UNIVERSITY OF DELAWARE | Treatment Efficacy & Language Learning Lab

COMMUNICATION SCIENCES & DISORDERS

R01 PROTOCOL

Recasting or Book Reading by Parents or Clinicians

[NCT ID not yet assigned]

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Table of Contents

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Protocol Title

Recasting and book reading under ideal (dose-controlled) and typical (dose-variable) conditions: The role of fidelity and adherence in production and comprehension outcomes for children with DLD

Research Sites

- University of Delaware (UD)
- University of Maryland (UMD)
- Remote administration

Procedures

Intake

Families will contact the TELL Lab at the University of Delaware. The lab will not know who the child is until the family contacts the lab. Families can make contact with the lab by calling, emailing, or completing a survey managed via RedCap. Periodically, families will be directly referred by a community partner such as Parents as Teachers.

When a family indicates interest in the study, the lab will attempt to make contact up to three times via call, email, and/or text (dependent on preferred communication methods.)

When contact has been successfully made, the study will be explained, intake staff will answer any questions the family may have, and basic intake/screening questions will be asked.

For those families who wish to continue and are eligible based on screening questions, we will schedule an initial meeting to review consent. We may meet with families via a secure video calling service, such as the HIPAA protected Zoom client. If we meet with the family virtually, we will conduct a "tech check" meeting prior to the first assessment of the child to ensure that everything goes smoothly.

Families will receive an email invitation following this intake/screening call which contains: a personal Zoom link, a link to the relevant language registry, a link to the consent form so they may review in advance, and a calendar invite which also contains the Zoom link.

Day-of the consent meeting, families will be resent this email.

Consent

Consent may be documented on paper or online using REDCap's eConsent tool. At the first appointment we will obtain consent and conduct the tech-check (telehealth option) or obtain consent and begin screening procedures (in-person option) to determine study eligibility. During the consent process, families will be presented with a visual aid to support their understanding of the possible conditions into which they may be randomized. This visit will take up to 90 min. First, we will explain the protocol to the parent/guardian and answer any questions they may have. The parent/guardian then consents to the child's screening, pre-testing, treatment, and post-testing. The caregiver also consents to their own participation at that time. If the caregiver who will be participating in treatment and interviews is the child's parent or guardian, we will use a single consent form; if the participating caregiver is not the child's parent or guardian, a separate consent form will be provided. Up to two caregivers may consent to participate, though only one caregiver will be trained to provide intervention.

We will not obtain formal, written assent from the child. Children under 8 rarely understand a formal assent process and the language involved is likely too complex for children of this age with language impairments, even using a modified approach. Rather, we will invite children to participate in individual tasks. Activities will be presented up to 3 times, re-presented at different times or in different orders to make them acceptable to the child (e.g., We have lots of games today. Would you like to play a listening game or a talking game?). We will also monitor the child's behavior throughout the session, attending to their body language and requests for breaks. In cases of inattention or refusal we will consult with caregivers about the child's willingness to participate and consider changing time of day (e.g., after lunch instead of before lunch), including the caregiver in the activity, or otherwise adapting the environment to make the child more comfortable, etc. We reserve the right to terminate participation against the wishes of the caregiver if we believe the child is unwilling to continue.

Tech Check

To ensure that a family participating via telehealth can engage in research remotely, we will meet via UD's HIPAA-compliant Zoom client to obtain consent and then review the technology available to the family and verify that it is adequate for all aspects of the research protocol. For cases in which the technology available is inadequate, we will then

have an opportunity to provide loaner technology to the family, to potentially include a wifi hotspot, an inexpensive webcam to serve as an additional viewer, a headset and splitter, and/or an inexpensive tablet. This ensures equitable participation. During the tech check, the staff person will ask the family to identify barriers to successful participation in advance of the first appointment, and work through any potential solutions.

