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San Diego State University
INFORMED CONSENT FORM OR MINOR ASSENT FORM
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SUICIDE PREVENTION FOR SEXUAL AND GENDER MINORITY YOUTH: CASE SERIES

IMPORTANT THINGS TO KNOW ABOUT THIS STUDY:

This research study is a suicide prevention project designed specifically for LGBTQ+ young people, ages 15-29 called Queer CARE. The purpose of the research is to develop ways to help queer young people who are at risk for suicide with managing thoughts of suicide and to find out if we can deliver the intervention in the way that we planned.

The reasons that you may want to participate in this study is that you may learn more about ways to cope with thoughts of suicide. You may also be linked to community resources and affirming mental health care which could be helpful to you.

We are asking 40 people to take part in this study. This study has two phases. In this phase, we are asking 10 people who join this study to complete 2 assessments over 3 months. You will also receive the help of a mental health advocate during the 3-month period of time. The study involves filling out surveys, taking part in interviews, and meeting and communicating with a mental health advocate.

For this part of the study, we want to know whether we can deliver the intervention as we planned. We do not know if we can deliver the intervention in the way that we planned. We do know that part of the intervention has helped other people who are at risk for suicide.

You do not have to join this study. You can choose standard methods to treat your condition instead of taking part in this study. These are the reasons you might want to join this study: 1) you may learn more about how to manage suicidal thoughts; and 2) you may be connected to mental health care and community resources. These are the reasons you might not want to join this study: 1) you might reflect on unpleasant memories or talk about certain things that you may find distressing and may experience anxiety as a result; and 2) you might have concerns about the privacy of the information that you share with us.

We will give you details about the purposes, procedures, risks, and possible benefits related to this study. We will explain other choices you have. We will also give you any other information that you need to make an informed decision about joining this study.

The following information is a more complete description of the study. Please read this description carefully. We want you to ask us any questions that will help you decide whether you want to join this study. If you join the study, we will give you a signed copy of this form to keep for reference in the future.

WHO SHOULD I CONTACT IF I HAVE QUESTIONS OR CONCERNS?

Principal Investigator: Kristen J. Wells, PhD
SDSU Department: Psychology
Address: 6363 Alvarado Court, Suite 103, San Diego, CA 92120
Phone: 619-594-1919
Email: kwells@sdsu.edu

Principal Investigator: Aaron Blashill, PhD
SDSU Department: Psychology
Address: 6363 Alvarado Court, Suite 103, San Diego, CA 92120
Phone: 619-594-2245
Email: ajblashill@sdsu.edu

WE ARE INVITING YOU TO JOIN THIS RESEARCH STUDY.

We are inviting you because you have previously attempted suicide and you have recently had thoughts of suicide.

A total of 40 people will be included in this study. This study has two phases. Ten people will be included at San Diego State University (SDSU) in this phase of the study.

Research is not the same as treatment or other medical or psychological care or therapy. The purpose of research is to answer scientific questions.

WHY ARE WE DOING THIS STUDY?

We are doing this study to find out the best way to deliver an intervention to help people who are at risk for suicide. We want to know if we can give the intervention in the way that we planned. We also want to know if we can collect data in the way that we planned.

WHAT IS THE TIME COMMITMENT IF I JOIN THIS RESEARCH STUDY?

Your participation will last three months. You will complete surveys and interviews. You will fill out two surveys. One will be today, and the second will be in three months. You will also meet with a mental health advocate who will help you make a safety plan for when you may be thinking about suicide. The mental health advocate will contact you using a way that you prefer (for example, on the phone) throughout the three-month study period. The mental health advocate may also meet with you at a location that you choose if you prefer that. The mental health advocate will contact you or meet with you to provide you with support and to help you access resources that may be helpful to you. It is difficult to guess how much time you may spend with the advocate because it depends on your needs.

The research scientist could stop your participation in the research study at any time even if you want to still be in the study. This would happen if:

- They think it is in your best interest to stop being in the study.
- You are not able to do all the things needed in the study.
- The whole study stops.

If you stop being in the study, your information collected before you stopped being in the study will be included in the study.

WHAT WILL I BE ASKED TO DO IN THIS RESEARCH STUDY?

To determine if you can join the study, we will ask you some questions today. You will be asked your age, your sexual orientation and gender identity, the county in which you live, the language(s) that you speak and read, and whether you have thought about harming yourself or harmed yourself in the past. If your answers indicate you can participate then we will ask you to fill out a survey and complete an interview.

During the study, you will be asked to complete two surveys. You will complete the first survey today and also participate in a brief interview, which will be audio recorded. You will be asked to fill out the survey yourself, and a member of the study staff can help you with it. The interview will be done by a member of our team. We will also ask you to complete an assessment in three months to fill out a new survey and take part in a new interview, part of which will be audio recorded. In the event that you are not able to visit SDSU, you will be given the option to complete study assessments remotely, using Zoom (a free video calling platform) with audio and video capabilities.

