: Study Planning (Months 1 to 6):

In the first 6 months of the project, we will finalize recruitment protocols, develop recruitment materials in English and Spanish, complete all requirements and receive approval for protection of human subjects, build our study database, hire and train additional community members required to conduct the annual home visits for the BB3 and Injury Prevention interventions, and expand and test the content of the BB3 app.

Collaborate with Primary Care Clinics and Bright Beginnings Staff

We will continue to collaborate with the Child Health Clinic and Rocky Mountain Youth Clinics to identify recruitment champions in each clinic, develop protocols to recruit patients, and develop plans for dissemination of our research findings to their patient populations. In addition, we will continue our close collaboration with BB3 staff to hire and train CHWs to conduct the annual home visits for the BB3 intervention.

Iterative Refinement of BB3 App

We will engage the PAB to view elements of the current app with messages and social media features. PAB members will be guided to a bulletin board and asked to respond to queries to identify what they like and dislike about specific elements of an app, such as short video vignettes; ideas for praising children; posting successes; quizzes to help parents understand the benefits associated with increased engagement.

We will incorporate PAB feedback in ongoing refinement of the app to ensure it functions as intended. We will load a beta-version of the app on their phones and specifically track what they engage with and any problems with navigation and access within the app, by documenting their "click-trail" (where they go within the app) and time spent on each activity. For each activity there will be a database to store information, e.g. if there is a video element, we will track whether users clicked on each video and how much time they spent watching; if there is a logging element, we will collect data input by users on the number of times they praised their children; read to them, etc. We will address problems with functionality iteratively, resolving each as it

arises and releasing updates of the app. We will conduct additional beta-testing of the BB3 app with our target population as described in a previously approved IRB protocol #15-1342.

6.3 Phase 2: Study Implementation and Data Collection (Months 7 to 36):

Study Population, Recruitment, and Randomization

We will recruit 200 English or Spanish-speaking parents of 10 to 15 month old children and their 200 children (secondary subjects) being seen for a well-child check at the Child Health Clinic and the Rocky Mountain Youth Clinic--Aurora. All together, these clinics saw approximately 5,000 children for 12 to 15 month well child checks in 2013, so we expect to successfully recruit all 200 parents and 200 children (secondary subjects) during the year recruitment period. Research Assistants (RAs) will recruit participants in the clinics. A set of screening questions will be given to each parent by the RA for potential participation using a survey developed in RedCap (See "Screening Questions Phase 2" document). Parents will be provided a $10 gift card for completing the survey in the clinic. The study team will explain the study to eligible parents, obtain verbal consent, and arrange the first home visit for receipt of the intervention and baseline measures. If we are unable to schedule a home visit at clinic at the end of the enrollment process, the study team will arrange a home visit with consented families within one month of the clinic visit when they were recruited. We will use a protocol that includes multiple attempts to contact on different days and at different times of day.

Randomization will be at the level of the individual/family and will be generated separately for English and Spanish speaking families prior to study initiation by the project statistician using the Plan Procedure in SAS. Following enrollment, families will be assigned to one of the study arms using the pre-specified randomization schedule.

6.4 Eligibility Criteria:

Eligibility criteria include low-income (based on insurance status of child being Medicaid or CHIP), lower educational level (less than college level education) parents of 12 to 15 month old children from the Rocky Mountain Youth Clinic and the Child Health Clinic who speak either English or Spanish or both and their 12-15 month old toddlers.

Exclusion criteria include:

- Parents with children born prior to 36 weeks gestation (premature infants)
- Children with chronic conditions known to affect neurodevelopment, such as trisomy 21, or children who have a positive screen on the Children with Special Health Care Needs screener [57]
- Parents who have already participated in the BB3 program
- Parents without access to a smart phone
- Parents who cannot read or converse in either English or Spanish

6.5 Study Arms:

Bright by Three (BB3) Intervention

BB3 includes written materials tailored for parents of children 10 to 24 months and 24 to 36 months. These materials are delivered to parents through an annual home visit when the

child is about 1 year and 2 years old. The 12 to 24 month written materials and visit focus on language and the importance of early developmental screenings for hearing, vision, and language delay. Materials for this program are based on the research of the Abecedarian Project (Learning Games), Hart and Risley (Language Power), and Whitehurst (Dialogic Reading). The 24 to 36 month written materials and visit emphasize health, safety, developmental milestones, engaging in conversation, language acquisition, the importance of playing and daily physical activity, dialogic reading, effective and positive discipline methods, and games/activities to stimulate healthy development. The home visits will be conducted by trained community health workers (CHWs) who are paid $50 per completed visit. These CHWs will be recruited, trained, and managed in collaboration with the BB3 nonprofit.

