

Official Title: Kindergarten Children Acquiring Words Through Storybook Reading
(KAWStory)

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KU WORD AND SOUND LEARNING CONSENT STATEMENT
Interactive Book Reading to Accelerate Word Learning by Children with SLI

KEY INFORMATION

- This project is studying a word learning program for children with language weaknesses.
- Your child's participation in this research project is completely voluntary.
- Your child's participation will take 2–26 weeks, depending on if your child qualifies for the full study.
- Your child will be asked to do the following procedures: preliminary evaluation, vocabulary test prior to training, interactive book reading, vocabulary test following training. More detailed information on the procedures can be found below.
- Your child can participate in-person at your child's school (with school approval) or virtually.
- The potential for risks, stress, or discomfort is largely non-existent. Your child may become bored or tired during testing or training sessions. Children will be given breaks if this occurs.
- For in-person sessions, research personnel will follow health and safety guidelines of your child's school/program.
- In terms of direct benefits, you will be given a written report detailing your child's performance on all standardized clinical tests administered during the preliminary evaluation which may be useful in educational and clinical planning. In addition, participation in this research program may help to improve your child's vocabulary because he/she may learn some of the 30 words taught. In terms of indirect benefits, the findings from this study will be used to improve treatment options for children with SLI.
- The alternative to participating in this research study is to contact your school speech-language pathologist or another provider to request an evaluation of your child's language skills and/or services to address your child's needs.

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 your child to participate in the present study. You may refuse to sign this form and not allow your child to participate in this study. You should be aware that even if you agree to allow your child to participate, you are free to withdraw at any time. If you do withdraw your child from this study, it will not affect your relationship with this unit, the services it may provide to you, or the University of Kansas.

PURPOSE OF THE STUDY

The purpose of the research project is to improve a training that has been shown to be somewhat effective in helping Kindergarten children with Specific Language Impairment (SLI) learn new words. Children with SLI have difficulty learning spoken language including vocabulary and sentence grammar without any obvious cause for their difficulty. The training we are using is called interactive book reading, meaning that an adult reads a storybook to a child and teaches the new words in the book. The goal of the proposed research is to determine the best balance of having the child listen to the new words versus having the child talk about the new words to help the child learn and remember the new words.

LOCATION

Your child is asked to participate in the tasks below at his or her school, after-school program, or the internet (e.g., Zoom). For school and after-school programs, the classroom teacher or leader will be consulted for scheduling issues. For sessions online, you will be consulted for scheduling. If sessions occur online, you will be asked to provide a quiet room free from distraction and an appropriate electronic device (phone, tablet, computer) for online participation.

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HEALTH AND SAFETY

The University of Kansas recognizes that the COVID-19 pandemic has changed the level of risk to you regarding your participation in this research. For sessions conducted in-person, all research personnel will follow health and safety guidelines (e.g., personal mask, social distancing) determined by the school or after-school program. As recommended by the Centers for Disease Control & Prevention (CDC), research personnel will have daily screenings before seeing your child and will disinfect areas and hands before and after completing sessions.

PROCEDURES

Time Summary Table. Total time commitment for all procedures is described below.

| Event: | | | | | | |
|--|--------------------------------------|---------------------------------------|--|---------------------------------------|---------------------------------------|---|
| Preliminary Evaluation | Vocabulary Test Prior to Training | Interactive Book Reading Training | Vocabulary Test Immediately Following Training | Vocabulary Test 4 Weeks Post-Training | Vocabulary Test 8 Weeks Post-Training | Vocabulary Test 12 Weeks Post-Training |
| 2-3 weeks | 1 week | 5-8 weeks | 1-2 weeks | 1 week | 1 week | 1 week |
| 4-5 hours | 1-1.5 hours | 5-7.5 hours | 1.5-2 hours | 1-1.5 hours | 1-1.5 hours | 1-1.5 hours |
| 4-8 sessions, lasting 30 to 60 minutes | 2 sessions, lasting 30 to 45 minutes | 15 sessions, lasting 20 to 30 minutes | 2-4 sessions, lasting 30 to 60 minutes | 2 sessions, lasting 30 to 45 minutes | 2 sessions, lasting 30 to 45 minutes | 2 sessions, lasting 30 to 45 minutes |
| You will be paid \$25.00 when your questionnaires are returned | | | You will be paid \$25.00 when the immediate vocabulary testing is done | | | You will be paid \$25.00 when the 12-week testing is done |

Preliminary Evaluation: As part of the preliminary evaluation, you will be asked to complete a questionnaire related to your child's development and environment. You and your child's teacher will also be asked to complete a questionnaire regarding your child's language and literacy skills. Your child's teacher will be asked to sign a consent form prior to completing the questionnaire. These questionnaires will require 15 minutes of your time and 10 minutes of the teacher's time.

