

A Pilot Study on Cost and Other Implementation Factors Comparing Telehealth and In-Person Therapy Service Delivery Following NICU Discharge

NCT number not yet assigned

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## Study Protocol and Statistical Analysis Plan

### **Participants and setting**

Participants included 20 high-risk parent-infant dyads hospitalized in an urban, level IV NICU. Consecutively eligible dyads from May 2023 to April 2024 were recruited if the infant was hospitalized in the NICU for > 7 days; received a referral for post-NICU physical therapy, occupational therapy, and/or speech-language pathology (or for the state-wide early intervention program) at NICU discharge; was referred to the Baby Bridge program at least 48 hours before NICU discharge; had a chronological age of < 6 months at the time of NICU discharge; and were from a family who spoke English. Infants who lived any distance away from the hospital were enrolled; however, infants who were not going to reside in the state of California following NICU discharge were excluded. Infants were deemed 'high-risk' for developmental challenges if they were recommended by the NICU medical team for therapy. Although we acknowledge that the term "high risk" can refer to high risk of medical complications or high risk of cerebral palsy, we use the term "high risk" to define the infant's need for therapeutic interventions across a multitude of constructs including for language, cognition, self-regulation, sensory, motor, and feeding. A member of the research team attended weekly discharge rounds and reviewed the electronic medical record. Within discharge rounds, communication between the medical team and research team occurred, and the medical team referred infants to the Baby Bridge program through an online referral process in REDCap. The research team then screened and recruited those who were eligible.

Enrolled infants and families were randomized to receive Baby Bridge services either through telehealth or in-person visits. Parent-infant dyads were enrolled at least 2 days before NICU discharge to enable rapport to be established (between the Baby Bridge therapist and family) through a visit to the NICU when possible and via telephone, text or email messaging when an in-person visit was not possible prior to discharge. This first contact was attempted to be in-person in the NICU for both the telehealth and in-person groups. Enrolled infants and families then had a Baby Bridge telehealth or in-person visit scheduled within one week of discharge (depending on their group assignment). Subsequent individual weekly visits were adapted to in-person or telehealth (varying from assigned group) when needed or deemed appropriate (requested by the family or therapist or when an in-person visit was felt to improve the quality of the therapy session). Weekly Baby Bridge programming was conducted until other therapy through the state-wide early intervention program commenced, as in the infant was receiving therapy services as recommended. We also tracked rates of enrollment, rates and reasons for any cancellations, and completion of the program (defined as being seen until community-based early intervention services commenced). Infants were withdrawn if they were transferred to another hospital or if they were readmitted to the hospital and additional contact was not possible or feasible.

### **Sociodemographic and medical data**

Sociodemographic and medical data were collected from the electronic medical record for each dyad enrolled to better understand differences between groups as well as to define sample characteristics. Sociodemographic factors collected included: infant

race, insurance type (public or private), maternal age, number of siblings, home distance from the hospital, and categorization of home residence (urban with <3,000 people per square mile, suburban with between 1,000 and 3,000 people per square mile, or rural with <1,000 people per square mile). Medical factors collected included: estimated gestational age at birth, the primary condition of the infant (congenital anomaly, preterm birth, or neurological condition not related to preterm birth or congenital anomaly), number of days of endotracheal intubation, number of days of hospitalization, and whether or not the infant was orally feeding at time of hospital discharge.

### **In-person group assignment**

For those assigned to the in-person Baby Bridge group, the first visit was scheduled in the home within one week of NICU discharge, and attempts were made to see the infant weekly in the home environment for a one-hour therapy session. Scheduled visits were confirmed with families via text messaging the day before each visit. Visits were rescheduled to telehealth in the event of therapist illness, parent preference or parent/child illness, or distance or therapist schedule limitations. Changes of visits from in-person to telehealth were tracked along with their reasoning.

### **Telehealth group assignment**

For those assigned to the telehealth Baby Bridge group, a first telehealth visit was scheduled within one week of discharge, and weekly telehealth visits were scheduled thereafter. However, parents were informed that in-person visits were an option when needs arise. Adaptations from a telehealth visit to an in-person visit were made in the event of therapist clinical judgment due to the medical complexity or feeding/tonal abnormalities of

the infant and parent preference or rapport building. Visit adaptations were tracked along with the reasoning for them.

### **Implementation outcomes**

We defined measures for this study based on previous implementation research (Lewis et al., 2015; Proctor et al., 2011; Proctor et al., 2009). The primary outcome of interest for this study was cost difference between telehealth and in-person visits of the Baby Bridge program. We also investigated implementation outcomes of adoptability, feasibility, adaptations, and acceptability. Many of the procedures here mirror a previous article on feasibility, which enrolled a different sample to assess the same outcomes in context of telehealth only, whereas this manuscript enables exploration of the differences when comparing to an in-person model.

