

ORI IRB# 00000278

Protocol Version

Official Title: SIBTime: Media-enhanced Technology for Promoting the Behavioral Health and Family Relationships of Typically Developing Young Siblings

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### **Study Protocol**

We conducted a 4-week intervention among 43 parent/child dyads (children were typically developing preschool age siblings of a child with a disability) to assess feasibility of the bilingual SIBTime tool in terms of its usefulness, ease-of-use, cultural appropriateness, and potential for efficacy. The test used a within-subjects pre-post design to detect changes in: parenting and family adjustment, self-efficacy for parenting, parent engagement in target activities with child, usability, and family usage of the technology. We also collected a post-test evaluation of consumer satisfaction and parent recommendations for program modifications.

### **Statistical Analysis Plan**

The evaluation had three main goals: (a) determine whether statistically significant effects were found between T1 (pretest) and T2 (posttest) on the outcome measures; (b) determine the program effect sizes; and (c) determine the parent's reaction to the program and amount of program use. An intent-to-treat analysis using one fully-imputed dataset and paired t- tests were used to determine whether or not there were significant increases in the outcome measures from pretest to posttest. The point-biserial r is provided as a measure of effect sizes with the convention .14 small, .36 medium, and .51 large (Rosenthal & Rosnow, 2008). Examination of descriptive statistics for the user satisfaction items informed on parent's reaction to the program.

### **Power Analysis**

Based on the pre-post within-subject design with 43 student-parent dyads, accounting for 10% attrition, and a two-tailed alpha set to .05, the study would have sufficient statistical power ( $> .80$ ) to detect a medium or larger effect size (Cohen's  $d = .41$ ) for change in the proposed outcomes. We believe that these differences are not so small as to be meaningless to participants, but not so large as to represent unrealistic expectations of changes brought about by the intervention. For ancillary analyses involving correlations the study is powered to detect medium or larger effects ( $r = .38$ ).

## **Informed Consent for SIBTime**

You and your child are invited to participate in a research study to test SIBTime, a mobile app designed to help families support young typically developing brothers and sisters (siblings) of children with disabilities.

The project is led by *Jessie Marquez and Patricia Vadasy, Ph.D.* of Influentes Innovations in Eugene, OR.

After reviewing the study details, please ask any questions you might have before agreeing to participate. **If You Decide to Participate, You will be Asked to:**

The SIBtime study is funded by the National Institute of Minority Health and Health Disparities (grant # [1R43MD015947-01](#)).

The SIBTime study will take place online over 4-weeks.

- First, we will send you an electronic survey to complete. The survey will have questions about demographics, family routines, and parents' confidence about supporting young sibling children.
- Then we will send you a link to download the SIBTime app and simple instructions about how to use it. We will also check in with you by text or phone to see if you need any help with this.
- We'll ask you to use SIBTime app with your young TD child at least three days a week for about 10 minutes.
- The app activities will include 1) Five video storybooks about ways that typically developing (TD) young siblings connect with their parents and families. 2) Five 2-minute audio bedtime reflections that will guide you to recall thoughts and feelings about the time you spend with your child, 3) A chart for tracking your parent-child connection experiences, and 4) a moderated forum for sharing with other parents.
- Each week during the 4-week study, you will receive three reminder texts to use the app and to answer any questions you might have about the app.
- At the end of the 4-week study, we will send you another electronic survey. This one will have questions about family routines, how confident you feel supporting your young (sibling) child, and how satisfied you are with the SIBTime app.

At that point, you will receive \$75 in the form of check or gift card, whichever you prefer.

## **Risks and What Will Be Done to Reduce the Risks**

Here are some risks involved for you and your child as participants:

1. We collect and store names, email addresses, mailing addresses, and phone numbers to communicate with you about the study. Because it is possible that someone who is not authorized could see it, we take these precautions to protect your confidentiality and your information:

1. Any information you give us will be kept strictly confidential. The consent and surveys you complete will be submitted through an encrypted system. We will keep all information in a locked file. We will remove all names from all the information we get from you (except this consent form). An ID# will be assigned to the information you give us, and only authorized staff will have access to the locked file that links your name to your ID#.
2. The mobile app account we set up for you will not have your name on it. We will use a number instead.
3. We have a Certificate of Confidentiality, a legal assurance from the federal government that will help us protect your privacy even if the records are subpoenaed. We will not give information to anyone unless you provide a signed release telling us to do so, or unless we have reason to suspect: 1) abuse, neglect, or endangerment of a child or elder; 2) or that anyone is in immediate danger of seriously hurting himself/herself or someone else. In these situations, we may have to make a report to the appropriate authorities.
4. If the U. S. Department of Health and Human Services (DHHS) audits our research project, they can have access to information about you. However, they cannot report it to the police or use it for any reason besides the audit.
5. A description of this clinical trial will be available on <http://www.ClinicalTrials.gov> . This website will not include information that can identify you. At most, the website will include a summary of the research results. At the very end of the project, we will post a study consent form to the same website. The consent form will not have names on it. You can search this website at any time.

2. You might feel uncomfortable if you are unsure about how to answer questions on the surveys. You will be able to call or text us if you have questions and we will provide support.

## **How We will Use the Data We Collect**

We will not share information about you with others. After we remove all identifiers (names) from the data we collect, the non-identifiable data could be used in publications, future research studies, and/or shared with other researchers without additional informed consent from the subject or the legally authorized representative.

## **Benefits to You and Your Child for Participation**

You and your child could enjoy using the SIBTime app together. You could enjoy being a part of research that supports the educational and health outcomes of young siblings.

## **Your Right to Withdraw from the Study**

Your participation is completely voluntary and private. If you decide to participate, you can stop participating at any time without penalty.

## **Request for more information**

If you have questions about the research at any time, or if you have a visual or other impairment and require this material in another format, please call: Melanie Santiago-Ruiz, Research Assistant (785) 282-4986, 1776 Millrace Dr., Eugene, OR 97403. ORI's TDD number is 800-735-2900

If you have questions about your rights as a research subject, call the Office for the Protection of Human Subjects, Oregon Research Institute, (541) 484-2123. ORI's TDD number is 800-735-2900.

You will be given a copy of this form to keep. Your signature below indicates that you:

- (1) have read and understand the information provided above,
- (2) agree to participate,
- (3) consent to your child's participation,
- (4) may withdraw your consent at any time and stop participating at any time without penalty,
- (5) may withdraw your consent for your child's participation at any time without penalty to you or your child
- (6) have received a copy of this consent form.

Printed Name \_\_\_\_\_

Signature \_\_\_\_\_

Date \_\_\_\_\_