

Official Title: Sexual and Gender Minority Youth (SGMY) and Online Interventions to
Increase Help-seeking for Anxiety and/or Depression

NCT number: NCT06083987

Date of document creation: 4/14/2023

Date of last modification: 10/12/2023

STUDY TITLE

SGMY Mental Health Help-Seeking Factorial Trial

PI

Dr. Ana Radovic

Study Coordinator Contact information

Email: sovalab@pitt.edu

Phone: 412-368-2619

FUNDING SOURCE

National Institute on Minority Health and Health Disparities

STUDY INFORMATION

This is a research study about how young people ages 14 to 19 who identify as LGBTQ+ or a sexual or gender minority seek help for their mental health online and what they think of new interventions we are designing. We are recruiting 96 young people.

This study takes about 4 weeks. There are three parts. The first part is taking a survey. The second part involves joining a private online community on a Discord server (discord.com) and looking through some online content and participating in discussions. The third part is taking an end-of-study survey.

After you complete the first survey (or baseline), we will then randomize you to one of 16 different groups. Randomization by the computer is similar to flipping a coin to decide which group you will be in. In each group, there is a different combination of 4 different mini-online tools to try. One group will get no mini-online tool but will still be asked to participate in a non-mental health related discussion. One will get all four. And the other groups will get different combinations. You will be prompted via text message each week to remember to participate in the group. After 4 weeks are over, you will get a follow up survey.

Participants will have access to different channels in the Discord server based on which group they are in. Discussion outside the server is discouraged to protect anonymity. If you do not already have a Discord account (or you have one that includes real life

details about you like your name, birth date, etc) then we will ask you to create a new one and will give you instructions on how if needed.

The surveys will collect information about you like your age, sexual identity, gender identity, race, ethnicity, parent/guardian support, homelessness, socioeconomic and social status, transportation access, prior mental health treatment, whether you have a Primary Care Provider health insurance status, access to mental health professionals as determined by county, health resources and services, and past experiences with a mental health provider. We will also ask about your opinion about the mini-interventions you tried, and about your mental health symptoms, thoughts and beliefs about mental health and seeking help and identifying as LGBTQ+.

Any information you enter on the Discord server can also be used in the future for research for text analysis. If you accidentally put any identifying information (e.g. your school name) we will remove that prior to analysis.

All survey data we collect from you is stored on a secure online survey platform called Redcap which the University of Pittsburgh has used for many years. And the data we extract from that online survey platform will be stored on a secure University of Pittsburgh server. We may share data without any information that can trace the data back to you (identifiers) with other researchers in the future.

If you have more questions, you can contact us at the study email, sovalab@pitt.edu. If you have questions about your rights as a research participant, you can contact the Human Subject Protection Advocate at the University of Pittsburgh IRB (Institutional Review Board) Office at 866.212.2668.

RISKS

We don't expect that there are any major risks to you for participating in this study.

There may be some minor risks, the main one being in the situation that someone obtains confidential information about you. To prevent that, we will take several steps. We use a secure survey platform called RedCap. Data we take from RedCap will be stored on Pitt secured OneDrive.

Discord is not encrypted and so information could be potentially intercepted and used by others not associated with the study which is why we ask for all individuals to not share personal or identifiable information about themselves on Discord.

The email and mobile phone you provide will be used for communication about the study and reminding about study tasks and surveys. We advise you to ensure to password protect your email. We also encourage you to lock and password protect your smartphone to ensure privacy.

Text Messages: Text messages may not be encrypted or secure during their transmission or storage and it is possible they could be intercepted and used by others not associated with this study.

Email: Emails may not be encrypted during transmission or storage and may be intercepted and used by others not associated with this study.

Another risk is feeling embarrassed when answering questions during the survey. We encourage you to only answer questions you feel comfortable with.

Another risk is being “outed” if others see emails from this study. To reduce this risk, e-mails will come from sovalab@pitt.edu and not have titles that include LGBTQ+ in them. Again, we encourage you to make sure to password protect your phone and email.

BENEFITS

While there may not be a direct benefit for participating in the research study, we will provide you with crisis resources at the end, which you might find helpful. If you have questions about anything we have discussed, we can do our best to answer them.

PAYMENTS

The maximum that you can earn is \$100.

You will earn \$35 for the completion of the baseline survey.

After the 4th week, if you complete the follow-up survey you will earn \$65.00

This will be given to you via electronic gift cards.

CONFIDENTIALITY

Anything you tell us in the survey or on the Discord server will remain confidential. We will download text from the Discord server which we may analyze as research data. To protect your confidentiality, any information that might identify you, your family, friends, or others will be removed.

To help us protect your privacy, we have a Certificate of Confidentiality from the National Institutes of Health. This Certificate means Dr. Radovic and her team can legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers 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 or for information that must be disclosed to meet the requirements of the federal Food and Drug Administration (FDA).

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 assent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of child abuse and neglect or harm to self or others.

The data we obtain for this study may be shared with other groups such as the National Institutes of Health, UPMC Children's Hospital of Pittsburgh, and the University of Pittsburgh Office of Research Protections.

Information collected from this study may be shared with other investigators interested in this topic; however, this information will be shared in a de-identified manner (i.e., without identifiers).

Your survey data may be uploaded along with all other study data to the National Data Archive (NDA), but this will be without any identifiers.

WITHDRAW

Participation in this research study is entirely voluntary. If at any point in the survey you don't want to answer a question, we can skip it, and if you want to stop the survey or continue it later, that is fine, too. Whether or not you participate is up to you.

You may withdraw from the study at any time and there is no penalty for withdrawal.

ASSENT TO PARTICIPATE

I understand that I am encouraged to ask questions, voice concerns or complaints about any part of this research study during this study. Any future questions, concerns or complaints will be answered by a qualified individual or by the investigator(s) listed on the first page of this assent document at the telephone number(s) given. I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator. I understand that I may contact the Human Subjects Protection Advocate of the Human Research Protection office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations that occurred during my participation. By typing my full name, date of birth, and mother's maiden name, I assent to participate in this research study.

Do you assent to participate in the study? (yes/no)

What is your mother's maiden name?

What is your date of birth?

Type your full name: