

Clinical Trial Consent Form Cover Sheet

Protocol ID: 23676

ClinicalTrials.gov ID: NCT06587139

Project Title: Evaluation of Teen Connection Project for Trans and Gender Minority Youth (TCP)

Principal Investigator: Dr. Katie M Edwards, PhD, University of Michigan

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Teen Connection Project: An Online Mentoring Program for Trans and Gender Diverse Youth (Youth/Mentee Assent)

IRB #: 23676

Short Title: TCP (Teen Connection Project)

Official Title: PILOT RCT OF TCP: Development and Pilot Evaluation of an Online Mentoring Program to Prevent Adversities Among Trans and Other Gender Minority Youth

Contact Information:

Email: tcproject@unl.edu

Phone: (402) 433-6449

Website: <https://go.unl.edu/tcp>

***Please allow one business day for us to return calls, texts, and emails. If you are in crisis, call 911 OR you can reach out to a 24/7 hotline which is on the resource sheet provided at the end of this survey. You can also get a copy at our website (above).**

This form tells you more about the research project so that you can decide if you want to be part of it. You **do not** have to get your caregivers' / parents' permission to be part of this project.

What is the key information I should know?

1. You are being asked to do some surveys and participate in an online mentoring program for trans and gender diverse youth. The program is 90 minutes, once a week, for seven weeks. There will be three longer surveys which you will be asked to do before and after the program. They will take you about 30 minutes each to complete. There will also be shorter surveys you will be asked to do after each program session.
2. You can earn up to \$200 for being in this research project.
3. Participation is voluntary; you do not have to do this.
4. You do **not** have to get your guardian/caregiver's consent to do this project.
5. You can stop participating at any time.
6. *There are minimal risks* to participating in this research study. Risks include feeling upset or other negative emotions and breach of confidentiality. These are discussed in more detail below.
7. You may or may not benefit personally from this research study.
8. You may text or call (402) 433-6449 or email (tcproject@unl.edu) if you have questions about this form.



Why am I being asked to be in this research project?

We are asking you to be in this project because you are between the age of 14 and 17 and identify as transgender or non-binary, which includes being gender queer, gender fluid, agender, Two Spirit and/or another gender minority.

Why are you doing this research project?

TGDY (transgender and gender diverse youth, like non-binary, gender queer, gender fluid, etc.) have many strengths and some challenges. We want to make a program for TGDY that help them to use their strengths to overcome things that are hard. Your voice is important in helping us make this program.

What are you asking me to do in this research project?

Overview of your commitment and responsibilities as a part of this project. We are asking you to do two things in this project: (1) take surveys online and (2) be part of an online program. If you agree to be in this project, we will ask you to take an online survey at three different time points. Each time you take the survey, it will be about 30 minutes. As a participant in this study, it is your responsibility to come to online program sessions as scheduled and let us (the research team: tcproject@unl.edu) know right away if anything negative happens because of being in this research project. Negative things include being upset by anything happening in this project and/or someone like a parent/caregiving finding out you were in the study and you getting in trouble or hurt because of that. We want to know right away if anything like this happens. If you cannot commit to doing these things, we ask that you NOT sign up for this project.

You will do the online program either in between the surveys or after the last survey. This means that some TGD teens will get the program pretty soon and other TGD teens will get the program in about five months. We use a computer program to randomize who gets the program when, kind of like flipping a coin. You have a 50% (1 in 2) chance of doing the program soon (within a few weeks) and a 50% (1 in 2) chance of doing the program in about five months. You will find out when you will do the program after you take this first survey.

Your total participation in this study will be about 13-14 hours over a five- or seven-month period depending on when you are assigned to get the program. The table on the next page provides a summary of what you are being asked to do:

