

An Integrative Approach to Improve Child Outcomes Through Research-based Parent and Teacher Interventions

NCT03431545

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SUPPORTING SPROUTS from HOME to SCHOOL

Parental Consent

HSC-MS-15-0841

INVITATION TO TAKE PART

You and your child are being invited to take part in the research project entitled "Supporting Sprouts from Home to School" under the direction of Drs. Ursula Johnson and Beth Van Horne with the Department of Pediatrics at the University of Texas Health Science Center at Houston.

Your decision to take part is voluntary and you may refuse to take part, or choose to stop taking part, at any time. A decision not to take part, or to stop being a part of the research project, will not change the services that are available to you or your child from the University of Texas Health Science Center at Houston.

You may refuse to answer any questions asked or written on any forms. The video recording is done for study purposes only and will not be shared with anyone outside of the research study. Please read the consent form carefully. You will be given a copy of it to keep if you decide to permit your child to take part. This study has been reviewed by the Committee for the Protection of Human Subjects of the University of Texas Health Science Center at Houston as HSC- MS-15-0841.

DESCRIPTION OF THE RESEARCH

Purpose: The purpose of this study is to learn whether a combination of two research-proven programs, a responsive caregiving parenting program and a teacher training program, will have an effect on infants' and toddlers' language, cognitive, social-emotional, and self-regulation skills.

Procedures: Early Head Start schools will be assigned to one of two programs on a random or chance basis (like flipping a coin). That is, it is like pulling names out of a hat – you have an equal chance of being assigned to either program.

If your child's school is randomly assigned to Program 1, your child's classroom will receive developmental information handouts that will help you in your role as a parent as well as a book and a toy for you to use with your child.

If your child's school is randomly assigned to Program 2, your child's teacher will receive training to support the development of children in the classroom. The first six children in your child's class to sign up for participation will receive a family coach. If you are not one of the first six to sign up, you will be placed on a waiting list and may get to participate later in the year. Each participating family will be asked to complete weekly online training sessions. If your child is an infant, there will be 11 weekly sessions. If your child is a toddler, there will be 14 weekly sessions. Each weekly training session will last for approximately 1.5 hours (90 minutes); 45 minutes to complete the online session and 45 minutes to discuss what you have learned with your Family Coach through a video call (e.g., Skype). You will be loaned a device to complete these meetings. You will learn how to be responsive to your child's needs and interests and promote your child's language skills. Also, your Family Coach will provide you with behavior strategies to help your child manage his or her emotions and behavior. To help you learn these new strategies, you will practice them with your child and video the interactions to discuss with your Family Coach during each weekly video call.

In both Programs 1 and 2, you and your child will also take part in two parent/child assessments. During these assessments, we will test your child's communication, problem solving, and regulation skills. We will also video record you and your child interacting together. We will ask you to complete some questionnaires about your thoughts about parenting and your child's behaviors. Each of these assessments visits will take about 1.5 hours and will be in your home – or another

location, if you prefer. They will be scheduled at your convenience. Your child will also be assessed at school two times. The school pre-assessment will occur in the fall and the post assessment will occur in the spring.

TIME COMMITMENT

Families will complete two assessments for 1.5 hours each (total of 3 hours). We will schedule the first one at the beginning of the school year and the second will occur about 15-20 weeks later.

Families randomly assigned to Program 2 will complete two assessments for 1.5 hours each, plus 11 or 14 weekly online training sessions that are 1.5 hours each (total of 20.5 – 25 hours). This will all occur over about 13 – 16 weeks.

BENEFITS

The direct benefits of the study include learning more about your child and his or her needs and skills as you will be given developmental information. Additionally, the information gained from this study will also help parents and professionals working with children to learn how best to support their learning and development.

RISKS/DISCOMFORTS

The risks for you and your child taking part in this study are no greater than those in your everyday life. If you find some questions uncomfortable to answer, please tell us. You can decide not to answer any question, and you are free to stop the visit or interview at any time. If your child becomes tired or frustrated s/he will not be pushed to go beyond his/her abilities. Short breaks are routinely scheduled throughout the assessment. If this occurs, your child will not be pressured to respond and will be allowed to take a break or ask questions. There is also a risk of loss of confidentiality, although we will make every effort to keep your information private.

STUDY WITHDRAWAL

Taking part in this study is voluntary and you or your child may refuse to take part, or may stop taking part, at any time without penalty, loss of benefits, or change in your child's present or future care. If your child is withdrawn from the study, the data collected up to the withdrawal will be kept for the study.

COSTS, REIMBURSEMENTS, AND COMPENSATION

There is no cost for any part of this study. You will be compensated for your time by receiving the following:

- Each family will receive a \$50 debit card for completing the pre-assessment and a \$50 debit card for completing the post-assessment.
- Each family will also receive a book and toy.
- If you are randomly assigned to the Program 2 group, you will also receive up to \$75 on a debit card for participation in the weekly online training sessions.
- You will be issued a UTHHealth ClinCard, which is a debit card that will be updated with funds following completion of each visit. All information is stored in a secure fashion and will be deleted from the system once the study has been completed.
- If you receive payment for taking part in this study, please be informed that you will be asked to complete a W-9 form that will be forwarded to the accounting department as a requirement of the Internal Revenue Service. You will also be issued a 1099-Misc form from this study for tax reporting purposes.