In addition to the annual home visit and written materials, the BB3 intervention combines both text messaging and access to social media in a single app that will be downloaded on user phones. Whenever there is new content in the app (e.g. text message or new posting on Facebook) a notification or "badge" will appear to alert users to the new material. We have worked with speech therapists and pediatricians with expertise in early child development to create a library of app content that is medically accurate and engaging. Content is amenable to change based on user feedback, but will generally have a structure to support a combination of uni-directional and bi-directional text messages tailored to child age and social support available through Facebook. During the two year intervention period, we will send 3 text messages per week that are tailored to the child age, so will contain information most relevant for that age regarding TRPP behaviors. Messages will prompt participants to get more information and share their experiences via Facebook. We will maintain the Facebook page and post at least daily during the 2 year intervention period. We will create subgroups within Facebook targeting age subgroups—e.g. those aged 12- 15 months, 16-18 months. We can moderate discussions within each subgroup on topics relevant to each age. However, a “main” English and Spanish BB3 page will be available to all in the BB3 so they can benefit from a larger community to share photos, post videos, and give general social support in child engagement. The text messages and Facebook content have been translated into Spanish by native Spanish speakers. Finally the BB3 app includes a ‘gamification’ component that allows users to set goals and earn points by logging minutes of reading and completing activity ‘challenges’, such as playing a game of peek-a-boo with their child. Once users have earned set numbers of points, they will receive ‘badges’ that they can share on Facebook or via other social media sites.

Text for Child Safety (TCS) Injury Prevention Intervention

The TCS intervention will provide an evidence-based health intervention that is parallel in theoretical framework, mode of intervention, and in dose to the BB3 intervention. The control intervention will be provided a booklet of written safety material (English or Spanish) from nationally espoused organizations.[56,5]

TCS participants will also receive safety text messages two to three times per week which have been derived and modified fromnationally espoused safety organizations and other safety programs.[55-57] These text messages will provide safety strategies for injury risks based on the child’s age and developmental stage.

Study Flow

Families will be recruited, consented, and randomized as described above. Every home visit will be completed by two members of the study team to help ensure the safety and comfort of the study team members and participants.

Table 1. Overview of timeline for data collection and intervention delivery

	T1 (12 to 15 months old)	Maintenance	T2 (24 to 27 months old)	Maintenance
BB3	Visit 1—TRPP and child development measures Visit 2—injury prevention measures + BB3 intervention	BB3 'app' + contact info update	Visit 1—TRPP and child development measures —injury prevention measures + (BB3 'booster' intervention)	BB3 'app' + contact info update
TCS	Visit 1—TRPP and child development measures Visit 2—injury prevention measures + TCS intervention	safety text messages + contact info update	Visit 1—TRPP and child development measures Visit 2—injury prevention measures + TCS 'booster' intervention	safety text messages + contact info update

T1—Baseline visit and intervention delivery (when child is 10 to 15 months of age)

For all consented parents/families in the BB3 and the TCS intervention arms, 2 initial home visits will be arranged by the study team—the first (about 45 minutes) for collecting baseline measures related to parental talking, reading, playing, and praise (TRPP) behaviors and child socio-emotional and language development, and the second (about 45 to 60 minutes) for delivering either the BB3 or TCS intervention and collecting injury prevention measures. See Table 2 for a description of the study measures and the timing of when each measure will be collected. Families will receive $30 for completion of the first home visit and $40 for completion of the second home visit. If a family chooses to have one, longer baseline visit (about 1.5 hours) rather than two shorter visits, they will receive $70 upon completion of that visit.

For families assigned to the BB3 intervention, the study team will coordinate these home visits with the CHW who will deliver the BB3 intervention; for families assigned to the TCS intervention, a study team member will deliver the intervention. For the BB3 intervention, the CHW will provide the BB3 written materials and a demonstration of how the materials can be used. They will also help the parent download the BB3 app onto their phone or tablet and demonstrate how the app works. For families assigned to the TCS intervention, the study team member will provide the TCS written material booklet, sign the parent up to receive text messages, and review what to expect with the text messages.