In order to participate in the eye-tracking tasks, families must utilize a laptop or desktop computer. In the event that a local family does not have one of these devices during the tech check, the labs will work with the family to complete the task in their home or in a lab. For distance families, the lab will work with the family to identify possible sources (school, library, university, etc) who may be able to loan a device for this task.

Screening

Caregivers will complete the following questionnaires:

- Case History Form – Identifiable: asks about the caregiver's and child's contact information
- Case History Form -- Deidentified: asks about the caregiver and child's demographics, language experience, education experience, and clinical/educational services obtained
- Social Communication Questionnaire (SCQ): a routine screening for autism spectrum disorders
- Focus on the Outcomes of Communication Under Six (FOCUS) Questionnaire: a clinician/parent/guardian evaluation form that measures a child's change in communicative participation over time following speech-language therapy.
- Behavior Rating Inventory of Executive Function - Preschool Version (BRIEF-P): a standardized rating scale that measures the range of executive function in preschool-aged children
- A Multilingual Approach to Parent Language Estimates (MAPLE): This is structured interview will be used to document exposure to languages other than English. The MAPLE will only be used if the case history indicates exposure to another language that might need to be documented.

Caregivers will also be asked to provide a copy of a child's IEP or clinical treatment plan and other available clinical reports.

Children will complete the following tasks:

- Hearing Screening: audiometry screening administered by lab staff (5-10 min.) OR screening using the Sound Scouts app (10-15 min.) If the child has completed a recent hearing screening, the family may provide this report which will be uploaded to RedCap, in lieu of a screening.
- Differential Ability Scales, 2nd ed. (DAS-2) Matrices Subtest: a nonverbal IQ screening (approx. 10 min.)
- Diagnostic Evaluation of Language Variation - Norm Referenced (DELV-NR): a standardized grammar assessment (approx. 40 min.)

To meet our research definition of DLD, a child must:

- not have any exclusionary diagnoses (see Study Population and Recruitment section below)
- pass a hearing screening
- obtain a DELV-NR standard score < 85
- obtain a DAS-2 Matrices t-score > 35
- obtain an SCQ total score < 15

Pretesting

Children who meet the research definition of DLD (as outlined above) will receive additional testing to determine if they qualify for treatment. The first pretest visit may overlap with the final screening visit if it is convenient for the participating family. Pretesting will be completed within two weeks of treatment initiation. All scores will be stored in RedCap.

Elicited Production Tasks (30-40 min. each)

There will be two 20-item elicited production tasks to assess children's ability to produce GRAMMATICAL STRUCTURE 1 and GRAMMATICAL STRUCTURE 2. Each task will begin with 3 training items to make sure participants understand the procedure (totaling 23 items per task). To qualify for the study, a child must score below 40% accuracy on both elicitation tasks.

In the GRAMMATICAL STRUCTURE 1 task, children will be shown 20 pairs of pictures that depict an agent (the doer) acting on a patient (the person or thing the action is being done to). For example, one item might show a picture of a girl hugging a teddy bear next to a picture of a boy hugging a toy dog. The examiner would describe the first picture using the GRAMMATICAL STRUCTURE 1 sentence and then prompt the child to describe the second picture with the focus on the patient, asking "What happened to the dog?" The child should make a verbal response describing the picture that can be scored for accuracy (target: GRAMMATICAL STRUCTURE 1.)

In the GRAMMATICAL STRUCTURE 2 task, children will be shown 20 pairs of pictures that contain two agents or objects that are differentiable by how they are being acted upon, one of which is pre-marked (e.g., with a gold star). They will be told that the examiner has the same set of pictures, but they are missing all the markings. The child must describe the marked item so the examiner can mark it on their page. For example, one item might show a picture of a girl reading a book (with a gold star) next to a picture of a boy reading a book (unmarked). The examiner would ask, "Which book has the star?" The child should make a verbal response that can be scored for accuracy (target: GRAMMATICAL STRUCTURE 2).

