Feasibility of a Multi-Level School Intervention for LGBTQ Youth
NCT04041414

Informed Consent/Assent Document
for Proud & Empowered! Intervention Participation

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University of Southern California
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Informed Assent/Consent to take part in a Human Research Study

KEY INFORMATION

A person who takes part in a research study is called a "research subject." The use of "you" in this consent form refers to you as the research subject.

The following is a short summary of this study to help you decide whether or not you should participate. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

You are invited to take part in this research because you identify as LGBTQ+ and attend a school selected to be part of this study.

What should I know about being in a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You may discuss whether to participate with family, friends and/or your doctor.
- You can ask any questions before making a decision.

Why is this research being done?

We are trying to learn whether an intervention – Proud and Empowered! – is helpful in improving the lives of LGBTQ+ students. The goal of the study is to understand whether mental health, coping skills, and other outcomes improve among LGBTQ+ students who are part of the Proud & Empowered intervention.

How long will I take part in this research?

If you decide to be in this study, you will participate in the Proud & Empowered intervention either this semester or next semester (based on the condition to which your school is randomly assigned). Your participation may last the entire school year or only the second semester, depending which condition your school is randomly assigned.

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You will be asked to participate in an intervention group once a week for 10 weeks during the first semester of the school year and complete three surveys about sensitive information and some personal experiences. Regardless of the condition your school is assigned to, you will be asked to complete three surveys: one at the beginning of the school year, one 10 weeks after the first survey, and one at the end of the school year.

If you are in a school assigned to receive the intervention in the first semester, you will also receive training on community organizing, and then plan a social action strategy in the Spring semester with other students aimed at improving the climate for all LGBTQ+ students in the school.

More detailed information about the study procedures can be found under the *"What can I expect if I take part in this research*?" section.

Is there any way being in this study could be bad for me?

You are providing highly sensitive, personal information in this study. Some of the survey questions may make you feel uncomfortable or become upset. If this happens, we have listed some resources within the survey that you can contact and who can provide you with support.

More detailed information about the risks of this study can be found under the *"What are the risks and possible discomforts?"* section.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your participation in this research. However, possible benefits may include better understanding how to cope with stress and connecting with supportive students and staff at your school. Possible benefits to others may be improving the overall climate at your school, and increasing knowledge about what interventions help LGBTQ+ young people.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate or not to participate. Remember, being in this study is up to you and no one will be upset if you don't want to take part or even if you change your mind later and want to stop.

Your alternative to participating in this research study is to not participate.

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DETAILED INFORMATION

To follow, please find more detailed information about this study than already provided above.

About this consent form

Please read this form carefully. It provides important information about participating in research. You have the right to take time in making decisions about participating in this research. If you have any questions about the research or any portion of this form, you can ask us at any time. If you agree to participate in this research you will be asked to verbally agree. A copy of this form will be provided to you for your records if you wish.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at your school. You may also contact Jeremy Goldbach, Ph.D. at (213) 821-6460 with any questions, concerns or complaints about the research or your participation in this study.

This research has been reviewed by the USC Institutional Review Board (IRB). If you wish to speak with someone from the IRB, you may contact the IRB at (323) 442-0114, by email at irb@usc.edu, or by mail at the following address:

USC Institutional Review Board (IRB)
1640 Marengo St., Suite 700
Los Angeles, CA 90033

The IRB is available between the hours of 8:00 AM and 4:00 PM, Monday to Friday. Contact the IRB for any of the following:

- If your questions, concerns, or complaints are not being answered by the research team,
- If you cannot reach the research team,
- If you want to talk to someone besides the research team,
- If you have questions about your rights as a research participant, or
- If you want to get information or provide input about this research.

Participation is voluntary

It is your choice whether or not to participate. If you choose to participate, you may change your mind and leave the study at any time. Refusal to participate or stopping your participation will involve no penalty or loss of benefits to which you are otherwise entitled.

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How many people will take part in this research?

About 75 people will take part in this research.

What can I expect if I take part in this research?

As a participant, you will participate in the Proud & Empowered intervention either this semester or next semester (based on the condition to which your school is randomly assigned).

We will ask you to complete three surveys as part of this study: at the beginning of the school year, at 10 weeks after the first survey, and at the end of the school year. The survey will ask you to respond to questions about sensitive information and some personal experiences at home, within school, within community and within your relationships. You will also be asked to respond to questions about your mental health, different behaviors, and drug use. All surveys will take about 30 minutes to complete. You will create a unique code that will be used to link to your survey responses so that no one at the school will know how you answer.