Home Assessment: Parents assigned to both the TCS and BB3 intervention will undergo an in-home/vehicle assessment for safety hazards and receive a real-time report regarding any

hazards identified. This assessment will evaluate for presence and/or installation of appropriate prevention measures for the 6 broad injury categories including:

- Motor vehicle occupancy: Appropriate size/location of child restraint devices (if available/applicable)
- Drowning: pool (4 sided fence); access to other standing water sources
- Fire/burn: hot water temperature, smoke alarms, access to cooking appliances/cords
- Suffocation: easy access choking hazards; cords
- Falls: stair gates, window guards decks
- Poisoning: location of household medicines/chemicals; cupboard locks; carbon monoxide monitor; posting poison control numbers
- Posting of first Aid/CPR information and clinic numbers
- Firearms and sharps

Parental Survey: Parents of both groups will complete questionnaires regarding:

- Prior injury experiences and injury prevention education
- Current safety practices
- MV occupant: CRD frequency of use; CRD ever in MVC; leaving children in car
- Drowning: supervision around pools, baths; turning over exterior buckets
- Fire/burn: hot water temperature setting, smoke alarm testing; supervision around cooking appliances/cords
- Suffocation: supervision around choking hazards; cords
- Falls: supervision around heights (changing tables); stairs; windows; decks
- Firearms (unlocked/loaded) and sharps
- Knowledge of poison control numbers, clinic numbers, First Aid/CPR
- Child injuries during the year
- Attitudes/beliefs about safety practices and competency to apply these safety practices

If a family is not able to complete the series of home visits, the study team will attempt to contact the enrolled parent by phone and complete the parent report measures by phone. Parents who do not complete the home visits but complete the parent report measures by phone will receive a $40 gift card.

T2—2 year old follow up visit and 'Booster' intervention (when enrolled child is 24 to 27 months of age)

Similar to the process described above for the baseline intervention and data collection, all enrolled parents/families will receive a 2 year old follow up visit when the enrolled child is 24 to 27 months of age to collect follow up study measures and deliver a 'booster' dose of either the BB3 or TCS intervention. Families will receive $50 for completing the visit. If a family is not able to complete the 2 year follow up home visits, the study team will attempt to contact the enrolled parent by phone and complete the parent report measures by phone. Parents who do not complete the home visits but complete the parent report measures by phone will receive a $40 gift card.

'Maintenance' Phase (time between home visits)

Two times each year, between home visits, we will ask parents to complete a brief online, mailed, or phone survey updating their contact information. They will not receive an incentive for this survey. We will also use methods known to help retain participants in a

longitudinal study including sending birthday and holiday cards.

Families who participate in all of the home visits for intervention delivery and data collection over the 2 year period will receive a total of $130 ($80 in Year 1 + $50 in Year 2).

Data Collection and Outcomes for Specific Aim 1 (BB3), Specific Aim 4 (TCS), and Specific Aim 6 (TCS):

Table 2. Primary and Secondary Outcomes, Data Sources, and Data Collection Methods

Data Source	**Data Collection Tool/Method**	**Outcome**
Parent survey at T1 and T2	Survey developed by study team based on the Theories of Planned Behavior and Social Cognitive Theory using measures on attitudes, norms, self-efficacy and intentions validated from other research as a template	Parental attitudes, norms, self-efficacy, and intentions toward target behaviors (talking, reading, playing, praise)
Parent reported measure at T1 and T2	Stim-Q (at ages 1, 2, 3, and 4) completed by parent at home visit, or, if home visit not possible, by telephone interview	Parental behaviors
Parent reported measure at T1 and T2	Parenting Stress Index, short form; completed by parent at home visit or via telephone interview	Parents' positive regard for child
Parent reported measure at T1 and T2	MacArthur-Bates CDI short form (at ages 1 and 2) completed by parent at home visit or via telephone interview	Child language development
Parent reported measure at T1, and T2	Survey regarding prior injury prevention education, current safety practices, knowledge of poison control numbers/clinic numbers/CPR/First Aid, report of child injuries during the past year, attitudes/beliefs about safety practices	Safety knowledge attitudes/beliefs, self-reported competency of families, self-reported child injuries