The elicited production pretesting task for GRAMMATICAL STRUCTURES 1 and 2 will be transcribed and coded within one week of administration.

Eye tracking Tasks (20-30 min. each)

Children will also complete three 36-item eye tracking tasks to assess online comprehension of the two treated grammatical structures and a third sentence frame that will serve as a control structure. Each task will begin with 8 practice items that may be repeated once to make sure participants understand the procedure (totaling up to 108 items per task). Grammatical Structure 1 and Grammatical Structure 2 will be counterbalanced for order of administration. Grammatical Structure 3 will always be presented last.

Children will listen to pre-recorded audio while looking at pairs of pictures that depict possible interpretations of the words heard in the sentence. This will look similar to the presentation of picture pairs in the elicitation tasks, but the prompts and images used in the two tasks will be different. For example, one item in the GRAMMATICAL STRUCTURE 1 task might show a picture that depicts GRAMMATICAL STRUCTURE 1. The child would hear the GRAMMATICAL STRUCTURE 1 sentence. After the offset of the sentence and eye gaze measures have stabilized, the child will be prompted to point to the image on the screen that goes with the sentence they heard.

The eyetracking task for GRAMMATICAL STRUCTURES 1, 2, and 3 will be hand-coded within 4 weeks of administration. Reliability will be completed within 4 weeks of initial coding being completed.

Telehealth Participants

We will use webcam technology to capture child looks to the screen. Children will be asked to sit still at a comfortable distance from the screen in good lighting. PCIbex will be used to present and record presentation of stimuli and child looks to the screen. These looks to the screen will then be blindly coded by lab staff as to direction of looks (or inattention). All procedures save for calibration will be similar to those described above.

Language Sample

In addition to the elicited production and eye tracking tasks, we will collect a structured language sample for 15-30 min. or until 100 utterances have been recorded. This serves two purposes: 1) to compare spontaneous production of GRAMMATICAL STRUCTURES 1 and 2 at pre/post; and 2) to ensure the child's language level is high enough that they

can likely benefit from treatment. To qualify for the study, a child must have a mean length of utterance (MLU) of 2.5 words or greater. They must also produce simple SVO (subject-verb-object) sentences (e.g., I see you).

To accommodate the family's schedule, the structured language sample may be collected during pretesting, parent training, or the first week of treatment.

The language sample will be completed using the XYZ protocol. The language sample will be transcribed and coded within one week of completion.

Descriptive Language Tests

The following tests help to provide a more comprehensive profile of the child's language skills, but will not be used determine eligibility:

- Pearson Picture Vocabulary Test, 5th ed. (PPVT-5): receptive one-word vocabulary (15-30 min.)
- Expressive Vocabulary Test, 3rd ed. (EVT-3): expressive one-word vocabulary (15-30 min.)

To minimize the total number of visits needed by family, descriptive language tests may be administered during screening, pretesting, parent training, or the first two weeks of treatment.

Lab staff may administer the PPVT-5 or EVT-3 during screening if it would be helpful for the child and maximize family time and information needs. For example, a child with a language impairment may become fatigued after a difficult task involving complex language (such as the DELV-NR). To give them something less demanding, the examiner may switch to the PPVT-5 (because it requires pointing rather than talking) or the EVT-3 (because it only requires the child to name a picture rather than engaging with complex language). These tests may also provide clinical information for the family to share with their providers, one of the benefits of being in the study.

Condition Assignment

A series of condition assignments will be held by staff at UD's Center for Research in Education & Social Policy (CRESP). Once a participant complete pretesting and qualifies to continue, lab staff will request a condition assignment from CRESP. The child and their caregiver will be randomly assigned to one of four treatment conditions:

- recast therapy "in the lab" (or another mutually agreeable location, or via telehealth)
- book reading "in the lab" (or another mutually agreeable location, or via telehealth)
- recast therapy at home
- book reading at home

Assignment of treatment structure will be counterbalanced between GRAMMATICAL STRUCTURE 1 and GRAMMATICAL STRUCTURE 2.

