

Title of Research Study: Using Text Messaging to Promote Young Men's Health (txt2protect)

Investigator: Brian Mustanski, PhD

Supported By: The National Cancer Institute and Northwestern University

Key Information:

The first few pages of this document include a summary of this study to help you decide whether or not to participate. Detailed information is provided after the summary.

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

You are being asked to take part in this study because you are male, between the ages of 18-25, identify as gay, bisexual or queer and/or are physically attracted to men, and are the exclusive owner of a cell phone with an unlimited text messaging plan.

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.

Why is this research being done?

The purpose of this study is to compare two different versions of a text messaging sexual health program for young gay, bisexual and queer men. Your participation in this study will help us to determine the usefulness of these interventions. We hope to use this information to later modify, enhance, or expand the interventions to better address the needs of men in this community. To evaluate their effectiveness, we will need to ask you questions about yourself, including questions about your sexual orientation, sexual experiences, health practices, and health knowledge.

How long will the research last and what will I need to do?

Your participation in this study will last for approximately 9 months.

You will receive text messages about things like relationships, sex, and how to protect yourself from sexually transmitted diseases. You will be asked to complete three brief online surveys.

More detailed information about the study procedures can be found under the section **What happens if I say "Yes, I want to be in this research"?**

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

The primary risk of participation is that your privacy may be broken if someone sees the messages on your cell phone. It also is possible that a question in the surveys might make you feel uncomfortable. If this happens, you can select “I do not want to answer” or skip the survey question.

More detailed information about the risks of this study can be found under “**Is there any way being in this study could be bad for me? (Detailed Risks)**”

Will being in this study help me any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include your learning about HIV/STIs and options for preventing them. Information collected in this study may be used to later modify, enhance, or expand interventions to better address the needs of men in your community.

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

Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled. Your alternative to participating in this research study is to not participate.

Detailed Information:

The rest of this document includes detailed information about this study (in addition to the information listed above).

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the Principal Investigator, Brian Mustanski, at (312) 503-5421.

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 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.

How many people will be studied?

We expect about 460 people will be in this research study.

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

If you agree to participate, you will be invited to take part in a 9-month study. There are two different text messaging programs that we are testing. We do not know which program works better to promote healthy sexual behavior for guys like you. You will be randomly assigned to one of the two programs. This means you have an equal chance of being assigned to either program. You will not be told which treatment you are getting, however the study team will know. We will not tell you to which program you are assigned to until after everyone has finished the program.

The study is split into two phases. During Phase 1, you will receive text messages every day for 3 weeks. During Phase 2, which lasts for the rest of the study, you will receive text messages only once or twice

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per month. The messages will talk about things like relationships, sex, and how to protect yourself from sexually transmitted diseases.

Before you start receiving the messages you will be asked to complete an online survey, which should take about 15-20 minutes. Please be prepared to sit and answer the questions in a private area.

You will then take part in the text messaging intervention called txt2protect (t2p). During Phase 1 you will receive about 10 messages every day for 3 weeks. Texts will be sent in small batches that should arrive about the same time every day. Each week will focus on a different topic. During Phase 2 you will receive text messages much less often (only a few messages per month).

At the end of Phase 1 (3 weeks into the study), you will be asked to complete an online survey to provide your initial feedback about the program. For example, we will ask you about your satisfaction with the program and your thoughts on the different topics that were covered. The survey will take about 25-30 minutes.

At the end of Phase 2 (9 months into the study), you will be asked to complete a final online survey. The final survey will ask you for your feedback on the text messaging program and will ask some questions about your sexual behavior and health-related practices since the study began. The survey will take about 15-20 minutes. During Phase 2 you may also be asked to complete up to three “pop-up” surveys that will include only one or two questions.

What happens if I say “Yes”, but I change my mind later?

You can leave the research at any time and it will not be held against you.

If you decide to leave the research, contact the investigator so that the investigator can remove you from the study and stop the delivery of text messages to your phone number.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment. No additional data will be collected after you withdraw. If you share your intent to withdraw, the investigator will ask if the information already collected can be used or whether it should be destroyed.

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

The text messages talk about being gay, bisexual, or queer and guys having sex with guys. It is possible that your privacy will be broken if someone sees the messages on your cell phone. Please think about what it would mean for you if this happens. We want you to be sure it's safe for you to take part in the program.

It also is possible that a question in the surveys might make you feel uncomfortable. If this happens, you can select “I do not want to answer” or skip the survey question. If the program messages make you feel uncomfortable, you can stop being in the study completely.

This study involves the use of your identifiable, personal information and there is a chance that a loss of confidentiality could occur. The researchers have procedures in place to lessen the possibility of this happening. See the section below titled: “What happens to the information collected for the research?”.

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

Taking part in this research study will not lead to any cost to you.

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What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution and the US Department of Health and Human Services (DHHS).

We will keep a copy of your survey responses so we can evaluate the effects of the program. Only Dr. Mustanski and people who work with him will be able to see your answers. You will be identified only by a unique subject number. Your contact information will be stored separately from your responses. All information will be kept on a password protected computer only accessible by the research team. The results of the research study may be published, but your name will not be used.

Data Sharing

De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include providing fraudulent data or the study team determining from your survey responses that you no longer meet eligibility requirements to participate in the study.

What else do I need to know?

You can receive up to \$75 in online gift cards (i.e., Visa prepaid card) for completing this study. Gift cards will be sent to your email address. You will receive a \$15 online gift card for completing the survey at the beginning of the study, another \$15 online gift card for completing the survey at the end of Phase 1, and a \$45 online gift card for completing the final survey at the end of the study (end of Phase 2). During Phase 2, you may also be eligible to take part in up to three e-raffles for an additional \$50 online gift card.

The study number for this project is: STU00202705

If you receive any doses of HPV vaccine during the study we may ask you to complete a medical release form at the end of the study. Signing this form indicates that you are willing to let a member of the study team contact your doctor to ask for specific information from your medical chart. The only data that would be requested is whether you received any doses (shots) of HPV vaccine while you took part in this study. If you do not sign the medical release form, your medical chart information will not be requested.

Consent

If you want a copy of this consent for your records, you can print it from the screen.

If you wish to participate, please click the "I Agree" button and you will be taken to the survey.

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