

Title: Word Learning in Children with Autism

Study ID: 00140285

Informed Consent Document

NCT03419611

Approval Date: 03/06/2019

INFORMED CONSENT STATEMENT

Multimodal Approach to Word Learning in Children with Autism

KEY INFORMATION

- This project is studying the effects of a multimodal therapy approach to word learning in children with autism.
- Your participation in this research project is completely voluntary.
- Your child's participation will take 30 minutes per session, 5 days per week, for a total of 2.5 hours/week over 4 months.
- You will be asked to do the following procedures: complete demographic information form, complete MacArthur-Bates Communicative Development Inventories, complete ADI-R interview, complete Preference Assessment. More detailed information on the procedures can be found below.
- We do not anticipate any risks.
- Your child may benefit from participation by learning the vocabulary words we teach. Participation may also help us learn the best ways to teach new words to children with autism who have trouble speaking.
- You can choose not to participate in this study.

DETAILED INFORMATION

INTRODUCTION

The Department of Speech-Language-Hearing at the University of Kansas supports the practice of protection for human subjects participating in research. The following information is provided for you to decide whether you wish for your child to participate in the present study. You may refuse to sign this form and not participate in this study. You should be aware that even if you agree for your child to participate, you are free to withdraw at any time. If you do withdraw from this study, it will not affect your relationship with this unit, the services it may provide to your child, or the University of Kansas.

PURPOSE OF THE STUDY

You and your child are invited to be in an intervention study. The study is designed to improve word learning in children with autism. If you decide to participate, we will conduct an intervention with your child to try to teach him or her to say and understand words.

PROCEDURES

If you choose for your child to participate, we will first send an audio recorder home to take a sample of the sounds your child makes during the day. We will use those sounds to make vocabulary words that have those sounds in them. We will try to teach these words to your child. The intervention will take place at your child's school. During the first sessions, we will get measures of your child's communication ability, development, and autism symptoms. After that, we will work with your child to try to teach him or her the vocabulary words. The intervention



includes speech sound practice, shared book reading, a touchscreen computer teaching task, and use of an iPad that speaks the words when a picture of the word is touched. Each session will take about an hour. Once a week we will ask the teacher to note any words that your child has used. Approximately every other month, we will re-send the audio recorder home to collect another sample of the sounds and words that your child is making throughout the day.

We expect to work with your child for approximately 4 months with a follow-up at around 6 months. Some sessions will be videotaped so members of our research team can determine how well your child is saying the words we are teaching. All information about your child, including videos will be kept in locked cabinets or on password protected computers and/or external hard drives.

RISKS

We do not anticipate any risks. If your child becomes upset during parts of the intervention, we will take breaks and try to re-introduce the activities.

BENEFITS

Your child may benefit from participation by learning the vocabulary words we teach. Participation will also help us learn the best ways to teach vocabulary words to other children with autism who have trouble speaking. You will also receive a letter with the results of your child's assessment(s). Results from the assessment are also shared with educators and speech therapists who work with your child.

PAYMENT TO PARTICIPANTS

No payment is offered for participation in this study.

PARTICIPANT CONFIDENTIALITY

Your name and your child's name will not be associated in any publication or presentation with the information collected about you or with the research findings from this study. Instead, we will use a study ID number rather than your name. Your identifiable information will not be shared unless required by law or you give written permission.

Permission granted on this date to use and disclose your child's information remains in effect indefinitely. By signing this form, you give permission for the use and disclosure of your child's non-identifiable information for purposes of this study at any time in the future.

CERTIFICATE OF CONFIDENTIALITY

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information or documents, that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding. Data from this study cannot be used as evidence, for example, if



there is a court subpoena, unless you have consented for this use. Information and documents protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings).

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institutes of Health. You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

PRIVATE INFORMATION (DATA)

We may use de-identified data in future research without additional consent from you. This means that we may remove any links between data we obtain and participants and then continue to analyze the data.

REFUSAL TO SIGN CONSENT AND AUTHORIZATION

You are not required to sign this Consent and Authorization form and you may refuse to do so without affecting your right to any services you or your child are receiving or may receive from the University of Kansas or to participate in any programs or events of the University of Kansas. However, if you refuse to sign, you and your child cannot participate in this study.

CANCELLING THIS CONSENT AND AUTHORIZATION

You may withdraw your consent to participate in this study at any time. You also have the right to cancel your permission to use and disclose further information collected about your child, in writing, at any time, by sending your written request to: Nancy Brady, 1000 Sunnyside Ave. Room 3008, Lawrence, KS 66045.

If you cancel permission to use your child's information, the researchers will stop collecting additional information. However, the research team may use and disclose information that was gathered before they received your cancellation, as described above.

QUESTIONS ABOUT PARTICIPATION

Questions about procedures should be directed to the researcher(s) listed at the end of this consent form.

PARTICIPANT CERTIFICATION



I have read this Consent and Authorization form. I have had the opportunity to ask, and I have received answers to, any questions I had regarding the study. I understand that if I have any additional questions about my rights as a research participant, I may call (785) 864-7429 or (785) 864-7385, or write the Human Research Protection Program, University of Kansas, 2385 Irving Hill Road, Lawrence, Kansas 66045-7568, or email irb@ku.edu.

If you agree for your child to participate in the study as describe above, please sign the next page. If you are mailing this consent form, please note that this form contains identifiable information (your name and your child's name) and has a small risk of being lost in the mail.



Print Child's Name

School/Teacher

Child's Date of Birth

Print Parent's Name

Phone

Email

Parent's Signature

Date

Researcher Contact Information

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OPTIONAL: PERMISSION TO USE VIDEOTAPE FOR ADDITIONAL PURPOSES

By checking the boxes below, I _____ hereby give my consent to allow project staff to use videotaped data of my child for the purpose of training, education, and feedback. **Sharing videotapes is optional and will not affect your participation in this research study.** I understand I can revoke my permission at any time and it will not affect my participation in the study.

I give permission to use videotapes of my child to be shared with select researchers and students. **Checking this box indicates that videos may be shown at conferences or in meetings with other researchers.**

I give permission to use videotapes of my child on researchers' websites for educational and community training purposes. **Checking this box indicates that videos may be available to anyone with an internet connection.**

Name: _____

Signature: _____

Date: _____