You will also meet with a mental health advocate who will help you make a safety plan for when you may be thinking about suicide. This session will be audio recorded. The mental health advocate will also connect you with resources that may be helpful to you. The mental health advocate will contact you using a way that you prefer (for example, on the phone) throughout the three-month study period. The mental health advocate may also meet with you at a location of your choice if you prefer that.

If you are not eligible to participate, we will provide you with a list of resources in the community that may be helpful for you. If you are not eligible to participate, we will keep your answers to the questions for our analyses.

Table of Study Visits and Time Requirements.

	Assessment 1 Day 1	*Time Between Assessments 1 and 2*	*Assessment 2 Month 3*
Interview and surveys	*X*		*X*
Meet and communicate with mental health advocate		*X*	
Total time	*3 hours*	*Variable amount of time*	*2 hours*

WHAT ARE THE RISKS OR DISCOMFORTS INVOLVED IN THE RESEARCH?

The risks of the study are the same as what you face every day. Even though we will keep information collected in surveys and interviews private, there is a possible risk of loss of privacy. We will do our best to keep the information that you share with us private. Since we need to get in touch with you in the future, we will need to have your contact information. When this information is stored on a computer, we will encrypt and password protect files that have the contact information. We will also not link this contact information to the data that we collect from you during the study. We will not use your name in our research but will assign a number to the surveys, interviews, and audio files. We will lock up all of the paper, audio, and computer files. Only the study staff will be allowed to access study records. If you do not feel comfortable while you are taking part in the study, you can stop being part of the study at any time.

Because we ask personal questions about you, you might remember unpleasant things or experience distress (such as anxiety). You will learn more about ways to recognize and cope with thoughts of suicide. You can refuse to answer any questions that you do not want to answer. You also can decide you want to stop participating.

We may discover new information during this research study. This new information my affect whether or not you want to still be in the study. We will tell you so that you can decide if you still want to be in the research.

ARE THERE ANY BENEFITS TO PARTICIPATION?

The information that you are providing may help you learn more about ways to reduce your risk for suicide. Everyone who takes part in the study will be provided with referrals to local mental health providers and local/national suicide crisis hotlines. A mental health advocate may help you get other information and resources that you need. However, we cannot be certain that you will receive any benefits by being in this study.

The information that is gained from the study may help other people get better health care and know more about preventing suicide. In other words, your participation may help people in the community improve their mental health.

ARE THERE ANY ALTERNATIVES TO JOINING THIS RESEARCH STUDY?

An alternative is not to participate in the study.

WILL MY INFORMATION BE PRIVATE?

We will keep your information private to the extent allowed by the law. There are many steps that we will take to keep your information private. As soon as the research team identifies a person who may be interested in participating, the person will be given a four-digit number starting at “0001.” The study number will be used on all data collection forms and computer files instead of the participant’s names. Research files (for example, surveys, interviews, audio files) will be kept at San Diego State University. These will be kept in a locked filing cabinet and on a computer that has a password protecting it. Only the study staff will be allowed to access study records.

The computers where study data will be stored may be connected to the internet. Study data may be stored on a university-managed Google drive which can only be accessed using a password-protected login. The study Google drive follows university IT security procedures. Access to the study Google drive will be limited to study staff. Files which have study data will not be linked to your name or contact information.

Some of the study data will be collected using the Qualtrics survey system. Qualtrics uses Transport Layer Security (TLS) encryption (also known as HTTPS) for all transmitted data. Access to the study survey and data will be limited to study staff who must use a password to access study surveys and data.

Audio tapes will be used to record informed consent, interviews, mental health advocate sessions, and key informant interviews. You will not be identified in these audio files. Audio files from the intervention sessions will be used to evaluate whether the mental health advocate delivered the session as planned. Audio files from the interviews with people who complete the study will be transcribed and used to see if the intervention and study procedures are feasible and acceptable. The audio recordings will be stored through the completion of these study activities or within three years. You will not be able to review and edit the recordings prior to study publication.

We will use the information we learn for published articles or for presentations to other scientists. Again, we will keep your information private. Others will not be able to identify you in those papers or presentations.

All data that you provide in this study will be de-identified. This means that the researcher will remove all information that can identify you (such as name, address, and birthdate) from the information that you provide in this research.

Data from this study will be submitted to the National Institute of Mental Health Database (NDA) at the National Institutes of Health (NIH). The National Institute of Mental Health Database is a large database where de-identified study data from many National Institute of Mental Health (NIMH) studies are stored and managed. Sharing your deidentified study data helps researchers learn new and important things about mental health more quickly than before.

