Official Title: Suicide Prevention Intervention for Vulnerable Emerging Adult Sexual Minorities

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UNIVERSITY OF PENNSYLVANIA
RESEARCH SUBJECT
INFORMED CONSENT FORM

Protocol Title:	Supporting Transitions to Adulthood and Reducing Suicide (STARS)
Protocol Number:	849500
Principal Investigator (PI):	José Bauermeister, MPH, PhD & Lily Brown, PhD 418 Curie Blvd., Philadelphia, PA 19104 215-898-9993
Emergency Contact:	24-Hour Emergency Number, Pennsylvania Hospital Crisis Response Center 215-829-5433
Sponsor	National Institute of Mental Health

Research Study Summary for Potential Participants

You are being invited to participate in a research study. Your participation is voluntary and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions related to participating before agreeing to join the study. If you have any questions about your rights as a human research participant at any time before, during or after participation, please contact the Institutional Review Board (IRB) at (215) 898-2614 for assistance.

This research study is being conducted to see if a WebApp called STARS can improve the health and well-being of emerging adults who identify as a member of a sexual and/or gender minority. We are asking you to participate because you indicated that you are a young adult living in the Philadelphia area who identifies as a member of a sexual and/or gender minority and reported past-month thoughts about suicide.

If you agree to join the study, you will be asked to complete the following research procedures:

1. You will be asked to participate in an interview with a study staff member about your thoughts and feelings today and complete a survey. You will also be asked to take a survey and complete a short interview again 2 months, 4 months, and 6 months from now (4 surveys total; 4 interviews total). The surveys will ask for general information about you (such as race/ethnicity, income, and education level). It will ask about your health habits, general mood, and important relationships in your life. It will also ask about your mental well-being, including negative experiences like depression and thoughts of suicide.

2. You will be asked to participate in a Safety Planning activity today. You may also be asked to use the STARS WebApp for the next 6 months. Half of people in the study will be asked to use the WebApp and half will not. Whether you are asked to use the WebApp will be decided randomly, like flipping a coin.

Your participation will last for 6 months, starting today. Your personal identifiable information will be kept for 5 years. Your deidentified data will be kept indefinitely.

You may not get any direct benefit from being in this research study. It is possible that you may benefit by learning life skills and accessing the resources provided by STARS. The findings of this study may also help develop treatments and support resources for other people in the future. The main risks of participating in this study are loss of confidentiality despite the security and privacy controls put in place for the study and that study topics may raise potentially distressing memories, thoughts, and feelings.

Your health care provider may be an investigator in this research study; however, you do not have to participate in any research study offered by your health care provider and it will not affect the services that you receive as part of your care.

Please note that there are other factors to consider before agreeing to participate such as additional procedures, use of your personal information, costs, and other possible risks not discussed here. If you are interested in participating, a member of the study team will review the full information with you. You are free to decline or stop participation at any time during or after the initial consenting process.

Why am I being asked to volunteer?

You are being asked to take part in a research study. Your participation is voluntary which means you can choose whether or not to participate. If you decide to participate or not to participate there will be no loss of benefits to which you are otherwise entitled. Before you make a decision you will need to know the purpose of the study, the possible risks and benefits of being in the study and what you will have to do if you decide to participate. The research team is going to talk with you about the study and give you this consent document to read. You do not have to make a decision now; you can take the consent document home and share it with friends, family, and your treatment team.

If you do not understand what you are reading, do not sign it. Please ask the researcher to explain anything you do not understand, including any language contained in this form. If you decide to participate, you will be asked to sign this form and a copy will be given to you. Keep this form, in it you will find contact information and answers to questions about the study. You may ask to have this form read to you.

Your doctor may be an investigator in this research study. As an investigator, your doctor is interested both in your clinical welfare and in the conduct of this study. You do not have to participate in any research study offered by your doctor.

What is the purpose of the study?

The purpose of the study is to learn more about how to develop treatments and programs that support and promote the mental health and well-being of young adults who identify as a member of a sexual and/or gender minority (SGM) and who are at risk for suicide. This research study is testing a WebApp called STARS to see if providing web content, tools, and social support specifically tailored to SGM identities can improve mental well-being and reduce mental health emergencies.

Why was I asked to participate in this study?

