Official Title: Creating Access to Resources and Economic Support

NCT: NCT05971160

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CARES Consent Form

CONCISE SUMMARY

You are being asked to take part in this research study because you are transgender and you are experiencing material hardship. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As staff discuss this consent form with you, please ask them to explain any words or information that you do not clearly understand. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

A grant from the National Institutes of Health (NIH) will sponsor this study. Portions of Tonia Poteat's and her research team's salaries will be paid by this grant.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to learn how small grants and peer support will affect the mental health of transgender and/or gender non-binary adults who have financial problems. All participants in the study will receive 1 microgrant of $150. Some participants will be chosen at random to receive more than 1 microgrant. Once you are enrolled in the study, I will put your name into a computer and it will randomly decide whether you will receive one or more microgrants. Some people in the study will also be randomly chosen to participate in peer mentoring sessions. I will let you know if you have been randomly selected for peer mentoring as well. The reason that some participants receive more microgrants and some receive peer mentoring is because we do not know if more microgrants and/or peer mentoring will be beneficial. This is the reason we are doing this study--to figure out what types of resources will help people the most, so we need to be able to compare people's different experiences to learn this. In the end, we will be able to identify ways that community organizations can better support the mental health of transgender and/or gender non-binary people and we will make recommendations,
based on what we learn, to community organizations that serve transgender and/or gender non-binary people.

People who participate in this study should identify as a transgender and/or gender non-binary person and report having at least one financial difficulty.

You should not be in this study if you do not think the study team will be able to contact you on a regular basis by phone or email.

If you choose to communicate with the study team via email, it is highly recommended that you use a personal email address rather than a work email address to ensure your privacy, as some employers reserve the right to view all employee emails.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

About 360 people will take part in this study. All participants will live in the United States of America.

WHAT IS INVOLVED IN THE STUDY?

If you agree to be in this study, you will be asked to sign and date this consent form.

If you decide to take part in this study, you will complete the steps listed below:

You will be randomly put into one of three groups at the beginning of the study. The group you are put in is completely random and is decided by a computer. It is like picking a name from a hat or rolling dice. No one knows in advance which group anyone will end up in. You have an equal chance of being in each group. Once you have been assigned to one of the groups, you cannot change which group you are in. If you, for whatever reason, do not like the group you are put in, you can choose not to participate in the study. However, if you do not like your group, you cannot reenroll for the study and try to get put in another group. You will have the choice of staying in the study and participating in that group or leaving the study.

Here is a little more information about the groups that you might be put in. Remember, you will only be put into one group, and you will stay in that group for the whole study. You will not interact with any other participants in your group and all of the activities that you do as a part of this study will be done independently or with the help of a researcher.

People in Group A will get a $150 microgrant during their first month of the study. They will be asked to fill out 4 surveys over the next 12 months. They will need to fill out the first 30-minute survey and provide their contact information before they can receive their microgrant. Participants from Group A might also be asked to participate in an interview with a researcher to learn more about them. People are randomly selected for interviews, and they are welcome to decline if they do not want to participate.

People in Group B will get $150 each month for 6 months (for a total of 6 microgrants that equals out to $900 over 6 months). They will also be asked to fill out 4 surveys over the course of 12 months. They will need to fill out the first 30-minute survey and provide their contact information before they can receive their microgrant. Participants from Group B might be asked to participate in an interview with a researcher to learn more about them. People are randomly selected for interviews, and they are welcome to decline if they do not want to participate.

People in Group C will receive $150 per month for 6 months and take part in a one-on-one peer mentoring session every 2 weeks for 3 months. They will also be asked to fill out 4 surveys over the course of 12 months. They will need to fill out the first 30-minute survey and provide their contact information before they can receive their microgrant. Participants from Group C might be asked to participate in an interview with a researcher to learn more about them. People are randomly selected for interviews, and they are welcome to decline if they do not want to participate.
Here are some more details to help you fully understand what will happen in this study:

Depending on which group you are in, you may do different activities. Here are the activities that people in all groups will do:

You will receive a $150 micro-grant at the beginning of the study. You will be given this money on a gift card. There are no rules around how you spend this money. It is given to you and you can spend it how you wish. We will ask you questions about how you spend your money so we can learn about the kinds of things people buy when they are given a bit of extra money.

You will be sent a financial education video every month for the first 5 months and 1 additional video in the 6th month, for a total of 6 financial education videos. The goal is to give you some helpful information about things related to finances, like opening a bank account or creating a budget.

You will complete a 30-minute online survey at baseline, 6 months, and 12 months. You will be paid for completing each survey.

You will complete a text message survey lasting less than 10 minutes at 3 months. You will be paid for completing this survey.

Other activities will only be for certain groups. Here is a breakdown of how this will work:

Groups B and C Only:

People that get randomly picked to be in groups B and C will get $150 micro-grants for 6 months (remember one group, group A, will get a micro-grant for one month), for a total of 6 monthly stipends. These will be in the form of an online gift card, the same as the first micro-grant.