During and after the study, the study researchers will send de-identified study data about your health and behavior to the National Institute of Mental Health Database. Other researchers across the world can then request your de-identified study data for other research. Every researcher (and institutions to which they belong) who requests your de-identified study data must promise to keep your data safe and promise not to try to learn your identity. Experts at the National Institute of Health who know how to keep your data safe will review each request carefully to reduce risks to your privacy. Sharing your study data does have some risks, although these risks are rare. Your study data could be accidentally shared with an unauthorized person who may attempt to learn your identity. The study researchers will make every attempt to protect your identity.

You may not benefit directly from allowing your study data to be shared with the National Institute of Mental Health Database. The study data provided to the National Institute of Mental Health Database may help researchers around the world learn more about mental health and how to help others who have problems with mental health. The National Institute of Mental Health will also report to Congress and on its website about the different studies using the National Institute of Mental Health Database data. You will not be contacted directly about the study data you contributed to the National Institute of Mental Health Database.

You may decide now or later that you do not want your study data to be added to the National Institute of Mental Health Database. You can still participate in this research study even if you decide that you do not want your data to be added to the National Institute of Mental Health Database. If you know now that you do not want your data in the National Institute of Mental Health Database, please tell a member of the study staff before leaving the assessment today. If you decide any time after today that you do not want your data to be added to the National Institute of Mental Health Database, call or email the study staff, and they will tell the National Institute of Mental Health Database to stop sharing your study data. Once your data is part of the National Institute of Mental Health Database, the study researchers cannot take back the study data that was shared before they were notified that you changed your mind. If you would like more information about National Institute of Mental Health Database, this is available online at http://nda.nih.gov.

After seven years, the computer files will be erased and the paper surveys will be shredded.

However, there are things that the law does not allow us to keep private. If at any time during the study eligibility screening or during the study we think that you will harm yourself, we will need to take action to protect your safety. We will first ask you some questions to find out your thoughts and plans to harm yourself. Then, we may contact a trusted adult to help you, help you get medical care, and/or call 911.

If we think that a child or older person is being harmed, we are required to report any suspected harm to authorities.

DO I HAVE TO JOIN THIS STUDY?

No, you do not have to join this research study. Even if you agree to join, you can decide later that you do not want to be in the research. If you choose not to join or later decide that you do not want to be in the study, there is no penalty or loss of benefits to which you are otherwise entitled.

WILL I BE TOLD ABOUT THE RESEARCH RESULTS?

We will not contact you with results of this study after this study is completed. However, you are welcome to contact us if you are interested in the results of the study.

WILL IT COST ME ANYTHING If I JOIN THE RESEARCH?

It will not cost you anything to be part of the study. There is no charge for parking at the Body Image, Sexuality, and Health Lab because it is located off of the SDSU campus. If you decide to meet the mental health advocate in a place in which you must pay for parking then you may incur parking fees. However, we can reschedule the meeting with the mental health advocate to take place at SDSU so that you will not incur a charge for parking. You will not incur any costs for downloading or using Zoom (a free video calling platform) to complete remote study assessments.

WILL I BE PAID IF I JOIN THE RESEARCH?

You will receive a $75 gift card after completing the first study assessment that includes answering survey and interview questions. You will receive a $50 gift card for completing a follow-up survey and interview three months after you enroll in the study. The gift cards will not be prorated if you decide to stop participating in the study. The total amount that could be given to you for participating in this study is $125.

WHOM DO I CONTACT IF I HAVE QUESTIONS OR CONCERNS?

If you have questions now, please ask. If you have questions later about the research, you may contact Dr. Kristen Wells at 619-594-1919 or Dr. Aaron Blashill at 619-594-2245. If you have any questions about your rights as a research participant, or in the event of a research related injury, you may contact the Division of Research Affairs at San Diego State University (telephone: 619-594-6622; email: irb@sdsu.edu). At any time during the research, you can contact the IRB for questions about research rights, to discuss problems, concerns, give suggestions, or to offer input.

CONSENT TO PARTICIPATE:

The San Diego State University Institutional Review Board has approved this consent form, as signified by the Board's stamp. The IRB must review the consent form yearly. The IRB approval expires on the date indicated by the stamp in the upper right-hand corner of this document.

Your signature below indicates that the study team has explained the study to you and you have read the information in this form. You have had a chance to ask any questions you have about the research. By signing this form, you are agreeing to join the study. You have been told that you can change your mind and stop participating in the research at any time. The researcher or a member of their research team has provided you with a copy of this consent form. This form includes contact information about who to contact if you have questions.

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Name of Participant (please print)

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Signature of Participant Date

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Signature of Investigator Date