STUDY INFORMED CONSENT

Examining the Efficacy of the TEACCH School Transition to Employment and Post-Secondary Education Program

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University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants

Consent Form Version Date: 5/6/2022
IRB Study # 19-0627
Title of Study: Examining the Efficacy of the TEACCH School Transition to Employment and Post-Secondary Education Program
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CONCISE SUMMARY

The purpose of this research study is to examine the effectiveness of the TEACCH School Transition to Employment and Post-Secondary Education (T-STEP) Program. Participants will undergo a screening that includes IQ testing and completion of questionnaires. Once screening is complete, participants will be randomly assigned to receive the full T-STEP Program (class, counseling, internship) or the Counseling Program for 12 weeks. Participants will also be asked to complete a pre-assessment, post-assessment, and a follow-up assessment 4 months after the completion of the 12-week program. The total study duration is approximately 9 months.

The greatest risks of this study include the possibility loss of confidentiality and experiencing anxiety or emotional distress. Participants may benefit from this study by learning new skills to help in school or at work.

If you are interested in learning more about this study, please continue to read below.

What are some general things you should know about research studies?
You are being asked to take part in a research study. To join the study is voluntary.
You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

The purpose of this study is to learn more about what kinds of interventions help autistic young adults. We want to compare the TEACCH School Transition to Employment and Post-Secondary Education (T-STEP) Program to a counseling program that includes career counseling, higher education counseling, and self-advocacy counseling. We want to know if one of these interventions works better for autistic young adults. You are being asked to be in the study because you are an autistic young adult, age 18-21, who has or will graduate from regular course of curriculum in high school.

How many people will take part in this study?

Each year about 48 people will be in this study. The study will last three years, and 144 total people will be in the study.

How long will your part in this study last?

You will be involved in the research study for up to one year. This includes assessment visits, a 12-week intervention, and a follow-up 4 months after completion of the intervention.

What will happen if you take part in the study?

If you agree to be a part of this study, then the following things will happen:

Your caregiver will be asked to complete a demographics form providing information about you and your family. Your caregiver will also be asked to report on your social skills, organizational skills, and emotion regulation skills targeted by this intervention. Please see the outline below for more details:

1. Baseline assessment
    a. You will be given a short IQ test and your caregiver will complete a questionnaire that measures autism traits. These measures will help researchers make sure you are a good fit for the study. If you are not a good fit, the researchers will let you know and connect you with other resources.
    b. You, with the support of your caregiver, will complete an interview. This interview asks questions about things like your independent living skills, educational experiences and your communication skills. Your caregiver will also complete the demographics form at this time.
    c. If the IQ test and the interview show you are a good fit for the study, you will be assigned by chance to an intervention condition. You will either be in the T-STEP Program or the Counseling Program. Regardless of your intervention condition, you will complete a pre-assessment.
2. Pre-Assessment
    a. You will be given some questionnaires to complete as well as a short work skill assessment. The questionnaires will be about things like how you cope with stress and different feelings and emotions you have.
    b. Your caregiver will also complete questionnaires about skills you have related to work and behaviors you might have relating to planning and organization.
3. Intervention
    a. If you are assigned to the 12-week T-STEP Program you will:
        i. Participate in 24 class sessions (2 sessions each week). Your caregiver will receive regular newsletters outlining topics being discussed in class.
        ii. Complete an Internship (2 hours each week plus support meetings)
        iii. Receive Counseling in career exploration, higher education, and self-advocacy (1 hour each week)

b. If you are assigned to the 12-week Counseling Program you will:
    i. Receive Counseling in career exploration, higher education, and self-advocacy (1 hour of counseling each week)

4. Post assessment
    a. After you finish the T-STEP or the Counseling Program you will complete the questionnaires and a work skill assessment again.
    b. The same caregiver will also complete questionnaires again.
5. Follow up assessment
    a. Four months after completing the T-STEP or the Counseling Program we will contact you to ask about your grades in college and if you are working.
    b. You will also complete some of the same questionnaires a third time.
    c. The same caregiver will also complete some of the same questionnaires a third time.

