Protocol Title:

Can a Novel Telemedicine Tool Reduce Disparities Related to the Identification of Preschool Children With Autism? (TAP-P)

Date: 04/25/2022

NCT05373173

Can a novel telemedicine tool reduce disparities related to the identification of preschool children with autism? (Aim 3)

Novel sample consent

You may save or print a blank copy of this consent form for your records if you wish. After you submit this form, you will be offered the opportunity to save or print a signed copy of this consent form.

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VUMC Institutional Review Board
Informed Consent Document for Research
Principal Investigator: Zachary E. Warren, Ph.D.
Study Title: Can a novel telemedicine tool reduce disparities related to the identification of preschool children with autism? (Aim 3)
Institution/Hospital: Vanderbilt University Medical Center

Revision Date:
Date of IRB Approval:
Date of IRB Expiration:

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1) Name of Participant:

_____
(First Last)

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2) Age:

_____

The following information is provided to inform you about the research project and your participation in it.

This consent form pertains to you and your child's participation in the research activities.

Please read this form carefully and feel free to ask any questions you may have about this study and the information given below. You will be given an opportunity to ask questions, and your questions will be answered. Also, you will be given a copy of this consent form.

Key Information: The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:

We are looking into new ways to evaluate preschool aged children with autism over telehealth.

Participation will involve two visits over a 7-day period.

The first visit will be over Zoom and the second visit will be at our research clinic at VUMC.

You will receive feedback about your child's development after the second visit.

There are no direct benefits to participating in this study. However, this study may help us understand more [illegible]

for ASD in new and better ways.

Detailed Information:The rest of this document includes detailed information about this study (in addition to the information listed above).

You are being asked to take part in this research study because you are the parent of a child who is at increased risk for autism spectrum disorder (ASD) and is between 36 and 72 months of age.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study.

Procedures to be followed and approximate duration of the study:

This study has two parts.

In the first part, you will fill out some forms and join a scheduled telehealth appointment. A psychologist will watch your child and talk to you over Zoom. The psychologist will ask you to play with your child in specific ways. The psychologist will also ask you some questions about your child. This is the experimental part of the study. Because we are testing out these new screening tools, you will not receive any test results at this visit. This appointment will take about 90 minutes.

In the second part, you and your child will come to VUMC for an in-person evaluation. During this standard of care assessment, a psychologist will play with your child and ask you questions about their development and behavior. At the end of the assessment, the psychologist will talk to you about whether or not your child has ASD. This appointment will take up to three hours plus travel time.

We will also ask you for feedback and give you two short questionaries to complete.

Expected costs:

There are no expected costs to participating beyond the cost of travel to VUMC for your in-person appointment.

Description of the discomforts, inconveniences, and/or risks that can be reasonably expected as a result of participation in this study:

The most common risk in this study is that some of the questions or activities may be uncomfortable or upsetting for you or your child. This is because we may ask questions about things that are hard or frustrating for your child. We will watch your child for signs of being upset, such as crying. We will take a break if your child is upset. We can stop the assessment if your child does not calm. You will be with your child whole time.

Another risk is a breach of confidentiality. We have steps in place to keep your and your child's information confidential.

Good effects that might result from this study:

a) The benefits to science and humankind that might result from this study.
The potential benefits to science and humankind that may result from this study include increased information about how to screen for ASD over telehealth. Conducting ASD screenings over telehealth will help to decrease travel and wait times for families.

b) The benefits you might get from being in this study.
There are no expected benefits to you for participating in this study.

Study Results:

When the entire study is complete, results will be published.

Alternative treatments available:

This is not a treatment study.

If you would like to recive more information about clinical pathways for reciveing an ASD evaluation for your child, please ask.

Compensation for participation:

You will be given a $100 Amazon gift card after your second appointment.

You are not allowed to accept any money for taking part in this study if you are not eligible to receive money from a U.S. person or company or the U.S. government because of U.S. national security and/or foreign policy laws. You can still take part in the study however, you will not be paid if you are a resident of a country restricted by the U.S. government's comprehensive territorial sanctions or if you are listed on the U.S. Treasury Department's Office of Foreign Assets Control's Specially Designated Nationals (SDN) list of prohibited individuals. You do not have to say why you choose not to be paid

Circumstances under which the Principal Investigator may withdraw you from study participation:

Study participation may also be discontinued in the event of repeated technology failures during tele-assessment. Should technology fail (e.g., lost connection that cannot be re-established), we will contact families by phone to schedule a second attempt. If this is also unsuccessful, will document this as part of our ongoing data collection processes while also routing families to appropriate clinical referral pathways.

If a child is in distress (i.e., crying, falling to the floor, shouting) then research staff will take a break and/or consult parents for input/help on how to best soothe their child.

The parent will always be given the option to take a break or end the evaluation if they think their child is too distressed to continue.

If a clinician thinks that the child appears to be too distressed to complete the evaluation, opportunities will be given to reschedule the assessment. If the parent declines, the clinician will note that the child was unable to complete the assessment and alternative clinical pathways will be provided.

What happens if you choose to withdraw from study participation?