Activity	Time for Activity (estimate)	Activity Details
Read this Assent Form	20 minutes (1x)	This form tells you more about the research project so you can decide if you want to do it. You can contact us with questions when deciding to do this research study. You can also contact us with questions, concerns, or feedback during and after the research study. You do not get paid to read this form.
Do a pre-program survey	30 minutes (1x)	You will be asked to do a survey before you do the TCP program. Details on survey content are below. You can skip questions you do not want to answer. You get paid \$10 for doing this survey.
Attend a Zoom meet & greet	10 minutes (1x)	You may be asked to attend a Zoom meeting so we can make sure you are who you say you are. We would ask you things like your name and your contact information that would be kept confidential. We have had people pretend to be TGDY so we do these Zoom meetings to make sure we can keep our community safe. You do not get paid for attending the Zoom screen. If asked to attend, you must come to this Zoom meeting; if you do not come, you will not get the \$10 for your pre-program survey.
Attend program sessions	90 minutes (7x so 10.5 hours)	You will be asked to participate in a program on Zoom with about 6 other TGDY and 7 TGD adult mentors. In the program you will learn about being proud to be TGD, healthy coping, and having safe and healthy relationships. The program will include lessons on these topics and time for you to meet 1-1 with a TGD adult mentor; you will get to provide input on who you want your mentor to be. You will not have contact with this person outside of the seven online sessions. You should only sign up for this project if you can commit to coming to all the seven sessions.
Do post-session surveys	10 minutes (7x so 70 minutes)	You will be asked to complete a short survey after each of the seven sessions telling us what you liked about the session, how to make it better, if anything upset you, and if/how it impacted you. You can skip questions you do not want to answer. You will get \$20 for each of these surveys.
Do a survey 2 months from today	30 minutes (1x)	You will be asked to do a survey two months from today. Details on survey content are below. You can skip questions you do not want to answer. The questions on this survey are very similar to the questions on the pre-program survey. You get paid \$20 for doing this survey.
Do a survey 4 to 5 months from today	30 minutes (1x)	You will be asked to do a survey four to five months from today. Details on survey content are below. You can skip questions you do not want to answer. The questions on this survey are very similar to the questions on the pre-program and 2-month survey. You get paid \$30 for doing this survey.

Survey Content. The surveys will ask about things like how you feel about yourself, including your strengths. We will also ask you about your mental health and behaviors, alcohol and drug use, sexual activity, and your relationships, including aggressive behaviors and unwanted sexual experiences. If we determine based on your survey responses that you are not answering honestly and pretending to be a TGDY, you will not be paid or allowed to continue in the project. You may be required to attend a brief Zoom meeting for us to make sure you are who you say you are. This is meant to protect the integrity of our research study and to protect our queer community as well.

Program Content. The program will have seven sessions, with one session per week, held at the same time every week. There will be options for the program so you can pick the day/time that works best for you. You will learn more about signing up for the program after you take the first survey today if you choose to participate. Each of the seven sessions will be about 90 minutes long. The sessions will happen online on a program called Zoom. After each of the seven sessions, you will be asked to take a short survey that will take about 5 to 10 minutes. The program sessions are meant to be fun! You will get to meet other TGDY and TGD adults (who will serve as mentors in the sessions). You will also do fun activities like watch videos and learn skills to help you have a healthy and happy future.

It is important that if you are accepted into the program that you come to all sessions. Please do not sign up for this project if you cannot commit to coming to all the sessions. Also, you should always be in a safe and private place when doing the program. No one else can hear or see you doing the program. Finally, you should know that you will **only** have contact with the mentors during TCP sessions and for a period of seven weeks only. However, you can have contact if you wish with the other TGDY in the program, but you do not have to.

Recording. We will video and audio record each session so we can see how things are going. We will not share these recordings with anyone outside of our research team. We, however, cannot guarantee complete confidentiality because these sessions will have other teens in the group, and we cannot guarantee that they will keep things confidential even though we will ask them to. Also, only program participants can attend (no parents, siblings, or friends).

Contact Information. We will ask you to give us your contact information when you sign up for this project. If at any point your contact information changes or one of the ways you said was OK to contact you is no longer safe, please reach out to us and we will make sure to update our information so that we only contact you in a way that is OK for you and safe. It is important we be able to contact you to remind you of program sessions and send you the link to the final, online survey. We will also use this to contact you if you say you are in danger of hurting yourself in a program session or on the survey.

What will you do with the information I tell you?

We will not share what you tell us with other people UNLESS you tell us during a program session or by email/text/phone or in a survey: (1) about a child, including yourself, being

hurt or abused, (2) that you plan to hurt yourself or someone else, and/or (3) if someone else, like an elderly or disabled person, is being hurt or abused. If you tell us that you or someone else is in danger, we will have to do a few things to make sure you are safe. Specifically, we will first set up a meeting with you on the phone or on Zoom to get more information about the situation. If after this meeting we are still concerned about someone, including yourself, being hurt or abused, we may then need to contact your trusted adult and/or the authorities (e.g., police, child protective services) in your area about what we know so that they can take steps to keep people safe. We will tell you that we are doing this, so you know what will happen next.

Before the start of the program, after the program, and three months after the program, you will be asked to answer questions on a survey to make sure that you are doing OK and that you are safe. The reason we are asking you these questions is because unsafe feelings can happen suddenly among some teens. If the questions on the survey tell us that you are not safe, one of our study staff will contact you. You can reach out to us if you need help with resources. We will respond within one business day. If you are ever in a crisis like thinking of hurting yourself, call 911.

This study involves the collection of private information (name, dates, etc.) so that we can link survey data across time, send you reminders about upcoming program sessions and surveys, and compensate you with gift cards. Information collected as part of research will be used for internal purposes by the research team only. It will not be used or distributed to other people outside of this research team for new research studies.

How might I feel being in this research project?