Home assessment completed by trained RA at T1, and T2	Motor vehicle occupancy: Appropriate size/location of child restraint devices (if available/applicable) Drowning: pool (4 sided fence); access to other standing water (buckets, bathtubs, toilet, etc) Fire/burn: hot water temperature setting, smoke alarm (function); access to cooking appliances/cords Suffocation: easy access choking hazards (eg. Items <quarter <3 feet off the ground); cords Falls: stair gates / window guards/ decks Poisoning: location of household products/medicine/marijuana; cupboard locks; CO monitor; posting poison control numbers Posting of first Aid/CPR information and clinic numbers Firearms and sharps	Presence of child safety hazards in the home and car environment
Caregiver Adverse Childhood Experience (ACE) Survey, T1	Paper form that lists the ACES and asks respondent to give a number; ONLY number gets entered into REDCap.	Guideline to learn about caregiver adverse childhood experience.
Electronic Medical Record review completed by trained RA at T2	Injury-related diagnostic codes and E-codes Disposition Date and location of visits associated with diagnostic codes	Medically-attended injuries

Validated measures used to assess parent behavior and child development (BB3): **The Stim-Q** is a reliable and valid of the cognitive stimulation provided in the home for children between 5 months and 6 years old. It can be completed by a parent in English or Spanish in about 20 minutes and has been used in several studies of interventions to support early childhood development.[21,22,62] **The Parenting Stress Index** has been validated with diverse populations to identify dysfunctional parent-child systems in families with infants to 10 year old children, can be completed by a parent in English or Spanish in about 20 minutes, and has been used in hundreds of studies related to early childhood development.[61-64] **The MacArthur-Bates Communicative Development Inventories (CDI)**—Words and Gestures, Words and Sentences, and CDI-III forms are norm- referenced measures of children's language development that can be completed by a parent in English or Spanish in about 20 minutes for children 8 through 37 months of age.[65]

Our **primary outcomes** are: 1) change in parental behavior based on the Stim-Q and 2) change in children's language development based on the CDI. Our **secondary outcomes** are: 1) parental attitudes, norms, self-efficacy, and intentions toward TRPP behaviors measured by a survey similar to the one used in our pilot study of BB2.0; 2) parental positive regard for their children measured by the Parenting Stress Index.

Measures used to assess the presence of child safety hazards in the home and car environment and parent safety knowledge and self-efficacy (TCS): The **Home Safety Survey** was developed using modified measures and identified hazards in validated home safety studies.[53,69,71] Surveys

are administered by trained research assistants to quantify in-home/car injury hazards within pre-defined high risk injury mechanisms for participant population's age/development. Such mechanisms include but are not limited to: falls, drowning, poisoning, suffocation, motor vehicle injuries and burns. **Parent Home Injury Surveys** were developed using a working group of injury experts and piloted by the PAB in both English and Spanish.

Independent and Mediating Variables (both BB3 and TCS):
Family demographics, presence of special health care needs, and receipt of additional home, clinic, or center- based services that support development will be measured at baseline (T1) and annual follow-up at 2 years of age (T2) using questions from the National Surveys of Children's Health and Children with Special Health Care Needs.[59,70] Primary caregiver depression will be measured at T1 and T2 using the PHQ-9[73] and level of social support will be measured using the Perceived Social Support Family and Friends scales[74]. Finally, parental Adverse Childhood Experiences (ACES) will be measured at T1 only using a measure created by the Center for Youth Wellness[73]. This measure does not ask parents to identify specific adverse experiences but, rather, provides them with a list of ACES and asks them to provide a number indicating the number of different ACEs they've experienced.
Health literacy will be measured by the Newest Vital Sign (NVS), a validated 6-item literacy test based on the ability to read and apply information from a nutrition label [76-80]. It was tested in samples of English- and Spanish-speaking primary care patients in the southwestern United States and has been shown to be a reliable and accurate measure of literacy, with particularly high sensitivity for detecting persons with limited literacy. It is available in both English and Spanish and can be administered in approximately 3 minutes.

<u>Data Collection and Outcomes for Specific Aim 2 (BB3):</u>
Cost Measures
We will collect data on costs associated with the implementation of BB3: (1) expenditures associated with employing CHWs and other staff who conduct the annual home visit (wages and benefits; recruitment and hiring); (2) expenditures associated with the training and supervision of CHWs who conduct the annual visit (wages and benefits of supervisors; training costs); (3) facility costs associated with the program (facility overhead, office furnishings, computers and other equipment); (4) office support costs (office supplies, transportation); and
(5) cost of printing the picture book and reproducing written materials for distribution to families.