CONFIDENTIALITY

You and your child will not be personally identified in any reports or publications that may result from this study. Any personal information about you that is gathered during this study will remain confidential to every extent of the law. A special number will be used to identify you in the study and only the researchers will know your name. The exception to this confidentiality is that if a member of our staff learns about abuse or neglect of children, or that you are at imminent risk of harm, we are required by law to contact the appropriate agency.

DATA SHARING

You and your child's identification number (not name) and information collected during the assessments will be entered into and stored in a secure electronic database at the University of Texas Health Science Center at Houston. This database

will be shared with the Early Head Start University Partnership Grantees funded by the Administration for Children and Families, who are reviewing video and assessment scores of groups of children enrolled in Early Head Start centers across the country. Your child's name and individual scores will never appear in reports written for this project, including publications written by University of Texas Health Science Center or other Early Head Start University Partnership Grantees.

QUESTIONS

Drs. Ursula Johnson will, at any time, answer any questions concerning this study. Dr. Johnson can be reached at University of Texas Health Science Center at Houston - Children's Learning Institute (713) 500-3767.

SIGNATURES

Sign below only if you understand the information given to you about the research and choose to take part. Make sure that any questions have been answered and that you understand the study. If you have any questions or concerns about your rights as a research participant, call the Committee for the Protection of Human Subjects at (713) 500-9244.

If you decide to take part in this research study, a copy of this signed consent form will be given to you.

Printed Name of Participant _____

Signature of Participant _____ Date: _____

Teacher Name _____ Center Name _____

Using language that is understandable and appropriate, I have discussed this project and the items listed above with the participant and/or his/her authorized representatives.

Printed name of person obtaining consent _____

Signature: _____ Date: _____

CPHS Statement: This study, HSC-MS-15-0841, has been reviewed by the Committee for the Protection of Human Subjects (CPHS) of the University of Texas Health Science Center at Houston. For any questions regarding subjects' rights or to report a research-related injury, call the CPHS at (713) 500-7943.

SUPPORTING SPROUTS

If you have agreed to participate in the study, please fill out this information sheet.

Child's Full Name (please print)

First Name Last Name

Parent's/Guardian's Full Name (please print):

First Name Last Name

Relationship to Child:

☐ Father ☐ Mother ☐ Other Caregiver _____

Parent's/ Guardian's Contact Information:

Home Phone: _____ Cell Phone: _____

Email: _____

Child's Physical Address:

Street Address _____ Apt# _____

City _____ State _____ Zip Code _____

Child's Date of Birth(mm/dd/yyyy): ----- **Child's Gender:** ☐ Male ☐ Female

Child Hispanic or Latino:

- ☐ Yes, Hispanic or Latino
☐ No, not Hispanic or Latino

Child's Race (mark all that apply):

- ☐ American Indian or Alaska Native
☐ Asian
☐ Black or African American
☐ Native Hawaiian or Pacific Islander
☐ White or Caucasian

Language spoken at home (mark all that apply):

☐ English ☐ Spanish ☐ Other: _____

Languages MOST spoken at home:

☐ English ☐ Spanish **(Choose One)**

Alternate Contact Information:

First Name _____ Last Name _____

Home Phone: _____ Cell Phone: _____

Email: _____

1. Which type of internet connection do you have at home?

- ☐ No internet connection
☐ Dial-up or wired broadband
☐ Wireless with AT&T U-verse or Comcast Xfinity
☐ Wireless with Clear Home Internet
☐ Wireless with satellite
☐ Wireless with other _____

2. If you have WIRELESS INTERNET access at home, are you able to watch TV shows, movies, or play games on your computer or tablet device?

- ☐ Yes
☐ No

3. If you use a cell phone or tablet device at home, how is your signal strength?

- ☐ No cell phone or tablet device
☐ Strong (phone calls are *rarely* dropped and *mostly* clear)
☐ Okay (phone calls are *sometimes* dropped and *sometimes* clear)
☐ Poor (phone calls are *frequently* dropped and *rarely* clear)

4. Do you do any of the following? Mark all that apply.

- ☐ Work one job outside of the home
- ☐ Work two or more jobs outside of the home
- ☐ Attend school
- ☐ Travel for long periods of time (e.g., more than two weeks at a time, two or more times a year)

5. Is there a child living in the home receiving free and reduced lunch at school?

- ☐ Yes
- ☐ No

6. What are you interested in learning about from the Supporting Sprouts program? Mark all that apply.

- ☐ Improving child's learning and development
- ☐ Improving play and daily interactions with child
- ☐ Building a positive relationship with child
- ☐ Other _____