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Online Consent Form
Northwestern University
Department of Medical Social Sciences

Protocol Title: Efficacy of Internet-based HIV prevention
Principal Investigator: Brian Mustanski, Ph.D.
Supported by: National Institute of Drug Abuse

What is the Purpose of this Study?

You are being asked to take part in a research study. This document has important information about the reason for the study, what you will do if you choose to be in this research study, and the way we would like to use information about you and your health.

You are being asked to participate in a research study to help us learn more about the health behaviors, practices, and outcomes of young men who have sex with men (YMSM). Presently, there are a limited number of proven HIV interventions culturally tailored to YMSM. The purpose of this study is to compare two different versions of an online HIV/ Sexually Transmitted Disease (STD) intervention for YMSM. 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 its effectiveness, we will need to ask you questions about yourself, including questions about your sexual orientation, sexual experiences, health practices, including drug use, health knowledge, and questions about your feelings and emotions. The study is being conducted by researchers at Northwestern University in Chicago, Hunter College in New York City, and Emory University in Atlanta.

We are asking you to be in this study because you are between the ages of 18 and 29 and identify as a biological male who is gay, bisexual, or have engaged in same-sex behavior. Participation in this study is voluntary, and entirely up to you. Your decision whether or not to participate will not affect your current or future relations with the University or its affiliates. If you decide to participate, you are free to withdraw at any time without affecting these relationships. This information will help you make an informed decision about whether or not you want to be in the study.

What will I do if I choose to be in this study?

If you consent to participate, you will be randomly assigned into one of two study groups. This assignment is based on chance, like a flip of a coin. Neither you nor the researcher chooses your assigned group. You will have an equal chance of being in either group.

You will be asked to answer all of our online questionnaires on a computer (five questionnaires total, approximately 15 - 30 minutes each), complete the intervention within 3 weeks (topics may include condom applications, HIV information, same-sex relationships and may be presented in various formats like slides or videos), and maintain consistent online contact throughout the course of the study (a total of 12 months *after* enrolling).

Being in this research also involves taking at least two at-home urine tests and two at-home self-administered rectal swabs for STDs (at the beginning of study and at 12 month follow-up) using kits that we provide. The samples will be analyzed by the Centers for Disease Control and Prevention (CDC) Division of STD Prevention laboratory. If you test positive for any STD and/or HIV we will refer you to a site of your choosing where you can receive free or low-cost confidential treatment. Every effort will be made to maintain your confidentiality, with the exception that positive STD test results (such as

Gonorrhea and Chlamydia) will be reported to the Department of Public Health by your name and contact information. We are required to make these reports so that the Department of Public Health can make sure you are offered treatment and so that they can track the frequency of these infections.

If you agree to participate in this program, we will ask you to do the following things:

1. Go to a computer that has a strong Internet connection, preferably at a private place like your house, and log onto our website using the information we will provide you. Complete the first set of online questionnaires. Remember that the questions must be completed all at once. The website will not save your responses if you have to log off for any reason. Please be prepared to sit and answer questions in a private area for approximately 30 minutes. After you complete the first online questionnaire, we will mail your first at-home, urine-based STD test kit and at-home self-administered rectal swab STD test kit.
    a. The box that contains the kits will arrive to your mailing address in 3-5 business days and will be a plain, cardboard box. The return address label on the box will say "Northwestern University". The instructions for how to use the test kits are provided in the box.
    b. First, you will be asked to give specimen information as well as your assigned unique ID number, date of birth, and date and time of collection on each order form.
        i. For urine collection, you will then be asked to label a specimen tube, collect a urine sample in a small cup, transfer a small amount of urine from the collection cup into the specimen tube using a dropper provided in the kit. You will then be asked to place the urine specimen tube into a clear plastic biohazard bag.
        ii. For the rectal sample, you will be asked to self-administer the rectal swab, transfer the swab into the sheath and place the tube in an individual zip-lock biohazard bag.
    c. If you have questions or need help with the STD kits, you may call Keep It Up! staff at 312-725-4682 or email them at kiu2@northwestern.edu .
    d. You will ship your urine and rectal samples directly to the CDC lab in a postage-paid return mailer.
    e. You can get results within two weeks after mailing your kits to the lab. To open the email and access your results, you must enter the study ID that was provided in the forms mailed to you with your test kits. You will be able to download and print out a hard copy of your results.
    f. If you have not viewed your test results within14 days after they become available, we will contact you by phone or your preferred method of contact to remind you to open the secure email and view your results. If permission is given, study staff can tell you your test results over the phone. When you get your STD results, research staff will be available to help you and find resources for treatment if necessary.
    g. After your STD test kits are received by the CDC lab, you will receive a $30 pre-loaded Citi Visa card.