Treatment Procedures

In the recast therapy conditions, an adult will interact with child and recast (restate, with a correction) a child's utterance as the target structure for that child. The goal is 960 recasts over the course of the study (1 recast/minute, for 16 hours).

In the book reading conditions, an adult will read specially designed illustrated syntax stories to the child, in which each story contains 30 models of the target structure. Each of six different books should be read 5-6 times, with a goal of 960 models of the target. Variations described below are related to the different administration procedures.

We will teach all caregivers home data collection techniques.

Parents will be provided with a digital audio recorder and a method to upload the data to a secure server. We will recommend that parents inform all members of their household (as well as visitors) when the recorder is on. If an individual does not wish to be recorded, the recorder can be easily switched off at any time. Caregivers will be asked to record on 16 pre-selected days (2x/ week) to coincide with delivery of treatment.

All caregivers will also take a grammar quiz to determine their knowledge of the target and control structures and meta-linguistic skills in general. This quiz will either be administered via REDCap (preferred) or on paper.

Lab Program

Caregiver Training Visit (60-90 min.)

The caregiver will take the grammar quiz which will be scored within 30 days of completion. Home data collection procedures for recording will be reviewed, and we will pre-schedule 16 treatment visits during an 8-week period. We will ask the caregiver to pre-plan 16 days to do recordings and to designate a cell phone number to receive reminders via text message. We will send a reminder text the morning of each planned recording day, as well as 24 hours prior to each treatment visit, and again 30 min. prior to each treatment visit.

Treatment Visits (16 visits, up to 60 min. each)

Individual treatment visits will last up to an hour. Visits may be audio- or video- recorded. The goal is for treatment to be provided twice a week for eight weeks. Two additional weeks are allocated to account for absences and makeups, allowing 10 weeks to elapse between pretest and posttest. Treatment is ideally provided at UD/UMD lab spaces but may also be arranged to be provided at other mutually agreeable locations (daycare, library, etc.) as long as the space provider, family, and lab all agree. Alternatively, we may meet with families via a secure video calling service, such as Zoom. Canceled/missed visits will be tracked, along with reason for missing, but may be made up during the 10-week treatment period. For telehealth participants, recorders may be exchanged by mail (with postage paid by the lab) or lab staff may briefly visit the participant at home for recorder swaps. No-contact drop-off/pickup will be used if necessary due to COVID-19 concerns.

Recast Condition

Visits will consist of play-based interactions between the clinician and the child that elicit simple descriptions of real or virtual objects and activities that the clinician can recast into the target structure. The clinician will track the number of recasts provided, with a goal of obtaining 60 recasts per visit. Materials will be selected to support elicitation of the target and to meet child interests/engagement. At the end of each visit, the clinician will report on child learning, child engagement and their own self-efficacy and treatment fidelity and the child will be asked to report on how much they enjoyed the session. 25% of treatment sessions will be transcribed and coded for recast fidelity within one week of completion and 25% of those will be coded for reliability completed within two weeks of completion.

Book Reading Condition

Visits will consist of reading two of the specially designed books. The clinician may provide a brief period for movement or play in between the two books to ensure engagement in the second book (doing jumping jacks, getting a drink of water, building a tower with Legos, playing a non-language based virtual game). At the end of each visit, the clinician will report on child learning, child engagement and their own self-efficacy and treatment fidelity and the child will be asked to report on how much they enjoyed the session. 25% oof book reading sessions will be transcribed and coded for reading fidelity within one week of completion, and 25% of those will be coded for reliability completed within two weeks of completion.

Home Program

Caregiver Training Visit (60-90 min.)