We will also collect data on expenditures associated with the maintenance of the mobile technology including (1) expenditures related to employing staff to develop and maintain Facebook and text message content (wages and benefits; recruitment and hiring); (2) expenditures related to employing staff to moderate Facebook pages and manage bi-directional texts (wages and benefits; recruitment and hiring); and (3) text messaging charges.

Data Collection Protocol
All cost measures will be obtained from administrative records. Employment-related expenditures such as wages and benefits, travel expenses, and office supply purchases are

routinely recorded. Care will be taken instruct administrators responsible for the maintenance of financial records to classify expenditures according to the categories specified above.

Data Collection and Outcomes for Specific Aim 3:
Assessment of Barriers and Facilitators to Successful BB3 Program Implementation

The RE-AIM framework was designed to guide evaluation of interventions with a pragmatic perspective that keeps future dissemination and implementation in mind.[72,73] *Reach* refers to the number and characteristics of individuals who participate in an intervention. *Effectiveness* refers to the impact of the intervention on outcomes, including unintended or negative outcomes. *Adoption* describes the number and characteristics of settings, such as primary care clinics, that identify participants and provide the intervention. *Implementation* describes fidelity to and cost of the intervention. *Maintenance* at the individual level describes maintenance of behavior change due to the intervention at least 6 months after the intervention has ended.

We will use some elements of the RE-AIM framework to guide our evaluation of program implementation.
We will assess **reach** by determining the proportions and characteristics of eligible children/families who are referred from clinics, successfully contacted, and receive the initial home visit at 1 year old and follow up home visit at 2 years. We will assess **implementation** using a cost analysis (as described above for Aim 2) and key informant interviews. We will conduct in-depth, semi-structured interviews with at least 2 support staff members and 2 physicians from each of the 4 primary care clinics; the Executive Director, Chief Operating Officer, and Volunteer Coordinator at the BB program; and at least 3 CHWs hired to deliver the BB3 intervention. In concordance with established qualitative research methods, trained interviewers will use an interview guide to ask a combination of broad, open-ended questions and focused questions eliciting information about changes made by clinics and program staff during study implementation and about barriers and facilitators to implementation of the BB program. Since these key informants will have equal familiarity with the BB3 program, we will ask them general and specific questions about each of the interventions. The study team has used this methodology in many previous studies. The interviewer will take detailed notes, and two recorders will be used to record verbatim dialogue. We will assess **effectiveness** and **individual-level maintenance** of behavior change as described above for Aim 1. Focus groups with parents, described in detail below, will be used to identify negative or unintended consequences of the BB3 intervention.

Assessment of Parents' Engagement with the BB3 Program and BB3 App
To identify barriers and facilitators to engagement of families with BB3, we will conduct English and Spanish-speaking focus groups of parents who received the BB3 intervention, parents who received the injury prevention intervention (4 groups). Focus groups will be conducted by a trained focus group facilitator with a co-moderator using a semi-structured format. A focus group guide will be developed and pilot-tested prior to use with study subjects. Incentives to participate will be provided. Focus groups among parents who participated in the study will

concentrate on the following content: positive and negative opinions about receiving home visits, the content of the home visits, and use of CHWs to deliver the home visits; use of the BB3 written materials; and barriers and facilitators to implementing recommended TRPP behaviors. Focus groups among parents who did not participate in the study will focus on reasons for not participating.

To evaluate the effectiveness of the Community Health Workers explanations and guidance of the BB3 app, we will conduct English and Spanish-speaking key informant phone interviews with parents who received the BB3 intervention. The phone interviews will be conducted by Professional Research Assistants and a key informant script will be used. Incentives to participate will be provided. The interviews will focus on positive and negative opinions about how the CHW explained how to use the BB3 app, the participants' experience downloading and using the app, and their experience working with the CHW during the home visits. The phone interviews will be recorded. Finally, CHW will also complete a demographics survey which will include questions about their technology use.

We will measure parents' receipt of text messages, viewing the Facebook page, and posting content on the Facebook page. While most text messages will be unidirectional, at least one message each week will be bi-directional, seeking responses from participants to a quiz or question. We will store responses as one indicator of engagement. Additionally, Facebook stores analytic data to document exposure to each message and specific responses to each message (whether participants "like" a message or "share" a message—the former an indicator of having read a message, and the latter indicating both reading and forwarding it to a member of their social network). We will also document whenever participants take initiative to post a response or new message. We will track posts, responses to messages by message type and content and assess differences in engagement by both of these variables and demographics.