    If you test positive for an STD at the start of the study, we will send you at-home STD test kits at each follow-up (3 month, 6 month, and 12 month follow-up). You will take at-home STD tests a total of four times during the study. You will be given a $30 pre-loaded Citi Visa card at each follow-up for completing the STD test kits in addition to the online activities.

2. You will then take part in the online intervention. You will have exactly three weeks to complete the entire online intervention (about 2 hours total). You cannot complete the entire intervention in one sitting. You need to log into the website at least three different times to complete the intervention. Also, you will need to wait a minimum of 24 hours between sessions before beginning the next module. After you finish the last intervention module, you will complete the post-intervention assessment. At this point, we will compensate you with another $20 pre-loaded Citi Visa card.

3. In approximately 3 months after your last assessment date, we will ask you to complete another assessment and a booster session which allows you to revisit the different modules. After you complete the 3-month booster session and assessment, we will give you either a $20 or $30 pre-loaded Citi Visa card. Participants who only complete the 3 month booster session and assessment will receive a $20 pre-loaded Citi Visa card. Participants who take at-home STD tests, in addition to completing the 3 month booster session and assessment, will receive a $30 pre-loaded Citi Visa card.
4. We will ask you to complete another assessment 6 months after you complete the intervention. You will again have the chance to revisit the different modules. After you complete the 6-month booster session and assessment, we will give you either a $20 or $30 pre-loaded Citi Visa card. Participants who only complete the 6 month booster session and assessment will receive a $20 pre-loaded Citi Visa card. Participants who take at-home STD tests, in addition to completing the 6 month booster session and assessment, will receive a $30 pre-loaded Citi Visa card.
5. Finally, we will ask you to complete another assessment 12 months after you completed the intervention modules. At this time, we also will mail you another at-home, urine-based STD test kit and at-home self-administered rectal swab STD test kit. You will follow the same procedures described above in Step 1. After completing the assessment, and after your STD test kits are received by the CDC lab, you will receive an additional $30 pre-loaded Citi Visa card.
6. Your participation in the study can last up to approximately 13 months. You will spend approximately 4½ hours online completing assessments and going through the different online modules. If you are diagnosed with an STD at baseline, you will receive a total of $140 in pre-loaded Citi Visa; if you are not diagnosed with an STD at baseline, you will receive a total of $120 in pre-loaded Citi Visa cards.
7. In addition, you will qualify for an online raffle for a $50 pre-loaded Citi Visa card every month during your participation. Based on our projected recruitment of 264 participants per year, we estimate that your odds of winning a raffle are 1 in 264 (or 3.78%) for every month you are enrolled. To be eligible for the raffle you will need to reply to our email request within 48 hours. Replying to the email will confirm your email address and automatically enter you into the raffle.

What are the possible risks or discomforts?

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

1. Some of the questions may involve sharing highly personal information about your sex life, mental and emotional health, any alcohol or drugs you may have used, and potentially criminal behavior. Although this information is confidential, some of these issues could make you feel uneasy or embarrassed. If there are questions you do not want to answer, you do not have to do so. You can stop taking part at any time. A staff member will be available if you want to talk about anything that comes up during the study. We will also refer you to counseling services if you want.
2. You may find some questions unpleasant or hard to answer. You can stop taking the questionnaire at any time and withdraw from the study. The staff will answer any questions and discuss any concerns you may have about the questionnaires either in person, by phone, or email.
3. You may experience anxiety while waiting to receive your STD test results from the CDC lab. You may call Keep It Up! staff about your urine and rectal sample STD tests if you wish to speak with trained support staff. If the result of your test is positive, you may experience distress. You may also ask Keep It Up! research staff for help in finding treatment.
4. Your STD test results are confidential. We will ask you to provide your name, mailing address, phone number, and an email address so that we may send you the test kit and contact you if you have not returned your test kit. Your contact information will not be stored with the answers you give to the

survey questions or with your STD test results. A rare but possible risk of participating in this study is that someone besides the study staff could gain access to your name, mailing address, phone number or email address. This is a rare risk and we will take precautions to ensure this does not happen.