You will be videotaped during assessments and intervention sessions. This will help researchers monitor the study.

If circumstances require remote or online interactions instead of in person interactions these same procedures will be followed using online platforms.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. This study will help researchers learn what intervention works best to help autistic young adults. The benefits to you from being in this study may be learning new skills to help you in school or at work. After the post assessment we will give you some recommendations about your strengths and weaknesses to help you continue to learn skills to help with work or school. We will also refer you to Vocational Rehabilitation, a state agency that helps people with disabilities find and keep employment. When the whole study is complete, we will send you a newsletter about what the researchers learned from the study.

What are the possible risks or discomforts involved from being in this study?

The greatest risks of this study include the possibility loss of confidentiality and experiencing anxiety or emotional distress.

If you feel anxious or distressed at any time you may speak with a program instructor in a private setting. An instructor will also meet with you regularly for the program and will give you opportunity to share any anxiety or distress you are feeling.

Parts of this program are conducted in a group setting. You are asked to maintain confidentiality of all discussions that happen in this group setting. If you feel embarrassed at any time during the group setting you may speak with a program instructor in a private setting to share your feelings and concerns.

While all laws and regulations will be followed, someone at the community college may know you have autism because you are participating in the program.

There may be uncommon or previously unknown risks. You should report any problems to the researcher.

If you choose not to be in the study, what other treatment options do you have?

Your participation in this study is voluntary. While you will not be able to receive the T-STEP Program if you do not want to be in the study, you can receive other services through the UNC TEACCH Autism Program if you do not participate.

What if we learn about new findings or information during the study?
You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will information about you be protected?
To keep information about research participants private, the researchers follow all rules for security and confidentiality of medical records from the state and federal government and the UNC Health Care System. We will keep all papers locked in research offices and electronic data will be saved on secure, encrypted servers.

You will not be identified by your name in any publications. We will do our best to keep the research records private but there may be times when federal or state law requires sharing your records, including personal information. This is very unlikely, but if it is ever required, UNC-Chapel Hill will take steps allowable by law to protect your personal information. The U.S. Department of Defense is providing funding for this study and they are allowed to review research records.

As a requirement from the sponsor, data collected through this study will be shared with the National Database for Autism Research (NDAR). Your name will not be included in this data and your privacy will be protected.

What if you want to stop before your part in the study is complete?
You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

If you withdraw or are withdrawn from this study all data collected up until the point of withdrawal will be retained, however no additional information will be collected unless you provide additional written permission for further data collection at the time of your withdrawal.

Will you receive anything for being in this study?
You will be given $25 for the completion of a pre-assessment, $25 for the completion of a post-assessment, and $25 for completion of a follow-up assessment. If you complete all three assessments, you will be given a total of $75.

Will it cost you anything to be in this study?
It will not cost you anything to be in this study.

Who is sponsoring this study?
This research is funded by the Department of Defense. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a

summary of the results. You can search this website at any time.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Participant's Agreement:
I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

CHECK √ ONE STATEMENT IN THIS BOX to show whether you want to be in the part of this study.

____**Yes,** I voluntarily agree to participate in the research study about the T-STEP program.

OR

____ **No,** I choose not to participate in the research study about the T-STEP program.

_____ I **allow** videos/audiotapes to be used for educational or training purposes such as presentation at scientific conferences or workshops.

OR

_____ I **do NOT allow** videos/audiotapes to be used for educational or training purposes such as presentation at scientific conferences or workshops

_____ _____
Signature of Research Participant Date

_____
Printed Name of Research Participant

_____ _____
Signature of Research Team Member Obtaining Consent Date

_____
Printed Name of Research Team Member Obtaining Consent

_____ _____

Signature of Witness if applicable; e.g. literacy issues, visually impaired, physically unable to sign, witness/interpreter for non-English speaking participants using the short form) Date

_____

Printed Name of Witness