### **Cost**

Cost is an important factor when determining feasibility of an intervention. When resources are limited, it can aid in choosing one intervention over another. For the purposes of this project, we estimated costs associated with each Baby Bridge visit. We did not assess cost across group assignment, due to the allowed adaptations to each visit type. Cost was defined in relation to the organizational cost of providing Baby Bridge visits and included the time that the therapist spent conducting therapy sessions (billable time), administrative time (documentation, communication with families), driving (for in-person visits), and mileage reimbursement. The total billable and non-billable time that the therapist spent (including therapy session time, administrative time, and drive time) was

multiplied by \$50 per hour, an hourly wage that matches typical rates across the United States and in California (29-1122 *Occupational Therapists*, 2024). Mileage reimbursement was calculated at the \$.67 per mile, the California mileage reimbursement rate for employees (2024 *Updated Mileage Reimbursement Rates for Use of Personal Vehicle and Private Aircraf*, 2024). Further, the number of billable minutes (in evaluation, for therapeutic activities, or therapeutic exercises) were put in context of Current Procedural Terminology (CPT)/Healthcare Common Procedure Coding System (HCPCS) codes and reimbursement amounts for Fee For Service Medi-Cal (California Medicaid) (though we acknowledge this reimbursement rate could differ drastically depending on actual insurance type). This enabled a total amount of reimbursable potential in context of the total cost of programming, with the ability to explore differences across telehealth and in person costs. Because many infants had some adaptations to their assigned type of therapy visit, rather than investigating across assigned groups, we analyzed cost based on actual visit type (telehealth or in person) rather than assigned group type.

### ***Adoptability***

Adoption refers to the uptake of Baby Bridge programming, measured at the organizational and provider level (Proctor et al., 2011). This can include health care professionals' buy-in and support of the program that enables infants and families to receive Baby Bridge services. We tracked the number of infants referred, approached, and enrolled. Adoption was operationalized to include the total number of infants approached versus enrolled (enrollment rate).

### ***Feasibility***

Feasibility is defined as the extent to which Baby Bridge programming can be successfully used or carried out within a given agency or setting (Proctor et al., 2011). To understand the feasibility of Baby Bridge telehealth programming, we captured timing (if the first visit was conducted within one week of discharge); average time from NICU discharge to first Baby Bridge visit); frequency of visits; rate and reasons for any therapy visit cancellations; the completion rates (percentage of enrolled infants who completed programming); and the timing of transition to community-based therapy. Feasibility was defined a priori as all Baby Bridge visits attempted within the first week, infants seen at least 3 visits per month while in the program, and that 80% would be successfully transitioned to early intervention programming.

### ***Adaptations***

Adaptations include intentional changes made to programming (from the way it was intended) in order to enable real-world uptake by aligning the intervention to the context it exists in (Moore et al., 2021). To aid in understanding specific adaptations made to telehealth versus in-person programming, we captured the proportion of visits conducted via telehealth in the telehealth group and proportion of visits that occurred in-person in the in-person group. Reasoning for such adaptations was tracked as described above in the telehealth and in-person assignment sections.

### ***Acceptability***

Acceptability is the perception among stakeholders, specifically the consumers or parents, that the Baby Bridge program is satisfactory. Using Proctor's model (Proctor et al., 2011) as a guide and through adaptation of a previously reported measure of acceptability (Karlsson & Bendtsen, 2005), the Baby Bridge Parent Survey was developed to determine if programming was acceptable to parents. The survey was developed, and five members of the research team added/revised queries to aid in comprehensive collection of perceptions as well as to aid clarity of each question's wording. It went through an iterative process with multiple revisions until no further feedback from team members was received and there was consensus on the inclusion of and the wording of survey questions. The survey took < 5 minutes to complete.

Upon completion of the Baby Bridge program, parents were asked to complete the Baby Bridge Parent Survey to query their perceptions about Baby Bridge programming. Survey questions were loaded into REDCap and administered electronically through a shared link to a REDCap survey. Parents received subject remuneration of \$50 after completing the survey. Parent satisfaction was measured based on a sum (possible range of 0-10) of the following questions from the survey:

1. Were therapy goals achieved through Baby Bridge programming (2=yes, 1=partially, 0=no)
2. How likely would you be to recommend the Baby Bridge program to other NICU parents? (3=definitely will, 2=probably will, 1=probably will not, 0=definitely will not)

3. How likely would you be to use Baby Bridge programming again? (3=definitely will, 2=probably will, 1=probably will not, 0=definitely will not)
4. Was there anything about the Baby Bridge program that you found confusing or complicated? (0=yes, 1=no)
5. Did you experience any challenges with the Baby Bridge program (0=yes, 1=no).

## **Analysis**

A power analysis to determine sample size was not conducted, as this is a pilot study aimed at understanding initial differences across groups while determining variance to aid in future sample size determination for a larger trial. Sociodemographic and medical factors are reported descriptively and differences across groups were investigated using independent samples t-tests and chi-square analysis.

## **Cost**

The cost of in-person visits vs. telehealth visits are reported descriptively. Differences in costs across telehealth and in-person visits were investigated using independent samples t-tests and linear regression models.

## **Adoptability**

Rates of enrollment are reported descriptively but not analyzed between groups, as enrollment occurred prior to group assignment.

## **Feasibility**

We investigated differences across groups (in-person versus telehealth) in whether the first visit occurred within 1 week of NICU discharge, average number of days between NICU discharge until first Baby Bridge visit, frequency of visits, number of therapy visit cancellations, and the completion rates using independent samples t-tests and chi-square analysis.

### ***Adaptations***

The proportion of visits conducted within the assigned group was investigated across groups using independent samples t-tests.

### ***Acceptability***

Satisfaction scores were compared across groups using independent samples t-tests.