- The *development and environment questionnaire* will ask you common background questions about your child and your family.
- The *language questionnaires* will require you as the parent to rate certain language skills and behaviors on scales indicating: how "like" or "unlike" the behaviors are of your child, what your child can do with help, and how often your child exhibits behaviors.
- The *language and literacy survey* will require teachers working with your child to rate your child's performance in the areas of language, reading and writing.

During the preliminary evaluation, your child will be given several tests commonly used by speech therapists to examine hearing, vocabulary, articulation, overall language expression, pre-reading/reading, memory, learning, and nonverbal reasoning. It is anticipated that this testing will require a total of 4 to 5 hours, spread across four to eight sessions, with each session lasting 45- to 60-minutes. The following tests may be given during the evaluation session to determine whether your child is eligible to participate in the research project.



- The *story and conversation tests* requires that your child listen to short stories, retell the stories and answer questions about the stories. Your child also will participate in a conversation about everyday school activities.
- The *sentence test* requires your child to make up a sentence about a given picture when provided with a verbal question or prompt.
- The *vocabulary tests* have children group pictures that are similar and explain how the pictures are similar, finish a starter sentence, answer questions about pictures, and describe a pictured event.
- The *articulation test* requires your child to name common pictures such as “house” or “cup.”
- The *pre-reading test* requires your child to say a word and then say it again without a part of the word (e.g., cupcake without cup = cake), say parts of a word and then combine them to say the full word (e.g., cup – cake = cupcake), match words that sound similar (e.g., cake-rake), and repeat made-up words.
- The *memory tests* require your child to repeat nonwords of various lengths.
- The *nonverbal reasoning test* requires your child to look at a set of pictures and select the one that is different from the others.
- The *learning tests* require your child to recall lists that are read aloud to them immediately and after a delay.

If your child is identified as having difficulty with language and vocabulary but age-appropriate hearing and nonverbal reasoning, then he or she will be invited to participate in the training as part of the research study.

Interactive Book Reading Training: In this study, your child will be taught 30 new words through book reading. Throughout the course of training, your child will be read 5 storybooks. Each storybook will contain 6 words that are likely to be new to your child. The words are taught by reading the book and expanding on the text to help your child learn the words. The new words are taught before reading the book, during book reading, and after book reading through your child talking and listening.

Your child will be randomly assigned to a training schedule. Training schedules vary based on how often your child is asked to talk about the new words during each reading of the book, as shown in the table below. In each schedule, your child will practice each of the 30 words a total of 6 times, but it will vary how much that practice involves listening versus talking. During listening, your child will hear the definition of the word, a synonym (i.e., a word with a similar meaning), and example sentences. During talking, your child will be asked to provide the definition, the synonym, and/or complete sentences using the word. Books will be read on 6 different occasions so that your child will practice each new word a total of 36 times. Sessions will be scheduled two to three times per week. You can request to know your child’s training assignment by calling (785) 864-4873. The assignment cannot be changed.

| Training Schedules: | | | |
|---|------------|------------|------------|
| | Schedule 1 | Schedule 2 | Schedule 3 |
| Level of talking | low | mid | high |
| # of talking opportunities in each session | 0 | 2 | 4 |
| # of listening opportunities in each session | 6 | 4 | 2 |
| Total # of practice opportunities in each session | 6 | 6 | 6 |

Testing During Training: During each training session, your child will be tested on his or her learning of 24 words, 12 that are taught as part of the training and 12 that are not. Each word will be tested in two ways:

- The *vocabulary definition task* will require your child to explain the meaning of each word.
- The *vocabulary naming task* will require your child to say the name of a picture illustrating each word.



Testing Before and After Training: Your child’s learning of the 30 taught and 30 untaught words (60 words total) will be examined prior to, immediately following training, and again 4 weeks, 8 weeks, and 12 weeks following the training. Each testing session will be divided into 2 visits so that your child is tested on 30 words during each visit. Each word will be tested using the definition and naming tasks described above.

In addition, several tasks from the Preliminary Evaluation will be repeated to look at potential changes in your child’s performance. These tasks will be re-administered as part of the testing immediately following training: (1) *vocabulary tests*; (2) a small portion of the *story and conversation test*; (3) one of the *language questionnaires*.