Sample Size and Statistical Power

We will enroll 175 subjects per arm. If the attrition is about 40% (our goal is to have much lower attrition), a sample size of 100 per arm will provide 80% power to detect a 0.4 SD difference in outcomes between any two groups. This translates to a 1.72 point difference in Stim-Q scores, a 1.58 point difference in CDI scores, and a 5.6 point difference in E/ROWPVT scores. If the attrition is 15%, a sample size of 150 per arm will provide 80% power to detect a 0.33 SD difference (Stim-Q 1.42 points, CDI 1.3 points, and E/ROWPVT 4.62 points). These differences are similar to differences found in previous studies of the ROR intervention which found a 1 to1.6 point difference in the Stim-Q, 7 to15 point difference in the CDI, and 3 to 9 point difference in the E/ROWPVT.[21,22,65]

7. DATA SAFETY AND SECURITY

A number of measures will be undertaken to ensure that participants' confidentiality is maintained and that data are secure. These include:

1. Study activities involving human subjects will not begin until approval has been grated from

2. Each participant will be assigned a randomly generated study ID. Other than one key that links participants to their study ID, all paper and electronic documents will be identified ONLY by the study ID.

3. Any paper-based study data that contain participant personal health information (PHI) will be stored in secure, locked areas at UCD. Only authorized personnel will have access to this data.
4. All computerized study data will be password protected and accessible to the study PIs and authorized analytic staff. All data are stored behind secure, https:// data firewalls.
5. Participants' PHI will not be disclosed in any reports or publications, nor will data be presented in such a way that the identity of individual participants can be inferred.
6. Online Data Storage: The majority of data will be housed on Research Electronic Data Capture (REDCap), a secure site for online data collection that is HIPAA compliant.

   Text Messaging Data Storage for the TCS intervention: We will use a third party SMS Gateway for message delivery called Salesforce. Salesforce uses a multi-layered approach to protect key information, constantly monitoring and improving the application, systems, and processes to meet security challenges. Users will be identified in the system only by a unique ID number and their telephone number. Links to ID and identifying information (Name, age, email, password, username, cell phone number) will be in a separate file stored on our secure server behind University firewalls. Text messages will not have identifiers and all of text messages will be outbound.
7. Data Storage for the BB3 app: Development and Informatics Service Center (DISC) follows operational, administrative and technical controls to ensure the security of data throughout its lifecycle. The data center employs a full-time IT Security Administrator to ensure best possible compliance to the National Institute of Science and Technology (NIST) SP800-53 security controls. The DISC has the ability to secure data from both online and physical sources. Access controls are employed individually to each server to ensure only those with authorized access can do so. Access can be restricted with virtual desktops to ensure data is kept only on the server and saved to other locations. Databases are restricted to their server environment and never copied to shared resources. The BB3 application is hosted in the DISC's HIPAA compliant data center. The Data Center also adheres to the federal NIST Special Publication 800-53 rev. 3 controls for security and compliance.
8. All data collected from participants will be provided to researchers in de-identified form, with all personally identifying information removed. Data that are provided to researchers is encrypted if it is transmitted across the Internet. At the end of the research study, all data are permanently de-identified for archive and distribution to other researchers, according to the schedule established by COMIRB.
9. All investigators and staff have completed the CITI Basic Course and CITI Health Information Privacy and Security (HIPS) Course.
10. User passwords will be protected with a unique one-way salted hash using bcrypt. All network traffic between the app and the back end will be over SSL (Secure Sockets Layer) - using a UC Denver provided SSL certificate. Authentication between the app and back end will be implemented following a token-based authentication pattern whereby untrusted devices (smart phones accessing the BB3 App) are granted a unique, random, expiring token in exchange for a

user's login credentials. All subsequent requests from the app must include this token, or be rejected. Upon expiration of the token a user will again be prompted for their login credentials to obtain a new token.