5. While we will do our best to protect all of your information, with any study there is always the risk of loss of confidentiality. There is additional risk depending upon the computer you use. You may be unaware of your computer's preinstalled tracking software, or tracking devices like "cookies". Furthermore, you should take precaution to ensure your own privacy in both the surrounding and space of outside of your computer as well as the privacy concerns within the computer you are using.

What are the possible benefits for me or others?

There are no direct benefits by being in this study. 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 assisted other young men. You may also enjoy answering some of the questions or viewing some of the content involved. Knowing if you have a STD may be of benefit to you. Other than this, you will receive no direct benefits.

What Alternatives are Available?

You may choose to not participate in this research study. You also have the right to leave the study at any time without penalty. This decision will not affect in any way your current or future care/services or any other benefits to which you are otherwise entitled.

Financial Information

There will be no costs to you for being in this study. Participants diagnosed with an STD at baseline will receive $140 in pre-loaded Citi Visa cards for completing the intervention, all follow-up surveys, and four sets of at-home STD tests. Participants who are not diagnosed with an STD at baseline will receive $120 in pre-loaded Citi Visa cards for completing the intervention, all follow-up surveys and two sets of at-home STD tests. You will also receive a handout that describes how the payment cards can be used. The payments are described below:

1. After you complete the first online questionnaire and your STD test kit sample is received by the CDC lab, you will receive a $30 pre-loaded Citi Visa card.
2. After you complete the intervention modules and posttest assessment, you will receive another $20 pre-loaded Citi Visa card.
3. After you complete the 3-month booster session and assessment, we will give you either a $20 or $30 pre-loaded Citi Visa card. Participants who only complete the 3 month booster session and assessment will receive a $20 pre-loaded Citi Visa card. Participants who take at-home STD tests, in addition to completing the 3 month booster session and assessment, will receive a $30 pre-loaded Citi Visa card.
4. After you complete the 6-month booster session and assessment, we will give you either a $20 or $30 pre-loaded Citi Visa card. Participants who only complete the 6 month booster session and assessment will receive a $20 pre-loaded Citi Visa card. Participants who take at-home STD tests, in addition to completing the 6 month booster session and assessment, will receive a $30 pre-loaded Citi Visa card.
5. After you complete the 12-month follow-up assessment and your STD test kit sample is received by the CDC lab, we will send you a final $30 pre-loaded Citi Visa card.
6. In addition, you will qualify for an online raffle for a $50 pre-loaded Citi Visa card every month during your participation. Based on our projected recruitment of 264 participants per year, we estimate that your odds of winning a raffle are 1 in 264 (or 3.78%) for every month you are enrolled. To be

eligible for the raffle you will need to reply to our email request within 48 hours. Replying to the email will confirm your email address and automatically enter you into the raffle.

For more details on using the pre-loaded Citi Visa cards, please visit our Keep It Up! website: http://www.kiu2.org/giftcard

What are my rights as a research participant?

If you choose to be in this study, you have the right to be treated with respect, including respect for your decision whether or not you wish to continue or stop being in the study. You are free to choose to stop being in the study at any time. You can skip questions in the survey and you can withdraw at any time by just exiting the survey. 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.

If you want to speak with someone who is not directly involved in this research, or have questions about your rights as a research subject, please contact the Northwestern University Institutional Review Board (IRB) Office. You can call them at 312-503-9338, or email them at irb@northwestern.edu.

The investigators have the right to stop your participation in this study without your consent if they believe it is in your best interest; if you were to object to any future changes that may be made in the study plan; or for any other reason.

What about my privacy and confidentiality?