Group C Only:

Participants in Group C will be matched with a peer mentor, who will meet with them one-on-one virtually every two weeks for three months for a total of six sessions. A peer mentor is a person that has been trained to help with goal

setting. Peer mentors will ask about areas of life where participants want to set goals and help them build strategies to accomplish those goals.

HOW LONG WILL I BE IN THIS STUDY?

Here is a summary of the timeline for this study. Please feel free to ask any questions as I go through this:

Please note: you must confirm your identity before we can send you a microgrant payment. If we cannot get in touch with you to confirm your identity, you will not receive your payment. If you miss consecutive payments, because we cannot get in touch with you to confirm your identity, we will backpay no more than 1 microgrant payment (meaning the maximum number of microgrant payments you can receive in one month is 2- your current payment plus one back payment). You can only receive backpayment for missed microgrants one time during your participation in this study. Any future missed grants will not be backpayed and will be considered missed. This means that, if we cannot get in touch with you, you could miss some or all of the microgrants listed below.

Beginning of Study/Month 1

ALL GROUPS:

You will complete an online survey lasting 30 minutes. You will receive $50 for completing this survey. You will watch a financial education video that lasts about 5 minutes. You will receive a $150 microgrant. GROUP C ONLY:

Every two (2) weeks, you will talk to a peer mentor for about 1 hour Month 2

ALL GROUPS:

You will watch a financial education video that lasts about 5 minutes. GROUP B AND GROUP C:

You will receive a $150 microgrant. GROUP C ONLY:

Every two (2) weeks, you will talk with a peer mentor for about 1 hour. Month 3

ALL GROUPS:

Will watch a financial education video that lasts about 5 minutes. You will complete a text message survey lasting no more than 10 minutes. You will receive $10 for completing this survey. You may be asked to participate in an in-depth interview that lasts about 1 hour. If you complete the interview, you will receive $50. GROUP B AND GROUP C:

You will receive a $150 microgrant. GROUP C ONLY:

Every two (2) weeks, you will talk with a peer mentor for about 1 hour. Month 4

ALL GROUPS:

You will watch a financial education video that lasts about 5 minutes. GROUP B AND GROUP C:

You will receive a $150 microgrant. GROUP C ONLY:

Your peer mentor will call you to check in and see how you are doing. Month 5

ALL GROUPS:

You will watch a financial education video that lasts about 5 minutes. GROUP B AND GROUP C:

You will receive a $150 microgrant. GROUP C ONLY:

Your peer mentor will call you to check in and see how you are doing. Month 6

ALL GROUPS:

You will complete an online survey lasting 30 minutes. You will receive $50 for completing this survey. You will watch a financial education video that lasts about 5 minutes. GROUP B AND GROUP C:

You will receive a $150 microgrant. GROUP C ONLY:

Your peer mentor will call you to check in and see how you are doing. Month 9

ALL GROUPS

You may be asked to participate in an in-depth interview that lasts about 1 hour. If you complete the interview, you will receive $50. Month 12

ALL GROUPS

You will complete an online survey lasting 30 minutes. You will receive $70 for completing this survey. If you agree to be contacted after the end of the study, we will share results of the study with you in an electronic newsletter

WHAT ARE THE RISKS OF THE STUDY?

While you are answering survey questions, you may experience some emotional discomfort or distress because some questions ask about issues that may be sensitive. You do not have to answer any questions that make you uncomfortable and we provide a "prefer not to answer" option for sensitive questions. You can select this response if you do not wish to provide an answer to that question.

If there is a breach of privacy or confidentiality, it is possible that someone outside of the study team may learn information about you that has been collected for this study. The study team will take every measure to protect your information. We describe these measures in the section below, "Will My Information Be Kept Confidential?"

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

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

Research is designed to benefit society by gaining new knowledge. By taking part in this study, you will help us learn about financial and mental health challenges for transgender people in the United States of America. This information will be shared with organizations that provide services to transgender people to help them learn more about the types of programs that are helpful.

You, as an individual, might not benefit directly from being in this study. However, by being in the study, you might learn more about managing money.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. For example, our study partners at Johns Hopkins University will help us store and manage the data you share with us, so our approved study partners at Johns Hopkins will be able to see the information you share with us. If you are assigned to the peer mentoring intervention, your contact information will be shared with the National Black Trans Advocacy Coalition (BTAC), since they will be overseeing this intervention for the study. We will provide BTAC with your contact information so that they can get in touch with you to schedule your peer mentoring sessions. BTAC will not share specific information that you discuss with your peer mentor, but they will tell us which sessions you have completed, so that we know how much of the peer mentoring intervention you have done. We will share as little information about you as we can and will only share your information in ways that help us do our research. Your personal information may also be given out if required by law but we will only do this if we are legally obligated. This study has a Certificate of Confidentiality, that means that we cannot be made to share your information in a criminal or civil investigation. Please see below for more information about a Certificate of Confidentiality to learn more.

