Title: Pilot RCT of a Daily Living Skills Intervention for Adolescents with Autism Spectrum Disorder in the Last 2 Years of High School

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CINCINNATI CHILDREN'S HOSPITAL MEDICAL CENTER
INFORMED CONSENT
FOR PARTICIPATION IN A RESEARCH STUDY

STUDY TITLE: Pilot RCT of a Daily Living Skills Intervention for Adolescents with Autism Spectrum Disorder in the Last 2 Years of High School

SPONSOR NAME: Department of Defense

INVESTIGATOR INFORMATION:
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Throughout this document, references to "You" may stand for either the research study subject or for the parents or legal guardians of the research study subject if the subject is under 18 years of age or otherwise unable to legally give informed consent to participate in the research study. The signature(s) at the end will clarify whether the research study subject is signing this consent form on their own behalf or via a legal guardian or legal personal representative.

We are asking you to be in a research study so that we can learn new information that may help others. If you decide not to be in this study, we will still take good care of you. If you decide to be in this study, you may change your mind at any time during the study and you can stop being in the study. Take all the time you need to make your choice. Ask us any questions you have. It is also okay to ask more questions after you decide to be in the study. You can ask questions at any time.

WHY ARE WE DOING THIS RESEARCH

Dr. Amie Duncan is a researcher at Cincinnati Children's Hospital. She studies people with autism spectrum disorders (ASD). We would like you to be in this study because you have ASD. We also want you to be in this study because we want to help you with some things that most people have to learn to do every day. We want to know what helps people like you become successful independent adults.

WHO SHOULD NOT BE IN THE STUDY?

If you do not have an Autism Spectrum Disorder, you should not be in the study. Also, some of the things we ask anyone wanting to be in the study might tell us that they would not be a good fit for the study. We would tell you right away if that happens.

WHAT WILL HAPPEN IN THE STUDY?

If you want to be in the study, the first thing you will be asked to do is answer some questions about yourself. We will ask you questions about your life, and how you think or feel about different things. Some things may be hard for you and some may be easy for you. We will ask your parent questions about how you are now and how you were when you were younger. We will also ask your parent about your school, your friends, and other things about your life. This first part will take about 2-3 hours each. We may video record part of this visit for training and reliability purposes only. If you have recently completed some of these tests as part of your clinical care or for a research study (within the last 2 years), we may use those results for this study. Some of this first part can be done over the phone or on live video, from your house. We may or may not do some of these things that way.

If you are eligible for the study, you will be randomly assigned to the daily living skills treatment group or a social skills group. Group sessions will be held either in-person, or via telehealth in the form of a HIPAA compliant Zoom video call.

Both the treatment group and the social skills group are 14 weeks, with other teens with autism and their parents that will teach you either 1) How to do different daily activities that most adults have to learn to do before going to college, working, or living on their own, or 2) Social skills like having conversations, handling arguments, dealing with teasing, and making and keeping friends. The parent interview will be audio recorded, and each group session will be video recorded. These will be destroyed after data analysis is completed.

In-Person Sessions: Each group session will be one and a half hours long. We will ask you to work on some things at home that you learn in the group. The two groups will happen simultaneously, on different days/times of the week.

Telehealth Sessions: One of the groups will have a group video session for both parents and teens at the same time (similar to if you were in person). The other group will have 60 minute individual sessions with each parent/teen to cover the teen group material, and the parents will have a group video session that is similar to the in-person group.

After the group is over, we will collect some of the same information we did before the group. We will do this right after group ends and again 6 months after that. We may also ask your parent to complete a phone call with us to see how you are doing 12 months, 18 months, and 24 months after group ended.

Finally, parents may complete a one-time 15-20 minute outcomes survey to assess their child's current status in education, work, independent living, social connectedness, and daily living skills after completing the intervention in the last 18-42 months.

WHAT ARE THE GOOD THINGS THAT CAN HAPPEN FROM THIS RESEARCH?

This research will hopefully help you learn or remember different daily activities and be able to do them by yourself. We hope that you being in the study will help us find out what helps adolescents and young adults with ASD learn skills that will assist them in daily living as an adult. We want to use this information to help other people with ASD in the future.

WHAT ARE THE BAD THINGS THAT CAN HAPPEN FROM THIS RESEARCH?

You may be asked questions that make you uncomfortable or cause you to remember situations that were upsetting to you. You may also become frustrated if you are asked questions during testing that you do not know how to answer. All people are going to be asked questions that they cannot answer. You do not need to answer any question that you do not wish to answer and you can stop the testing at any time. It is possible there is something we haven't thought of that may happen, but we will do our best to make sure it doesn't and we will make sure you know if it has something to do with you.

WHAT OTHER CHOICES ARE THERE?

You do not have to be in this study and you can let us know anytime and we will not be mad or upset. If you decide to start the study and then want to stop at some point, that is ok too. You will still be able to see your other doctors in the hospital if you need to. Make sure you ask us any questions you have about this form before you sign your name.

HOW WILL INFORMATION ABOUT YOU BE KEPT PRIVATE?

We will not tell anyone you are in this study. We will not put your name on any of the forms and we will keep them locked. Even though we will keep the data we collect from you, any future research that may use the data will not know it was yours. Neither your name nor any identifiable information (e.g. date of birth) will be connected to the data. The database where your information is held is only available to the study staff on this study. If you tell us that you may hurt yourself, we would tell your parents and other people so they could help you.

AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION FOR RESEARCH

To be in this research study you must also give your permission (or authorization) to use and disclose (or share) your "protected health information" (called PHI for short). If a parent or any other caregiver is your legal guardian, they should sign this consent in your place on the LAR line at the end of this document and include a description of their authority on the line provided.

What protected health information will be used and shared during this study?
CCHMC will need to use and share your PHI as part of this study. This PHI will come from:
- Your CCHMC medical records
- Your research records

The types of information that will be used and shared from these records include:
- Laboratory test results, diagnosis, and medications
- Reports and notes from clinical and research observations

Who will share, receive and/or use your PHI in this study?
- Staff at CCHMC Personnel who provide services to your child as part of this study (e.g., therapists who facilitate the intervention, clinical research coordinators who conduct assessment visits)
- Other individuals and organizations that need to use your child's PHI in connection with the research, including people at the sponsor and organizations that the sponsor may use to oversee or conduct the study.
- The members of the CCHMC Institutional Review Board and staff of the Office of Research Compliance and Regulatory Affairs.
- Per the Study Sponsor: The Department of Defense (DoD) is funding or supporting the study, and the confidentiality section allows the DoD access to research records as a part of its human subjects protection oversight activities.

How will you know that your PHI is not misused?
People that receive your PHI as part of the research are generally limited in how they can use your PHI. In addition, most people who receive your PHI are also required by federal privacy laws to protect your PHI. However, some people that may receive your PHI may not be required to protect it and may share the information with others without your permission, if permitted by the laws that apply to them.

Can you change your mind?
You may choose to withdraw your permission at any time. A withdrawal of your permission to use and share your PHI would also include a withdrawal from participation in the research study. If you wish to withdraw your permission to use and share PHI you need to notify the study doctor, listed on the first page of this document, in writing. Your request will be effective immediately and no new PHI about you will be used or shared. The only exceptions are (1) any use or sharing of PHI that has already occurred or was in process prior to you withdrawing your permission and (2) any use or sharing that is needed to maintain the integrity of the research.

Will this permission expire?
Permission to use your data will not expire unless you cancel it. You may cancel your permission at any time by writing to the researchers or calling the researchers listed in "Contact Information" (below).

Will your other medical care be impacted?
By signing this document you are agree to participate in this research study and give permission to CCHMC to use and share your PHI for the purpose of this research study. If you refuse to sign this document you will not be able to participate in the study. However, your rights concerning treatment not related to this study, payment for services, enrollment in a health plan or eligibility of benefits will not be affected.

WILL YOU BE PAID TO BE IN THIS RESEARCH STUDY?

Participants will receive a debit card of $50 for the pre-assessment, and a $25 debit card for both the post-assessment and 6 month follow-up. Parents will receive a $50 debit card at each visit (baseline assessment, post-treatment assessment, and 6 month follow up assessment). Parents will also receive another $25 for each of the 12 month, 18 month, and 24 month calls, if they complete them. You will receive $25 if you come to the pre-assessment and end up not being eligible for the study. Finally, parents will receive $25 for the outcomes survey. We will give you your payment in the form of a reloadable debit card (ClinCard) and we will explain how to use the card. We will provide you with a card and we will load money onto your card after each visit that you complete.

Because this research study involves payment for participation we are required by federal Internal Revenue Service (IRS) rules to collect and use your social security or tax ID number (SSN) in order to track the amount of money that we pay you. Unless you have given specific permission for another use of your SSN related to this research we will only use your SSN to keep track of how much money we pay you and your SSN will not be used as part of this research.

WHO DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?

For questions, concerns, or complaints about this research study or to report a research-related injury, you can contact the principal investigator, Amie Duncan, Ph.D. at 513-803-2416. You can also contact the coordinator, Carrie Fassler, at (513) 803-3580. Researchers are available to answer any questions you may have about the research at any time.

If you have general questions about your rights as a research participant in this research study, or questions, concerns, or complaints about the research, you can call the Cincinnati Children's Hospital Medical Center Institutional Review Board at (513) 636-8039. You can also call this number if the research staff could not be reached, or if you wish to talk to someone other than the research staff.

VIDEOGRAPHY AND AUDIO RECORDING

Video/audio recordings of in-person and video streaming visits are necessary and are made at no cost to you for research and auditing purposes. These recordings will only be available to study staff, and are instrumental in making sure all measures, in the visits and in the intervention sessions, are being conducted correctly and reliably. Therefore, if you do not consent to video or audio recording, you cannot be enrolled in this study. Recordings of group sessions will be destroyed once they have all been coded for reliability. All recordings, including from baseline, post-group, and 6 month follow up visits, will be destroyed after the study has been completed.

SIGNATURES:

The research team has discussed this study with you and answered all of your questions. Like any research, the researchers cannot predict exactly what will happen. Once you have had enough time to consider whether you should participate in this research you will document your consent by signature below. You will receive a copy of this signed document for your records.

_____
Printed Name of Research Participant

_____ _____
Signature of Research Participant Indicating Consent/Assent Date

_____ _____
Signature of Legally Authorized Representative (if applicable) Date

_____

*** If signed by a legally authorized representative, a description of such representative's authority must be provided**

Parent Consent as Participant
I have been given sufficient time to consider if I should participate in this study. I hereby give my consent to take part in this study as a research study subject.

_____ _____
Signature of Parent Research Participant Indicating Consent Date

Signature of Staff Obtaining Consent	Date