You are being asked to join this study because you have indicated that

- You are between the ages of 18 and 24,
- You live in the Philadelphia Metropolitan Area and do not plan to move out of the area in the next 6 months,
- You have experienced suicidal ideation within the last month,
- You identify as a member of a sexual and/or gender minority, and
- You have access to a smartphone.

How long will I be in the study?

The study will take place over a period of 6 months. This means for the next 6 months we will ask you to spend 4 days participating in study surveys and interviews. Each survey will take approximately 30 minutes to complete. Interviews will take an additional 30 minutes.

If you are invited to use the STARs WebApp, you will have access to that for the next 6 months. It would be available to you during the entire 6 months. You will be asked to spend at least 20 minutes using the app each week, though you will be free to use it more often if you would like. As a part of the STARS WebApp, you will be asked to participate in 6 peer mentoring sessions lasting 30 min each (180 min total).Where will the study take place?

You will be asked to come to Suite 600 N located at 3535 Market Street, Philadelphia, PA19104 based on a scheduled appointment in order to complete the initial behavioral assessments. Interviews at 2-, 4-, and 6- months may be done virtually through Microsoft Teams or Zoom or in-person based on your preference.

What will I be asked to do?

During your participation you will be asked to do the following:

- Day 1: Participate in an interview and complete a survey at location. This will take approximately 1.5 hours. Eligible participants will then complete a Safety Plan, which will take 45 – 60 min.
- Day 60: Participate in a survey and brief remote interview. This will take approximately 60 minutes in total.
- Day 120: Participate in a survey and brief remote interview. This will take approximately 60 minutes in total.

- Day 180: Participate in a final survey and remote interview. This will take approximately 1.5 hours.
- If you are asked to use the STARS WebApp, you will also be asked to use it for 20 minutes each week during your six months of enrollment and complete 6 peer mentoring sessions (30 min each; 180 min total).

What are the risks?

This program involves increasing understanding about some of your difficulties and your suicidal thoughts and behaviors. This may cause you to experience other emotions or distress, but the long-term effects from this are expected to be minimal. We will make every effort to minimize any discomfort you may feel during this process. If you feel any discomfort during the study, please inform a researcher. We will do everything that we can to make you feel better. This may include taking breaks between questionnaires or having a brief check-in with the investigators or, if you prefer, another clinician to make sure that you are doing okay. You have the right to stop participating in the study at any time, and there are no penalties or negative consequences to you if you choose to stop your participation.

The main risk is loss of confidentiality or private information despite the security and privacy controls put in place for the study. Several steps will be taken to protect your privacy as described in the section below labeled “How will my personal information be protected?” We will take careful precautions to protect your privacy, but complete privacy can never be guaranteed. Finally, you may be inconvenienced by receiving the study text message questions or application push notifications or being asked to complete the other assessments. By participating in the Study and if you are selected to use the STARS WebApp App, you consent to receive text messages and understand that standard messaging rates may apply. have the right to terminate participation at any time during the study. Please note that the research may involve risks that are currently unforeseeable.

How will I benefit from the study?

You may not receive any direct benefit from participating in this study. It is possible that you may benefit by learning life skills and accessing the resources provided by the STARS WebApp. Additionally, your participation could help us understand how to better support the mental health and well-being of SGM young adults, which can benefit you indirectly. In the future, this may help other people to develop treatments for other SGM populations.

What other choices do I have?

Your alternative to being in the study is to not be in the study. If you choose not to be in the study the following are other treatment choices that you may want to consider.

What happens if I do not choose to join the research study?

You may choose to join the study or you may choose not to join the study. Your participation is voluntary.

There is no penalty if you choose not to join the research study. You will lose no benefits or advantages that are now coming to you or would come to you in the future. Your therapist, social worker, nurse, or doctor will not be upset with your decision.

If you are currently receiving services and you choose not to volunteer in the research study, your services will continue.

When is the study over? Can I leave the study before it ends?

The study is expected to end after all participants have completed all visits and all the information has been collected. The study may be stopped without your consent for the following reasons:

- The PI feels it is best for your safety and/or health-you will be informed of the reasons why.
- You have not followed the study instructions
- The PI, the sponsor or the Office of Regulatory Affairs at the University of Pennsylvania can stop the study anytime

You have the right to drop out of the research study at any time during your participation. There is no penalty or loss of benefits to which you are otherwise entitled if you decide to do so. Withdrawal will not interfere with your future care.

If you no longer wish to be in the research study, please contact Jessica Webster at 215-898-9054 or starsstudy@nursing.upenn.edu and indicate that you would like to end your participation.

How will my personal information be protected during the study?

We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be disclosed if required by law. If information from this study is published or presented at scientific meetings, your name and other identifiable information will not be used. The Institutional Review Board (IRB) at the University of Pennsylvania will have access to your records.

People other than the researchers may need to see your information. This includes groups that make sure the research is done safely and properly. These groups include the University of Pennsylvania and the National Institutes of Health who make sure the research is done safely and properly.

The information we collect in this study is considered confidential, which means that it will be kept private except in specific situations. That includes your survey answers, your use of the STARS WebApp, and even that you are part of this project. To protect your information, we will keep your records filed under a number, not your name or email address. Your records will be kept either in a locked cabinet or on secure computer systems.

When you get access to STARS, you will be able to chat privately with a peer mentor using Zoom. You will get to choose between video, audio, and text chat. If you are assigned to the STARS group, you will meet with your peer mentor using Zoom. Sessions will be recorded and used for supervision of the peer mentors. Only audio from sessions will be recorded. Recordings may also be transcribed, but all identifying information will be removed in transcription (for example, names, places)

Your information will be shared with the research team which includes the Principal Investigators, and their research staff. We may also store and use your information for future research with other researchers; however, we will not share any information that could identify you.

To help us protect your privacy, we have a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, we cannot be forced to share information that may identify you, even by a court subpoena (order), in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. We will use the Certificate to resist any demands for information that would identify you, except as explained below. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then we may not use the Certificate to withhold that information. The Certificate of Confidentiality does not govern the voluntary disclosure of information by you that is not included in the survey, nor does it represent an endorsement of the research by the Secretary of Health and Human Services.

There are times when we may break confidentiality. We will break confidentiality if we think that you are being hurt by an adult or neglected by a caregiver, or if we think that you may hurt yourself or someone else. Depending on the situation, we may report that information to a crisis hotline, a healthcare provider, or local law enforcement, or an adult you trust. If you are in trouble and need to talk to crisis counselor, you can call the National Suicide Prevention Hotline at 800-273-8255.

We will ask for your home and email address. This is so that we can send your compensation, make sure you only fill out the survey once, and get Census data about the area in which you live. Your home address will only be used to get Census data about your neighborhood. Your home address will not be attached to any of your responses and will be stored in a separate file. We will use your email address to send you an electronic gift card when you complete study surveys. Complementary rideshare services are offered for travel to and from study appointments. If you agree to rideshare (Lyft, Uber), only your first name, address, and phone number (Optional- if you would like SMS ride status updates). Drivers are not informed of your participation in a research study. Transportation via ridesharing is optional. Declining this service will not affect your study participation.

If you agree to this Informed Consent, we will keep your email address for five years. Identifying information will not be linked to any of your answers. Also, it will not be used to contact you after the study is over, unless you give us permission below.

Who will have access to my data?

Your survey data will be accessible only to the study team. The study team's technology partner, One Cow Standing, will have access to your first name, email address, and phone number, but will have no access to your survey data.

Additionally, your data may be shared with additional parties as described in the “How will my personal information be protected during the study?” and “What may happen to my information collected on this study?” sections of this form above.

What may happen to my information collected on this study?

Your information will be de-identified. De-identified means that all identifiers have been removed. The information could be stored and shared for future research in this de-identified fashion. The de-identified information may also be shared with other researchers within Penn, or other research institutions, as well as pharmaceutical, device, or biotechnology companies. We will not share any identifiable information about you with future researchers.. This can be done without again seeking your consent in the future, as permitted by law. The future use of your information only applies to the information collected on this study.

This study is funded by the National Institute of Mental Health. The NIMH requires that a de-identified version of the final study database is uploaded to their archive system, called the NIMH Data Archive. In order to allow for this, we will secure a Global Unique Identifier (GUID) for you. This GUID will be created on a website from the NIMH using the following information: sex, first name, last name, middle name, date of birth, and city/municipality of birth. Once this information is entered onto the NIMH website, a GUID will be attached to the database for uploading into the archive. Your identifying information will not be included in this database.