The caregiver will take the grammar quiz which will be scored within 30 days of completion. Home data collection procedures for recording will be reviewed and we will pre-schedule 16 treatment visits during an 8-week period. We will ask the caregiver to pre-plan 16 days to do recordings and to designate a cell phone number to receive reminders via text message. We will send a reminder text the morning of each planned recording day, as well as 24 hours prior to each treatment visit, and again 30 min. prior to each treatment visit.

Recast Condition Visits 1 & 2

We will instruct the caregiver about the target structure and treatment strategies being employed, including how to STRATEGY. Typed language transcripts will be utilized to provide practice opportunities. Caregivers will be given an opportunity to ask questions about the structure being trained and then will participate in an active coaching session in which they attempt to carry out recast therapy with their own child. Tip sheets will be provided that describe key characteristics of the language structure and support elicitation of platform utterances. Materials that are appropriate for use that exist in the home will be reviewed and discussed. Training and coaching visits will be transcribed and coded for fidelity within 4 weeks of completion.

Book Reading Condition Visits 1 & 2

The caregiver will be shown STRATEGY. They will receive instruction on STRATEGY while maintaining the child's attention. This will include suggestions for STRATEGY. The caregiver will be given an opportunity to ask questions about the procedures and then will participate in an active coaching session in which they read one story with their own child and are coached on STRATEGY. Books will be provided to the family at the end of visit 2. Training and coaching visits will be transcribed and coded for fidelity within 2 weeks of completion.

Visit 3

Following training, the caregiver will take the grammar quiz. They will then be asked to provide 30 min. of treatment to the child, uncoached, as if they were providing treatment at home. This will be video-recorded to document skill at providing recasts following brief training. This data collection visit will be transcribed and coded within 2 weeks of completion. After this, home data collection procedures will be reviewed and caregivers will be asked to pre-plan sixteen 60-min or 32, 30-min treatment times during an 8-week period. Caregivers will be asked to collect recorded data on treatment days and log when they start and stop providing treatment each day. This log will be cross-referenced with home recordings so that appropriate segments of audio can be reviewed and transcribed in order to objectively document treatment provision.

We will ask caregivers to designate a cell phone number to receive reminders via text message. We will send a reminder text 24 hours prior to each planned treatment time, and again 30 min. prior to each planned treatment time.

Caregivers will periodically be asked questions regarding self-efficacy, child engagement, and how much they felt like their child learned each time they report providing therapy. The first 3-5 participants will also complete cognitive interviews partway through treatment to help us check that our questionnaires are easy to understand and that parents interpret our questions the way we intend them to.

Post-Testing

At post-testing, children will again complete the eye tracking and elicited production tasks for passives and relative clauses. We will also collect a second structured language sample of 15-30 minutes. The caregiver will complete the FOCUS questionnaire a second time as well.

While children are participating in the post-testing, the caregiver who participated the most in treatment (either by providing treatment or by supporting the child during clinician-provided treatment) will complete a questionnaire and then participate in a qualitative interview about their perceptions of treatment. Some caregivers will be recontacted for follow-up questions up to 8 weeks after their interview. This will ensure that our interpretations of interview responses authentically reflect participant views and maintain the trustworthiness of the data (Lincoln & Guba, 1985; Merriam, 2009). These interviews will be transcribed using otter.ai and coded with 4 weeks of completion. Interview notes and self-reflections will be uploaded within a week of the completion of the interview.

Wrap-Up

Upon completion of participation, participants will be provided with compensation as follows:

- $15 for screening
- $35 for pretest
- $10 per home recording returned, up to $160
- $100 for post testing
- $70 for caregiver interview during post testing

If the family completes the full study and turns in all 16 recordings, the total compensation would be $380. A family who ends treatment early will still be compensated for home recordings returned up to the date of treatment termination and may still be included in the post-testing or caregiver interviews if they are willing to do so.

If desired by families, the lab will provide a report detailing test scores and/or participation in study. Families will be asked to return any equipment they may still have including recording devices, chargers, etc. Clinicians will offer families additional therapy materials if desired.