Sometimes teens report being sad or feeling awkward when being asked on surveys about certain feelings and experiences. Remember that you can skip questions on the surveys that you do not want to answer. After every survey that you take and after each of the program sessions, we will make sure that you know of safe places and people you can contact if you need help for yourself or someone else. You can always reach out to us at any time if you or someone else you know needs help to be safe.

Do I have to be in this research project?

No, you do not. If you say you do not want to do this project, you will not be in trouble. You can stop being in the project at any time. You can also skip questions that you do not want to answer on the surveys. You also do not have to talk in the program sessions if you do not want to do so. If you decide you do not want to be in this project anymore, you do not have to tell us why you do not want to be in the project. Be aware, that depending on when you withdraw or decide you no longer want to participate, you will only be paid for the surveys you have already completed.

Will I benefit from being in this research project?

You may not benefit from being in this project. However, some teens tell us that they like to share their ideas and help other people. By being in this project, you are helping other TGDY live safe, happy, and healthy lives. You may also feel better about yourself and being TGDY after taking TCP.

Will other teens benefit from this research project?

We will ask you questions about what you like about the program and how to make it better for other TGDY. You will also help us make the surveys better. We will take all the feedback that you give us to make the program better before we offer it to more TGDY all over the United States! Your voice is important to us!

This project has a Certificate of Confidentiality. What does this mean?

To help us protect your privacy while you are in this project, this project has something called a Certificate of Confidentiality from the U.S. Government. We can use this Certificate to legally refuse to provide information that could identify you to others, such as if we received a subpoena (legal document) from a court asking for this information. We would use this Certificate to respond to any orders for information that would identify you, except as explained below: The Certificate cannot be used to refuse a demand for information from people who work for the U. S. Government who want this information to audit (review) projects that receive money or funding from the U.S. Government. You should understand that a Certificate of Confidentiality does not prevent you from providing information to other people about being in this research project. If someone has your written consent (permission) to receive information about your participation in this project, we cannot use the Certificate to refuse to provide that information. We will also still tell state or local authorities (e.g., the police, child protective services) if you tell us about a child (including yourself) being abused or hurt, or if you tell us that you plan to hurt yourself or someone else.

What will I get from being in this research project?

We will give you a \$10 gift card for the survey today, a \$20 gift card for the survey you will do in about two months from today, and a \$30 for the survey you will do in about five months from today. You will also get a \$20 gift card for completing a short survey for each of the seven-program sessions that you attend. We ask that you accept the payment via email in the form of a Visa gift card as this is the fastest and easiest way to get participants their compensation. If you receive the gift card through email, you will receive a Visa gift card within about a week. If you need to receive a gift card through text message, you will receive an Amazon gift card within about two weeks. If you need to receive a gift card through mail, you will receive a Visa gift card within a few weeks. In total, you can earn up to \$200 in gift cards for being in this project.

Even if you skip survey questions you will still get the gift card. However, you must get to the end of the survey to get the gift card. You will also still get the gift card if you do not talk in the sessions, but you need to stay for the entire session and do the brief survey (you can skip questions) after the session to get the gift card. You do not have to receive the gift cards if you do not want to do so. You will also get a certificate for completing the program.

What public information will be shared about this study?

Information about this study will be shared on our project website: go.unl.edu/tcp. Information about this study will also be shared on the website: ClinicalTrials.gov. This is a website that provides information about federally and privately supported studies like this one that are designed as clinical trials. A description of this clinical trial will be posted and made available on <http://www.ClinicalTrials.gov>, as required by U.S. Law.

Both of these websites will not include any 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 are my rights as a research subject in this research project?

You may ask any questions about this research project and have those questions answered before agreeing to participate in or during the study. For project related questions, please contact the TCP program office at (402) 433-6449. You can contact us by calling or texting us. You can also email us if you prefer at TCproject@unl.edu.

For questions concerning your rights or complaints about the research contact the University of Nebraska - Lincoln Institutional Review Board (IRB): Phone: 1(402)472-6965 Email: irb@unl.edu

This study was approved by the University of Nebraska – Lincoln Institutional Review Board.

Agreement: You are voluntarily making a decision whether or not to be in this research study. Signing this form means that:

1. you have read and understood this consent form,
2. you have had the consent form explained to you if you have needed it to be explained to you,
3. you have had your questions about the consent form answered and
4. you have decided to be in the research study.

You will be given a copy of the signed and dated consent form to keep.

I have read the procedure described above. By choosing “Agree,” I voluntarily agree to participate in this study.

Please type your name here:

<<Agree>>

<<I do not agree, I do not wish to participate [ineligible]>>

I commit to attending all seven program sessions.

<<Agree>>

<<I do not agree [ineligible]>>

Please sign here:

Dr. Katie Edwards

You will be given an electronic .pdf copy of this form.