Recordings: All activities will be video recorded and used to score your child’s performance. Tests that require spoken responses also will be audio recorded and used to score your child’s performance. All audio and video recordings will be stored in a locked cabinet in a room where access is limited to research personnel. Audio and video recordings may be used to train research assistants and undergraduate/graduate students in research or speech-language pathology procedures. Audio recordings of your child may also be used in a separate study. In the separate study, we will ask speech-language pathologists or speech-language pathology students to listen to a recording of your child speaking and to rate certain aspects of your child’s speech or language use.

RISKS

The potential for risks, stress, or discomfort is largely non-existent. Your child may become bored or tired during testing or training sessions. Children will be given breaks if this occurs. You are invited to observe all sessions.

When audio recordings are used for teaching or research purposes, your child’s name will be removed from the recording, and your child will not be identified by name. However, your child could potentially be identified based on the sound of his or her voice, especially by someone familiar with your child. Students and research participants will be asked to keep all study information confidential.

BENEFITS

In terms of direct benefits, you will be given a written report detailing your child’s performance on all standardized clinical tests administered during the preliminary evaluation which may be useful in educational and clinical planning. In addition, participation in this research program may help to improve your child’s vocabulary because he/she may learn some of the 30 words taught. In terms of indirect benefits, the findings from this study will be used to improve treatment options for children with SLI.

PAYMENT TO PARTICIPANTS

You will be compensated \$25 for each completed study milestone. The example below demonstrates how each milestone is defined.

| | |
|------------------|--|
| \$25.00 | Questionnaires returned |
| \$25.00 | Vocabulary test immediately following training |
| <u>+ \$25.00</u> | Vocabulary test following 12 weeks post-training |
| \$75.00 | |

Investigators will ask for your social security number in order to comply with federal and state tax and accounting regulations.

PARTICIPANT CONFIDENTIALITY

Your child's name will not be associated in any publication or presentation with the information collected about your child or with the research findings from this study. Instead, the researcher(s) will use a study number or a pseudonym



rather than your child's name. Your child's identifiable information will not be shared unless (a) it is required by law or university policy, or (b) you give written permission.

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

PRIVATE INFORMATION (DATA) – FUTURE RESEARCH USE

To perform this study, researchers will collect information about your child. This information will be obtained from questionnaires completed by you during the preliminary evaluation. Also, information will be collected from the study activities that are listed in the Procedures section of this consent form. Your child's name will not be associated in any publication or presentation with the information collected about your child or with the research findings from this study. Instead, the researcher(s) will use a study number or a pseudonym rather than your child's name.

The information collected about your child will be used by: Dr. Holly Storkel (principal investigator), members of the research team, KU's Center for Research and officials at KU that oversee research, including committees and offices that review and monitor research studies. In addition, Dr. Storkel and her team may share the information gathered in this study, including your child's information, with: collaborating researchers, colleagues, and representatives of the National Institutes of Health (the sponsor of the study). The purpose of these disclosures is to facilitate completion of the research (e.g., analysis of the collected data) and safety monitoring. Again, your child's name would not be associated with the information disclosed to these individuals. Some persons or groups that receive your health information as described above may not be required to comply with the Health Insurance Portability and Accountability Act's privacy regulations, and your health information may lose this federal protection if those persons or groups disclose it.

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 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, your child cannot participate in this study.

CANCELLING THIS CONSENT AND AUTHORIZATION

You may withdraw your consent to allow participation of your child 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: Dr. Holly L. Storkel, at Department of Speech-Language-Hearing, 1000 Sunnyside Avenue, 3001 Dole Center, Lawrence, KS 66045-7555 (785-864-4873; hstorkel@ku.edu).

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

CLINICAL TRIAL INFORMATION

This study is considered a Clinical Trial and information pertaining to the study will be posted on clinicaltrials.gov, in accordance with the NIH and ClinicalTrials.gov requirements.

QUESTIONS ABOUT PARTICIPATION

Questions about procedures should be directed to the researcher 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 child's rights as a research participant, I may call (785) 864-7429, write to the Human Research Protection Program (HRPP), University of Kansas, 2385 Irving Hill Road, Lawrence, Kansas 66045-7568, or email irb@ku.edu.

I agree to allow my child to take part in this study as a research participant. By my signature I affirm that I am at least 18 years old and that I have received a copy of this Consent and Authorization form.

Type/Print Participant's (Child's) Name

Date

Parent/Guardian Signature

Researcher Contact Information:
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