The study team will make every effort to protect your information. The study team will not share any information that can be used to identify you outside of the study team. The study team will assign you a unique ID number and that will be used in place of your name on all study forms and reports. That makes it more difficult for anyone outside of the study team to link you to the data that we collect for this study. All electronic survey and text data will be kept on password-protected, encrypted computers. Only trained members of the research team will have access to passwords. We will ask you about the best way to contact you about the study, and if anyone else has access to that mode of contact. If so, we will ask your permission to leave a message about the study that does not indicate what the study is about. We will only leave a message if we have your permission.

You will not be identified in any report or publication about this study. We may use de-identified data from this study in future research without additional consent.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, Duke University will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies for purposes such as quality control or safety. Participants will not be identified in any report or publication about this study. We may use de-identified data from this study in future research without additional consent.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:
1) The law requires disclosure (such as to report child abuse or communicable diseases but not for use in proceedings);
2) You have consented to the disclosure, including for your medical treatment; or

3) The research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others. This information may be further disclosed by the sponsor of this study. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed. Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

WHAT ARE THE COSTS TO YOU?

There is no cost for you to participate other than your time and effort. Standard messaging rates may apply when completing the short text message surveys.

WHAT ABOUT COMPENSATION?

You will be reimbursed up to $280 for your time participating in this study

Payment for completion of study activities will be as follows:

$50 for a 30-minute baseline survey; $50 for a 30-minute survey at 6 months; and $70 for a 30-minute survey at 12 months for a total of $170 $10 for one short text message survey at 3 months $50 per in-depth interview (12 participants per Study Arm); two (2) in-depth interviews for a total of $100 You will only receive incentives for study activities that you complete in full. Once you start the study you have one year to complete it, but some study activities will close after a certain period of time. We will let you know how long you have to complete activities before they close. If you do not complete an activity before it closes, you will not be paid for that activity. However, you can stay in the study and move on to the next activity. Some study activities involve a fraud check. This fraud check will make sure that only enrolled participants complete the study and that someone is not using your link to take surves on your behalf. We reserve the right to withhold your incentive payment if we suspect fraudulent activity. This means that you will not be paid for an activity if we think that someone, other than you, filled out the survey. If we suspect fraud, we will reach out to you to confirm whether you were the person that completed a survey or study activity. If we cannot confirm the study activity was completed by you, we reserve the right to withhold the study incentive for that activity.

Any payment provided for participation in this study, including the small grants, may be subject to applicable tax withholding obligations.

Your legal name, address, and U.S. taxpayer identification number (SSN or ITIN) are required to process payments and/or to report taxable income to the IRS. You must complete a W-9 (for U.S. persons) or W-8BEN and the Foreign Vendor Withholding Assessment with supporting documents (for non-resident participants) in order to receive payment for participation.

U.S. person participants must complete Form W-9 in order to receive payment for participation. If payment by Duke equals or exceeds $600 per calendar year for U.S. persons, Duke will report the amount to the Internal Revenue Service on Form 1099. Nonresident participants must complete Form W-8BEN and the Foreign Vendor Withholding Assessment with supporting documents in order to receive payment for participation. Payments to nonresident participants may be subject to tax withholding and are generally reported to the Internal Revenue Service on Form 1042-S. This information will not be linked to any of the study data and will only be used for payment purposes.

If you do not provide your SSN or ITIN, or complete the appropriate documentation noted above, we cannot issue you a payment for participation.

WHAT ABOUT RESEARCH RELATED INJURIES?

Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. Tonia Poteat at 919-684-9303 during regular business hours and at tonia.poteat@duke.edu after hours and on weekends and holidays.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

Participating in this study is completely voluntary. You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal. All data that have already been collected for study purposes will be sent to the study sponsor.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled. If you do not sign this consent form, there will be no consequences, but you will not be able to participate in the study. If you decide to participate and then later decide to withdraw, we ask that you contact our study staff and let them know that you are withdrawing from the study.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

The sponsor or regulatory agencies may stop this study at any time without your consent. Reasons why this might occur include loss of funding. You will also be removed from the study for misconduct such as harassment or abusive behavior toward any member of the study team. If this occurs, you will be notified of your withdrawal from the study. Soon after you enroll in the study, a survey will be sent to you by email, this is called the baseline survey. If you do not complete the baseline survey within 30 days of receiving it, you will be removed from the study.

Your data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name, are removed. Once your identifying information has been removed, we will no longer be able to tell which data came from you and cannot select that data for removal from the data set.

A description of this clinical trial is available on https://clinicaltrials.gov/ as required by U.S. Law. This website does not include information that can identify you. You can search this website at any time to find more information about this study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

If you have questions about your participation, please contact the researcher, Dr. Tonia Poteat, by calling 919-684-9303during regular business hours or by sending an email to tonia.poteat@duke.edu.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

Please select one:

◯ I have read the consent document and I wish to participate in the study.
◯ I have read the consent document and I DO NOT wish to participate in the study.

First Name _____

Last Name _____

Email Address _____

DUHS IRB
IRB NUMBER: Pro00113319
IRB REFERENCE DATE: 12/13/2023
IRB EXPIRATION DATE: 07/12/2025

Signature

_____

Date

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DUHS IRB

IRB NUMBER

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IRB EXPIRATION DATE

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Survey PDF