Participants can withdraw from the study at any time. If a participant withdraws from the study, research team members will offer other options for having the child evaluated for ASD.

Contact Information.

If you should h ons possibly injury, please feel free to contact Zachary Warren at +1 [redacted] or [redacted].

For additional information about giving consent or your rights as a participant in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to contact the Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Confidentiality:

All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed.

The information kept in your child's research record will be de-identified, meaning that your child's research documentation will be assigned a number and will not include your personal information. Any personal information we collect from you will be kept separate from your de-identified research data. Your personal information, including the log used to document your family's research number and results of the diagnostic evaluation, will be kept on a secure VUMC server or in a filing cabinet behind two locked doors. Only research personnel involved in this research study will be given access to your personal information unless you provide written permission for us to share your information with anyone else, such as your child's pediatrician.

This study may have some support from the National Institutes of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

Data from this study may be submitted to the National Database for Autism Research (NDAR). NDAR is a computer system run by the National Institutes of Health that allows researchers studying autism to collect and share information with each other. With an easier way to share, researchers hope to learn new and important things about autism more quickly than before.

During and after the study, the researchers will send information about you or your child's health and behavior to NDAR. However, before they send it to NDAR, they will remove information such as name, address, and phone number, and replace that information with a code number. Other researchers nationwide can then file an application with the National Institutes of Health to obtain access to your study data for research purposes. Experts at the National Institutes of Health who know how to protect health and science information will look at every request carefully to minimize risks to you and your child's privacy.

You and your child may not benefit directly from allowing you or your child's information to be shared with NDAR. The information provided to NDAR might help researchers around the world treat future children and adults with autism spectrum disorders so that they have better outcomes. NDAR will report to Congress and on its website about the different studies that researchers are conducting using NDAR data; however, NDAR will not be able to contact you or your child individually about specific studies.

You may decide now or later that you do not want to share you and your child's information using NDAR. If so, contact the researchers who conducted the study, and they will tell NDAR, which can stop sharing the research information. However, NDAR cannot take back information that has already been shared by the time you withdraw. If you would like more information about NDAR, this is available on-line at http://ndar.nih.gov.

Privacy:

Information about you collected through this study may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the research done with your information. This research may help us or other researchers learn more about ASD, diagnosing ASD over tele-assessment, and how families get services for their children.

Authorization to Use/Disclose Protected Health Information:

What information is being collected, used, or shared?

To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?

The people who may request, receive or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?

You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?

Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?

You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

You have the right to see and copy the PHI we gather on you for as long as the study doctor or research site holds this data. To ensure the scientific quality of the research study, you will not be able to review some of your research data until after the research study is finished.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

3) I have read this informed consent document and the material contained in it has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to participate.

◯ Yes ◯ No

4) Signature of patient/volunteer:

_____
(Click "Add signature" and use your mouse (or finger on a touchscreen device) to sign.)

5) Date:

_____
(Date of Volunteer Signature)

6) Consent obtained by (please enter full name and title):

_____
(Signature of staff that obtained consent.)

7) Date:

_____
(Date of staff signature.)

Can a novel telemedicine tool reduce disparities related to the identification of preschool children with autism? (Aim 3)

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You are not allowed to accept any money for taking part in this study if you are not eligible to receive money from a U.S. person or company or the U.S. government because of U.S. national security and/or foreign policy laws. You can still take part in the study however, you will not be paid if you are a resident of a country restricted by the U.S. government's comprehensive territorial sanctions or if you are listed on the U.S. Treasury Department's Office of Foreign Assets Control's Specially Designated Nationals (SDN) list of prohibited individuals. You do not have to say why you choose not to be paid

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Confidentiality:

All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed.

The information kept in your child's research record will be de-identified, meaning that your child's research documentation will be assigned a number and will not include your personal information. Any personal information we collect from you will be kept separate from your de-identified research data. Your personal information, including the log used to document your family's research number and results of the diagnostic evaluation, will be kept on a secure VUMC server or in a filing cabinet behind two locked doors. Only research personnel involved in this research study will be given access to your personal information unless you provide written permission for us to share your information with anyone else, such as your child's pediatrician.

This study may have some support from the National Institutes of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

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You may decide now or later that you do not want to share you and your child's information using NDAR. If so, contact the researchers who conducted the study, and they will tell NDAR, which can stop sharing the research information. However, NDAR cannot take back information that has already been shared. If you would like more information about NDAR, this is available on-line at http://ndar.nih.gov.

Privacy:

Information about you collected through this study may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the research done with your information. This research may help us or other researchers learn more about ASD, diagnosing ASD over tele-assessment, and how families get services for their children.

Authorization to Use/Disclose Protected Health Information:

What information is being collected, used, or shared?

To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?

The people who may request, receive or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?

You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?

Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?

You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

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3) I have read this informed consent document and the material contained in it has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to participate.

◯ Yes ◯ No

4) Signature of patient/volunteer:

_____
(Click "Add signature" and use your mouse (or finger on a touchscreen device) to sign.)

5) Date:

_____
(Date of Volunteer Signature)

6) Consent obtained by (please enter full name and title):

_____
(Signature of staff that obtained consent.)

7) Date:

_____
(Date of staff signature.)