8. POTENTIAL PROBLEMS AND ALTERNATIVE STRATEGIES

Recruitment of 200 parents and 200 children (secondary subjects) is critical to the success of our study. To ensure successful recruitment, we have engaged 2 primary care clinics that see about 5,000 children/families in our target population each year, planned for a one year recruitment period, and budgeted for appropriate incentives. If we are behind target for recruitment, we will engage other sites, such as WIC (Women, Infants, and Children program) offices that serve our target population and work with the existing clinics to change our recruitment methods. Retention can be an issue, particularly among low-income and minority families who may have more mobility and changes in contact information or disconnected phone numbers. We will use methods to increase retention including obtaining multiple forms of contact, making frequent contacts, and providing incentives with each visit. If families move out of state or are resistant to participating in a home visit, we can collect the majority of our measures via telephone. While we aim to have less than 40% attrition to minimize bias, our power calculations suggest that we can still identify significant differences between groups for our primary outcomes if 40% attrition does occur. The field of mobile technology and apps is changing rapidly, so we are likely to encounter the need to adapt the BB3 app. The BB3 app was built on a flexible platform, and our study team and resources, including Dr. Bull's 'Agile m-Health Laboratory', will enable us to adapt as needed. Finally, we anticipate that we could have difficulty reaching parents and completing focus groups for Aim 3. To address this problem, we will leverage our existing partnerships with the clinics and BB3 nonprofit to support recruitment and have budgeted for incentives.

9. PROTECTION OF HUMAN SUBJECTS

Risks to the Subjects

a. Human Subjects Involvement and Characteristics

The study will target 2 groups: low-income and minority English or Spanish-speaking parents and their children. We will recruit participants (parents and children) from the Rocky Mountain Youth Clinic--Aurora and the Child Health Clinic. These clinics see an estimated 5,000 twelve to fifteen month old children for well child checks in a typical year. We will enroll 200 parents and

200 of their children (secondary subjects) between the ages of 12 and 15 months who are seen at the Rocky Mountain Youth clinic--Aurora or Child Health Clinic.

b. Inclusion and Exclusion Criteria

English and Spanish-speaking parents and their children aged 12 to 15 months at the time of

recruitment will be included in our study. The exclusion criteria are: 1) children born prior to 32 weeks gestation, 2) children with chronic conditions known to affect neurodevelopment, such as trisomy 3) children who are identified as having special health care needs based on the Children with Special Health Care Needs screener, and 4) parents who report having already participated in the BB3 program.

c. Data Sources

The study team will identify potential participants before or after their visits at the Rocky Mountain Youth Clinic-Aurora or Child Health Clinic, assess their eligibility using a brief screening survey, and conduct the consent process. Consenting families will receive a home visit during which measures on paper or via the online REDCap database will be collected as described above. Additional home visits for data collection will occur when the enrolled child is around 2 years and 3 years old. At the conclusion of the study, we will also conduct key informant interviews and focus groups. In addition, we will conduct an electronic medical record review (as described in more detail above) to identify medically attended injuries. Data extracted from the enrolled children's EMR records will be recorded and stored in the REDCap database. Additional data sources will include the BB3 app database and BB3 Facebook page. These data will be stored on a secure, password-protected server at UCD that is accessible only to the study team.

d. Potential Risks

Potential risks posed by this investigation are mainly psychological or related to loss of privacy. One risk is the potential for study participants to misuse the Facebook group or feel discomfort in sharing information during the home visit data collection process or key informant interviews and focus groups. The research staff will carefully monitor the Facebook page to filter abusive language and place users on "moderation" if they continuously break the website rules. The research staff and CHWs will be trained to respond to any participants' discomfort about any questions during the data collection process in a sensitive manner. Participants will be reminded that they are not required to answer any question they prefer not to answer. Safety risks may be identified during the home safety assessment described in more detail above. Families will be notified at the time of the home safety assessment if any safety risks are identified.

Adequacy of Protection Against Risks

a. Recruitment and Informed Consent

Participants will be recruited from the Child Health Clinic and the Rocky Mountain Youth Clinic--Aurora. The strictly voluntary nature of the study will be clearly stated in the recruitment materials and in the consent form and the study team members will be reminded to reinforce this message throughout the data collection process.

There are no significant personal risks associated with any of these procedures. All data will be securely stored at UCD or in the REDCap database. All of the data will be password protected, and accessible only to authorized research staff members. Individual identities of participants will be kept strictly confidential.

