

**Title of Research Study: A pragmatic trial of an adaptive eHealth HIV prevention program for diverse adolescent MSM (IRB STU#00201997)**

**Investigator: *Brian Mustanski, PhD***

**Supported By:** This research is supported by Northwestern University and the National Institute of Minority Health and Health Disparities (U01-MD011281-01).

**Why am I being asked to take part in this research study?**

Researchers at Northwestern University have created a sexual health education program for teen guys who are gay, bisexual, queer, or are attracted to other guys. The program focuses on HIV/STI (sexually transmitted infections) prevention as well as other topics like healthy relationships. The program will be entirely online.

You are being asked to take part in this research study because you are (1) an adolescent male, (2) 13-18 years old, (3) identify as gay, bisexual, queer, or attracted to other guys, and (4) have had sexual contact with another person. Also, (5) you must be able to read written English and (6) have reliable and private access to the internet and a smart device (so a smart phone, laptop, desktop or tablet), and (7) be willing to engage in live-facetime/skype/video-chat contact if asked by the research staff.

**What should I know about 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 can ask all the questions you want before you decide.

**Is this an anonymous study or a confidential study?**

To be clear, “anonymous” means that we would never have access to your name and personal information. “Confidential” means that we would have access to the personal information you provide us (e.g., your name, address, email). This is NOT an anonymous study. This is a confidential study. It is confidential because we need to be able to link your data together across the different times we ask you questions. Additionally, we need your personal information so we can pay you. While this is NOT an anonymous study, only a select few people can access your information. Specifically, only study staff, the Institution Review Board, and funding agencies may be able to access your data. Additional information about your data is provide below.

**Who can I talk to?**

If you have any questions about this study you may contact: Dr. David Moskowitz is the person in charge of this research study and can be reached by phone at 312-503-0055 or by email at [david.moskowitz@northwestern.edu](mailto:david.moskowitz@northwestern.edu).

This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-9338 or [irb@northwestern.edu](mailto:irb@northwestern.edu) if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.

- You want to get information or provide input about this research.

**Why is this research being done?**

***Teen guys who are gay, bisexual, queer, or who have sex with guys are at risk for HIV, but there are not many programs to help them prevent HIV. Many people use the internet to look for information about health, but there are very few websites that provide young guys the information that meets their needs. This is why we created the SMART Project. The SMART Project is an online sexual health education program that was created specifically for teen guys.*** Your participation in this study will help us make the program better to help meet the health needs of teen guys in the LGBTQ (Lesbian, Gay, Bisexual, Transgender, and Queer) community. In order to test out how well the program works, we will need to ask you questions about yourself, including questions about your sexual orientation, sexual experiences, health practices, and health knowledge. After completing these questions, you will be directed to go through and experience the program.

**How long will the research last?**

Your participation in this study will last for 1 year (see below for more details).

**How many people will be studied?**

We expect that over 1,900 people will participate in this study.

**What happens if I say “Yes, I want to be in this research”?**

If you choose to be participate in this study, you will be asked to complete a survey that will ask you questions about you, your sexual health, and your life experiences. After the survey, you will receive an email with a link to our website and you will be asked to create an account. Once you have created they account, you will be able to access the sexual health education program. The program will include videos and activities that cover topics like HIV/STI prevention, coming out, and healthy relationships. Please be prepared to answer questions and view content in a private area where you will be able to access the internet.

You will be contacted by research staff every 3 months, and we will ask you to complete another survey. Each time you complete the survey, you will get a \$25 gift card. You will also be randomly selected (by a flip of a coin) to receive more videos, activities, and even some video chats with therapists.

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

***Participation in this study is completely voluntary, which means you do not have to participate in the study if you do not want to. You may say “no” at any time, and your decision will not be held against you.***

**The research team has the right to stop your participation in this study without your assent if:**

- The team believes it is in your best interest;
- You did not agree with any changes that may (or may not) be made;
- The research team believes that you do not understand the purpose or instructions of the program;
- The research team believes your identity to be fraudulent or misrepresentative;
- You do not conduct a quick facetime/video chat with research staff to verify your identity;
- Or for any other reason.