You will also participate in an intervention group for about 45 minutes once a week for 10 weeks during the semester. In this group we'll talk about specific issues that you and other LGBTQ+ youth might be facing and ways to deal with those issues, including stress and coping skills, disclosure, family, school-related stress, peers and friendship, race/ethnicity and social justice, and history of the LGBTQ+ community.

The intervention sessions will take place at school during school hours. You will need to miss class to participate in the sessions. We will schedule these sessions at different times and days each week so that you will not miss the same class every week.

If you are in a school assigned to receive the intervention in the first semester, you will also receive training on community organizing, and then work during the Spring semester with other students to plan a social action strategy aimed at improving the climate for all LGBTQ+ students in the school.

This will include two 1-hour training sessions in the Fall training on advocacy and organizing to create safe, respectful, and affirming schools for LGBGTQ+ youth and planning sessions of about 45 minutes each once or twice a month during the Spring with the school counselor and the USC study team to plan a project chosen during the training. You will then work with the group to implement your planned project during the spring semester.

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The training session, planning sessions, and project implementation will take place at school during school hours. We will schedule these activities at different times and days each week so that you will not miss the same class every week.

If you are selected and agree to be a popular opinion leader and do not want to participate in the intervention portion, you will be asked to participate in the training session, planning sessions, and implementation activities as stated above.

What are the risks and possible discomforts?

The survey will ask you to respond to questions about sensitive information and some personal experiences at home, within school, within community and within your relationships. You will also be asked to respond to questions about your mental health, different behaviors, and drug use.

You are providing highly sensitive, personal information in this study. If people not connected with the study learn this information, you could have problems getting a new job, keeping your current job, finding housing, or getting insurance (health, disability, or life insurance). In highly unlikely situations, you could be charged with a crime.

Some of these questions may make you feel uncomfortable or become upset. If this happens, we have listed some resources within the survey that you can contact and who can provide you with support. You may also skip or stop answering any questions that make you uncomfortable.

What happens if I say yes, but I change my mind later?

You can leave the research at any time. Your decisions will not be held against you.

If you withdraw from the study, you will no longer be able to participate in the study. No new information will be collected about you or from you by the study team. Your withdrawal has no effect on the lawfulness of the data processing that occurred prior to your withdrawal.

Will I be compensated for participating in this research?

You will be compensated for taking three surveys as part of this study: at the beginning of the school year, at 10 weeks after the first survey, and at the end of the school year. You will get a $20 gift card for the first survey, $25 for the second, and $30 for the last one, for a total of $75 in gift cards if you complete all three surveys. You will be paid separately for each survey completed and do not need to complete all of the surveys in order to receive payment.

What will I have to pay for if I participate in this research?

Research costs are paid by the sponsor or funding agency; routine health care costs are your responsibility and/or your healthcare plans.

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What happens if I am injured as a result of participating in this research study?
Costs for medical care from research-related injuries will not be paid by the sponsor or funder. You and/or your health plan/insurance will be billed for this treatment. There are no plans to offer any type of payment for injury. However, by signing this form you have not given up any of your legal rights.

If I take part in this research, how will my privacy be protected? What happens to the information you collect?
We will keep your records for this study confidential as far as permitted by law. However, if we are required to do so by law, we will disclose confidential information about you. Efforts will be made to limit the use and disclosure of your Personal Information, including research study records, to people who are required to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the USC IRB and other representatives of the research sponsor, the National Institute of Minority Health) and Health Disparities.

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

To help us protect your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to 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.

The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects or for information that must be disclosed in order 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 another member of your family from voluntarily releasing information about yourself, or your

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involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will 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. This protection does not prohibit the investigator from voluntarily reporting information about something that might put you or another person in danger. The investigators may choose to voluntarily report to the appropriate authorities certain cases with the potential of serious harm to you, or others, such as suicidality or child abuse.

This research is being funded by the National Institute of Minority Health and Health Disparities.

STATEMENT OF CONSENT

Minor/Youth/Adult Participant

I have read (or someone has read to me) the information provided above. I have been given a chance to ask questions. All my questions have been answered. By signing this form, I am agreeing to take part in this study.

Name of Research Participant	Signature	Date Signed

Person Obtaining Consent

I have personally explained the research to the participant and/or the participant's legally authorized representative using non-technical language. I have answered all the participant's questions. I believe that he/she understands the information described in this informed consent and freely consents to participate.

Name of Person Obtaining Informed Consent	Signature	Date Signed