

Efficacy of the Direct Instruction Language for Learning Program to Promote Expressive and Receptive Language in Children with Autism Spectrum Disorder

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NCT02483910

You Are Being Asked to Be in a Research Study

What Is a Research Study?

The main purpose of research studies is to gain knowledge. This knowledge may be used to help others. Research studies are not intended to benefit you directly, though some might.

Do I Have to Do This?

No. Being in this study is entirely your choice. If you decide to join this study, you can change your mind later on and withdraw from the research study.

Taking part in a study is separate from medical care. The decision to join or not join the research study will not affect your status as a patient.

What Is This Document?

This form is an informed consent document. It will describe the study risks, procedures, and any costs to you.

This form is also a HIPAA Authorization document. It will describe how your health information will be used and by whom.

Signing this form indicates you are willing to take part in the study and allow your health information to be used.

What Should I Do Next?

1. Read this form, or have it read to you.
2. Make sure the study doctor or study staff explains the study to you.
3. Ask questions (e.g., time commitment, unfamiliar words, specific procedures, etc.)
4. If there will be medical treatment, know which parts are research and which are standard care.
5. Take time to consider this, and talk about it with your family and friends.

Emory University and Children's Healthcare Consent to be a Research Subject / HIPAA Authorization

Title: Efficacy of the Direct Instruction Language for Learning Program to Promote Expressive and Receptive Language in Children with Autism Spectrum Disorder

Principal Investigator: Lawrence Scahill, MSN, PhD, Department of Pediatrics

Study-Supporter: United States Department of Defense

Introduction

You and your child are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide if you want your child to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you or your child to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:

- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as recommended by the U.S. government. When the study is done, this web site will include a summary of the results, but will not include information that can identify you. You may search this Web site at any time.

What is the purpose of this study?

Direct Instruction- *Language for Learning* uses face-to-face instruction and specific lessons to teach children language skills. This method has been used previously in children with language delays, but it has not been carefully studied in children with autism spectrum disorder. The purpose of this study is to see if Direct Instruction- *Language for Learning* is an effective way to teach language skills to children with autism spectrum disorder (ASD). This study will compare Direct Instruction-*Language for Learning* (DI-LL) to ongoing treatment as usual. The term, treatment as usual (TAU) means speech and language services that you child is already receiving (e.g speech therapy). This is a research study because we do not know if DI-LL will work in children with ASD.

What will I be asked to do?

About 100 children with ASD and moderate language delay will participate in this study at the Marcus Autism Center over five years. The study includes an initial screening assessment for eligibility. Children who are eligible for the study will be randomly assigned to receive either DI-LL plus ongoing treatment as usual or to continue with treatment as usual (TAU) alone. Random assignment means that your child has a 50:50 chance (like flipping a coin) of receiving DI-LL plus TAU or continuing in TAU alone for 24 weeks. The research team has no input on random assignment. It is done by computer program. DI-LL involves 40 to 48 sessions over 24 weeks (about 2 per week). Each session lasts about 90 minutes. Children in both groups (DI-LL and TAU) will also have assessments at Weeks 8, 12, 16 and 24 during the randomized trial. Children in TAU who do not show improvement at Week 24 will be offered DI-LL.

Screening Assessment: The screening assessment is to find out if the study is a good fit for you and your child. It will usually be conducted over two visits of about 150 minutes (2 ½ hours) each. These assessments are not experimental. They will include tests for ASD, IQ, language and daily living skills. A parent (primary caregiver) will be asked to complete surveys about the child's health, background, past treatments and behavior. Children on no medication or on a stable dose of medication can take part in the study. Children can also continue with interventions at school and outside school. To be eligible, there should be no planned changes in the treatment plan for six months. Children who are currently receiving DI-LL or participated in a DI-LL program in the past 2 years will not be included. Children with severe language delay will be referred for more intensive treatment.

Repeated Assessments: To measure progress during the study, there will be periodic assessments throughout the trial. These sessions will involve some of the same measures as at the screening visit. These visits will take from 1 to 2 hours.

Direct Intervention-Language for Learning Sessions: DI-LL uses demonstrations and pictures to expand vocabulary and teach language skills to children in manageable steps. The program includes up to 150 lessons. A test at the beginning of the program will help the therapist identify the right starting place for your child. Your child will be given tests along the way to measure progress.

Treatment as Usual: Children in both study groups will be allowed to continue treatments in school (e.g., speech therapy), outside school or medication.

What happens at Week 24?

All DI-LL subjects and positive-responders in the TAU group will be invited to return for follow-up assessments at Week 36 and Week 48. Subjects randomized to TAU who do not show a positive response at Week 24 will be offered DI-LL. These follow-up visits will use the same measures and assessments that were used during the randomized phase of the study.

Who owns my study information and samples? If you and your child join this study, you will be donating your samples and study information. You will not receive any compensation if your samples or information are used to make a new product. If you withdraw from the study, data and samples that were already collected may be still be used for this study.

What are the possible risks and discomforts?

DI-LL has not been carefully studied in children with ASD and language delay. You and your child may spend time and effort in the study treatment and not benefit from DI-LL. There are no known side effects from DI-LL, but there may be side effects that are not known at this time. It is possible that the researchers will learn something new about the risks or benefits of DI-LL during the study. If this happens, we will tell you about this new information. Then you can decide if you want your child to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

New Information

It is possible that we will learn something new about language interventions for children with ASD during the study. If this happens, we will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Will I or my child benefit directly from the study?

This study is designed to learn more about the use of DI-LL in children with ASD. The study results may be used to help others in the future. Your child's language and communication skills may improve during the study. But taking part in the study may not benefit you or your child directly. It is unlikely, but your child's language and communication skills may even get worse.

Will I be compensated for my time and effort?

You will be compensated for assessment visits. You will receive \$25 for the following visits: screening, baseline and Week 8, 12, 16, 24, 36 and 48 assessment visits. There is no compensation for the DI-LL sessions.

All payments are made using a prepaid debit card. It can be used exactly like a Mastercard. We load money onto your card electronically every time you need to be paid. The card system is run by Greenphire, an independent company specializing in payments for research studies and clinical trials. To issue your card, we need to give Greenphire some of your personal information. Banks and other financial institutions can access this information to verify your identity when you use your card. Emory University is required by law to report any payments we make to the IRS. To do this, Emory University Department of Finance needs to keep your Social Security Number on file. We are asking you to allow us to communicate your name, address, date of birth, research study name and Social Security Number to Greenphire and Emory University Department of Finance. If you want to receive e-mail or text alerts when payments are made to you, we will ask you to provide your e-mail or phone number as well. All of this information will be stored on computers owned by Greenphire. Greenphire will not have access to any other information collected during this study. Full instructions about using your card are included when we issue it. If you have any questions or concerns about the card system or the use of your personal information, please ask. If you are concerned about confidentiality, you can decline payment and still participate in the study.

What are my other options?

You do not have to be in this study to be treated for language delays. If you decide not to have your child in this study, there is care available to you outside of this research study. This could include speech therapy or other language-based treatments. The study doctors will discuss these with you.

Taking part in this study, however, may make your child unable to participate in some other research studies. For example, some studies exclude children who have received certain treatments. You should discuss this with the researchers if you have concerns. You may wish to look into other study options at websites like clinicaltrials.gov and ResearchMatch.org.

How will you protect my private information that you collect in this study?

Emory and Children's Healthcare will keep any research records that it creates private to the extent that this is required to do so by law. Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents.

Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.

Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Storing and Sharing your Information

Data without identifying information (de-identified data) from this study may be shared with the research community at large to advance science and health. Data from this study may be placed into public databases. To get access to information on these public databases, researchers will need to sign data use agreements. In this study, we are required to submit data to the National Institute of Mental Health Data Archive (NDA). The NDA is run by the National Institute of Mental Health (NIMH). It allows researchers who study mental illness to collect and share de-identified information. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

If you are currently participating or have participated in a research study at the Marcus Autism Center that collected the same information, we may access that information to eliminate duplication of procedures. Similarly, if you participate in a research study at the Marcus Autism Center in the future, we may share common data, as appropriate.

Medical Record

If your child has been an Emory and Children's Healthcare patient before, then your child will already have an Emory and Children's Healthcare medical record. Otherwise, your child will not have a medical record. An Emory and Children's Healthcare medical record will be made for your child if an Emory and Children's Healthcare provider or facility provides any treatment services or procedures outside of this study.

The results of study tests and procedures will be used only for research purposes and will *not* be placed in your child's medical record without your written permission. For this study, we collect an IQ test, language tests, ASD diagnostic tests, parent-rated measures of your child's behavior and everyday living skills. Some of the study assessments may help with your child's care. For example, the results of certain study tests. With your written permission, these study results will be put in your child's Emory and Children's Healthcare medical record. Anyone who has access to your medical records will be able to have access to the study information placed there. The confidentiality of the study information in your child's medical record will be protected by laws like the HIPAA privacy rule. State and federal laws may not protect from disclosure any of the research information placed in the medical record.

In Case of Injury

If your child gets ill or injured while in the study, the study staff will help you to get medical treatment. Emory and Children's Healthcare and the sponsor have not, however, set aside any money to pay you or to pay for this medical treatment. The only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory or sponsor employee. "Negligence" is the failure to follow a standard duty of care.

If you become ill or injured from being in this study, your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurer does not pay, then you will have to pay these costs.

If you believe your child became ill or injured from this research, contact Dr. Lawrence Scahill at 404-785-9336 or 203-494-1738. You should also let any health care provider who treats your child know that you are in a research study.

Costs

There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities.

Withdrawal from the Study

You have the right to leave a study at any time without penalty. The researchers also have the right to stop your child's participation in this study without your consent for any reason. For example, if they believe it is in the best interest of you or your child.