**Who will see me or my responses?**

Because this is all done online, it is important to make sure you are who you say you are. You can do this very quickly by facetime/video chatting with us through skype or a like app for less than one minute. Study staff will set this quick check before allowing you to enroll in the study. This check is necessary and needs to be accomplished before we can pay you for your time. In terms of your survey data, all of your responses to program content will be kept confidential, which means the only people who will be able to see your responses will be research staff. However, some people might review our records that may identify you in order to ensure we are following the required rules. For example, the Northwestern University Institutional Review Board may review your information. If they look at our records, they will also keep your information confidential. When we decide to write about the project, we will write about the information from everyone in the study and will not include your name or any information that will directly identify you.

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**Will being in this study help me in any way?**

Your participation in this study will not benefit you in anyway, but the study may still have a good impact on you:

- You will learn things about gay, bisexual, and queer health and sexuality that you probably do not know.
- The information from the study may be used to improve HIV prevention programs for people in your community. You may receive a benefit in knowing that you have helped other teen guys.
- You will be able to say that you helped researchers design a study that will teach guys like you around the country learn about safe sex and HIV prevention.
- You may also enjoy answering some of the questions or viewing some of the content involved.

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

Possible risks and discomforts you could experience during this study include:

- Some of the survey questions may ask you about your sex life, your mental and emotional health, and any alcohol or drugs you have used. Also, much of the content you will view will cover topics on sex and sexuality. Video/interactive content has been rated to PG-13 criteria by the Motion Picture Association of America (MPAA) and the Federal Communications Commission (FCC). Even with the PG-13 rating, some of these topics could make you feel uncomfortable or embarrassed. If there is material you do not want to respond to, you do not have to do so. You can stop participating at any time. A staff member will be available if you want to talk about anything that comes up during the study.
- There is a possibility that someone may find out that you are in this study if they see the website and content on your phone, so we ask that you please answer questions and review content in a private area.

### **Will it cost me anything to participate in this research study?**

If you choose to contact study staff by text, standard text messaging rates may apply, depending on your internet/phone service provider. However, study staff can always be contacted by email or by phone, which are free. There are no other costs associated with the study.

### ***What happens to the information collected for the research?***

The research team will work very hard to ensure your information is kept private, but we cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution and the National Institute of Minority Health Disparities.

We will ask you for your name, address, phone number, and e-mail. If you choose, we will use your phone and email to contact you to remind you about your surveys. We will give you a study ID number so your name is not connected with your surveys.

We will keep your name and other contact information linked to your study ID number in a password protected computer file on a password protected server at Northwestern University. Only the research staff that need this information to contact you will have access to it. Research staff members may contact you to remind you about completing surveys. We will only contact you using contact information that you have approved, and we will use discretion if you request it (this means we will not tell anyone who is calling or why we are calling). The link between your study ID name and your contact information will be destroyed after the completion of the study. The data that only has your ID number on it will not be destroyed. The information from this

study may be published in scientific journals or presented at scientific meetings, but your identity will be kept private.

We will not ask you about child abuse, but if you tell us about child abuse or neglect, or that you are at high risk of hurting yourself or someone else, we may report it to authorities. We have obtained a Certificate of Confidentiality from the federal government to help protect your confidentiality. However, we may still be required under certain circumstances to release your information.

***What else do I need to know?***

If you take part in this study and complete your surveys, we will send you a \$25 online gift card for your time and effort, for each survey you complete. This means that you should review all the content you are assigned and complete your surveys every 3-6 months in order to get paid. You will not get paid if you decide to stop being in the study or if you don't participate in the surveys. If you do not use the gift card within 6 months, it will lose \$3 for each following month that you don't use it.

***Assent/Consent***

If you wish to participate, please click the "I Agree" button and you will be contacted by study staff regarding the next steps.

If you do not wish to participate in this study, please select "I Disagree" or select X in the corner of your browser.

- I Agree
- I Disagree