We will ask you for your name, address, telephone numbers, email and social media addresses, driver's license number, and contact information from close friends or relatives who will always be able to contact you. We collect this information so that we can enroll you in the study and to stay in contact with you for the next 12 months. We will give you a study ID number so your name will not be on the questionnaire forms. Your personal information such as your name, address, and telephone numbers will not be released to anyone without your written approval. We will keep your contact information linked to your study ID number in a password protected computer file on a password protected server. Only study staff that need this information to contact you will have access to it. Staff members may contact you to remind you of study appointments or to schedule study appointments. 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). If we are unable to contact you with the information that you provided, we will use public databases, such as LexisNexis, to reach you.

We will contact you for the duration of the study unless you tell us that you wish to withdraw from the study. We will keep your contact information for up to two years after the end of the study which occurs in 2017. We will contact you periodically to update your contact information. We will do this because we may be able to continue the study and we want to be able to contact you to invite you to continue to participate. Two years after the end of the study we will destroy your contact information unless you tell us it is ok to keep it. You can contact us at any time and request that we destroy it.

The link between your study ID number and your contact information will be destroyed two years after the end of the study in 2017, unless we are able to continue the study and you agree to continue to participate. 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 strictly confidential.

To protect the privacy of your survey answers, the online questionnaires will be encrypted during transmission using SSL security. You can also help to protect your privacy by closing your Internet

browser when you are done with the survey. If you share your computer, you may also want to think about clearing your browser history (see the program help menu for instructions).

To protect the privacy of your STD test results, your results will be labeled with a unique study identification number and your date of birth only. The database where your contact information (name, mailing address, phone number, email address) is stored, and the separate database that stores your answers to the survey questions and STD test results, will only be accessible by the study staff and will be kept on a password-protected server. All data transfers to and from Northwestern University, and the CDC laboratory only include the unique study identification number and are made via a secure email. Urine and rectal samples collected for this study will be tested for chlamydia and gonorrhea. Any remaining sample material will be unlinked from patient identifiers (date of birth) and stored, up to 20 years, for possible future research. Any future studies with these samples will not involve analysis of your DNA.

Your STD test results are confidential. If your result is positive, we will confidentially provide your name, address, and phone number to your state's health department. This is required by law. It is the same procedure that takes place if you were to have a STD test completed at a clinic, doctor's office, or hospital. After we give this information to the state health department, someone from the state health department may contact you if they need more information. Your positive STD test result is still confidential once it is given to the state health department. The state health department will not give your name or address to any unauthorized individuals.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, we cannot be forced to tell someone about your participation, even by a court subpoena, 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. 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. A Certificate of Confidentiality does not prevent you or a member of your family from choosing to release information about yourself or your involvement in this research. We will only release your study records if you ask us in writing. For additional information about Certificates of Confidentiality see http://grants1.nih.gov/grants/policy/coc/faqs.htm.

Whom should I Call if I have Questions or Concerns about this Research Study?

You can call us with your questions or concerns. Dr. Brian Mustanski is the person in charge of this research study. You can call him at 312-503-5421, Monday through Friday, from 9am to 5pm, or email him at brian@northwestern.edu. You can also call Krystal Madkins, the Project Director, at 312-503-6529, or email her at kiu2@northwestern.edu, with questions about this research study.

To speak with the person in charge of the study in New York City, you can call Dr. Jeffrey Parsons at 212-206-7919 Monday through Friday, from 9am to 5pm, or email him at jparsons@chestnyc.org. You can also call Ruben Jimenez, the project coordinator in NYC at 212-206-7919, or email him at rjimenez@chestnyc.org, with questions about the research study.

To speak with the person in charge of the study in Atlanta, you can call Dr. Patrick Sullivan at 404-727-2038 Monday through Friday, from 9am to 5pm, or email him at pssulli@emory.edu. You can also call Craig Sineath, the project coordinator in Atlanta at 404-712-9211, or email him at rsineat@emory.edu, with questions about the research study.

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

Consent

You have read this consent form and have been told who to contact if you have more questions. Being in this study is entirely up to you. You have the right to refuse to be in the study or to stop being in the study at any time. Please print a copy of this form for your records. If you would you like to have a signed copy of this consent form, please email your request to the Principal Investigator at brian@northwestern.edu.

If you agree to the above information and would like to be in this study, please click on "I Agree" below.

If you do not wish to participate in this study, please select the Decline button, and your session will end.

I Agree

Decline