If potential medical problems are identified among participants, research staff will use established guidelines for referral to primary medical care. Research staff has been trained to emphasize the importance of participants contacting their personal or child's physician. If concerns regarding child abuse or an unsafe environment for children arise, research staff will report these concerns to the Colorado Department of Human Services (CDHS) via the local county department of social services (http://www.colorado.gov/cs/Satellite/CDHS-Main/CBON/1251633944381). The research staff and CHWs who will be doing the home visits will be trained to identify and report child abuse and neglect using a training module from the CDHS Child Welfare Training System (http://www.coloradocwts.com/community-training). In addition, all CHWs and research staff will be provided with a list of resources, available in the CHW training manual that they can provide to participants who identify needs outside of the scope of the study (for example, need for assistance with housing or food).

a. Protection Against Risk

Breach of confidentiality: All participant information will be kept strictly confidential through the following steps. First, each participant will be assigned a randomly generated study ID. Second, all study data that contain participant personal health information (PHI) will be stored in secure, locked areas. Only authorized personnel will have access to this data. All computerized study data will be password protected and accessible to the study PIs and authorized analytic staff. All data are stored behind secure, https:// data firewalls. Lastly, participants' PHI will not be disclosed in any reports or publications, nor will data be presented in such a way that the identity of individual participants can be inferred.

Potential Benefits of the Proposed Research to Human Subjects and Others

Individual parents and children will benefit from receiving the BB3 (early childhood development) or TCS (injury prevention) intervention materials. In addition, some individuals may see value in participating and may feel that doing so contributes to scientific knowledge and society as a whole. Society may benefit in the future through a better understanding of the BB3 program and effective methods to encourage parents to talk, read, play, and praise with their children to promote early childhood development. In addition, participants in the TCS injury prevention arm will be exposed to information about safety in the home and information about proper installation of child car seats. Even if these participants do not benefit, the results of this study may benefit children and parents in the future by increasing our knowledge of how to deliver tailored text messages about home and car safety.

Importance of the Knowledge to be Gained

Our proposed investigation will evaluate the effectiveness of the BB3 program augmented with

mobile health technology in changing parental behavior and improving child development; assess and compare the implementation costs of BB3; and identify barriers and facilitators to successful BB3 program implementation. We know that disparities in early childhood development can lead to persistent disparities in adult health and economic success. Interventions to increase children's exposure to parental talking, reading, playing, and praise behaviors can improve their development and reduce disparities**.** Therefore, effective, low-cost and high reach interventions to promote these parental behaviors are needed. We propose to conduct the first study of the effectiveness of linking parents of children at-risk for developmental delay to child development information and skills building activities using a low- cost, easy to use mobile app combined with an annual home visit and evidence-based written materials**.**

Additionally, our study will expand the current safety literature. Specifically, results from our TCS arm will help inform the feasibility and efficacy of using safety text messages in the home environment for child safety. We will assess TCS' efficacy at decreasing the number of safety hazards in the home and car, the number of medically attending injuries, and parental knowledge/self-efficacy of safety strategies.

Data Safety and Monitoring Plan

Dr. Allison, the PI, will have overall responsibility for participant safety monitoring. The risks for this behavioral intervention are minimal. All participants will be regularly reminded via the clinical and research staff to promptly report all adverse events (AE) to the PI or designated study representative.

Because this study is low risk and will involve no specific invasive or medical procedures, we will not convene a Data Safety and Monitoring Board. Given that some study measures assess injury risks, we will convene regular discussions among an injury expert advisory panel (Drs. Cinnamon Dixon, Carol Runyan, and Nancy Weaver) regarding potential safety risks identified and recommended safety countermeasures (i.e. informing family of risks and safety recommendations) in both groups.

10. TIMELINE

	Year 1				Year 2				Year 3			
Tasks/Milestones	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Hiring and training	x											
IRB and register w/ clinicaltrials.gov	x											
BB3 iterative development and testing	x											
Collaboration with Clinics and BB staff	x											
(T1) Enrollment of 12 to 15 month olds and baseline data collection		x	x	x	x							
Intervention implementation (for 1-2 y.o.)		x	x	x	x	x	x	x	x			

(T2) 2 year old evaluation/data collection							x	x	x	x			
Intervention implementation (for y.o.)							x	x	x	x	x	x	
Focus groups and key informant interviews for Aim 3													
Compare effectiveness of BB3 vs TCS													
Describe implementation costs of BB3													
Identify barriers and facilitators to BB3 impementation													
Dissemination of results to key stakeholders								x				x	

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