Authorization to Use and Disclose Protected Health Information The privacy of your child's health information is important to us. We call health information that identifies you or your child, "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for this study.

PHI that Will be Used/Disclosed:

The PHI that we will use or share for this research study includes:

- Research study records. We collect several identifiers including name, address, phone number, date of birth, and dates of study entry and exit as well as video images from therapy sessions and certain assessments.
- The entire research record for up to seven years after the study is over.
- Children's Healthcare offices involved in the study administration, clinical and billing.
- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.

If you authorize the Researchers to also access results of exams, procedures and tests you may have completed through another research study at the Marcus Autism Center, please initial here:

(initials)

Purposes for Which Your PHI Will be Used/Disclosed:

We will use and share your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study related treatment and for payment for such treatment. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, and Institutional Review Boards (IRBs). If you leave the study, we may use your PHI (such as your contact information) to inquire about your child's health status.

Use and Disclosure of Your Information That is Required by Law:

We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

Authorization to Use PHI is Required to Participate:

By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your PHI. If you do not sign this form, then you may

not participate in the research study or receive research-related treatment. You may still receive non-research related treatment.

People Who will Use/Disclose Your PHI:

The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study and give you study related treatment.
- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- The Department of Defense is the Sponsor of the study. The Sponsor may use and disclose your PHI to make sure the research is done correctly. The Sponsor may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
 - Emory and Children's Healthcare offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
 - Government agencies that regulate the research including the Office for Human Research Protections
 - Public health agencies.
 - Research monitors and reviewers.
 - Accreditation agencies.
 - Emory Department of Finance and Greenphire will use your PHI for compensation purposes.

Expiration of Your Authorization

Your PHI will be used until this research study ends.

Revoking Your Authorization

If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must write to: Dr. Lawrence Scahill, 1920 Briarcliff Road, Atlanta, GA 30329.

If you decide to revoke permission, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data are correct. If you revoke your authorization you will not be able to stay in the study.

Other Items You Should Know about Your Privacy

Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses (e.g., billing services). We will not disclose your PHI to anyone without your written permission

During the study, you will not have access to you or your child's PHI collected for the study. This is to preserve the integrity of the study. When the study ends, and at your request, you can have access to your and your child's PHI. If it is necessary for your child's health care, health information will be provided to your doctor with your written permission.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed to other people or organizations for research purposes besides this study.

National Database for Autism Research

Data from this study will be submitted to the National Database for Autism Research (NDAR). Your name, address, and phone number will be removed before it is sent to NDAR. This information will be replaced with a code number. Thus, your personal information will remain protected.

Contact Information

Contact Dr. Lawrence Scahill at 404-785-9336 or 203-494-1738 if you have any questions about this study or your part in it,

- if you feel you have had a research-related injury or a bad reaction to the study drug, or
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at <http://www.surveymonkey.com/s/6ZDMW75>.

If you are a patient receiving care at Children's Healthcare of Atlanta and have a question about your rights, please contact Kristine Rogers, Director of Clinical Research at 404-785-1215.

Consent and Authorization

Please print your child's name, your name and sign below if you agree to have your child in this study. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed consent to keep.

Name of Subject

Name of Subject's Legally Authorized Representative

Signature of Legally Authorized Representative

Date

Time

Authority of Legally Authorized Representative or Relationship to Subject

Name of Person Conducting Informed Consent Discussion

Signature of Person Conducting Informed Consent Discussion

Date

Time**Future Contacts**

In the future, we may want to contact you if new studies become available. Please initial below to indicate whether you would like to be contacted if there is a new study for which you might be eligible.

_____ I agree to be contacted by email, phone or standard mail regarding opportunities for related studies in the future. I understand that agreeing to be contacted does not mean that I agree to participate. I understand that I can withdraw my permission to be contacted at any time.

_____ I do not wish to be contacted regarding opportunities for related studies in the future.

PHOTOGRAPHY/VIDEOGRAPHY and AUDIO RECORDING PERMISSION FORM

Video recordings will be made of you and/or your child for research purposes. The recording procedures are outlined in the informed consent form. The recording is confidential material and will not be used without parental consent. Withdrawal of consent to use the videos for research purposes and/or a request to erase the recordings after the study is completed may be requested in writing.

In addition, with your permission, the Marcus Autism Center can use these photographic images, video or audio segments for reasons other than research purposes:

- ☐ For educational & training purposes and to evaluate treatment outcome _____
Legally Authorized Representative (LAR) Initials

- ☐ I decline to give my consent for any use of my and/or child's image or voice for educational or training purposes

LAR Initials

Your child's participation in this study is not affected by your willingness or unwillingness to consent to your child's image being used for educational or training purposes as described above.

LAR Signature_____
Date_____
Signature of Person Obtaining Consent_____
Date

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator, Dr. Lawrence Scahill, MSN, PhD, at 404-785-9336 or 203-494-1738. If you have any questions concerning your rights as a research subject, you may contact the Emory Institutional Review Board