Approved by NU IRB for use on or after 3/4/2019

Online consent template: Integrating Primary and Secondary HIV Prevention in Vulnerable YoungMen

NCT03284541

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Title of Research Study: ***Integrating Primary and Secondary HIV Prevention in Vulnerable Young Men***

IRB Study Number: STU00202802

Investigator: ***Michael E. Newcomb, Ph.D.***

Supported By: This research is supported by the National Institute on Drug Abuse.

Key Information about this research study:

The following is a short summary of this study to help you decide whether to be a part of this study:

We are conducting this research study to test two different programs for improving sexual health in young same-sex male couples. Your participation in this research study will last for about 1 year. At the beginning of the study, you will complete a survey that lasts for about 60 minutes, you will video-record yourself communicating with your partner about an issue in your relationships that will last for about 15 minutes, and you will have the option to receive urethral and rectal Chlamydia and Gonorrhea tests, which will take about 15 minutes to complete. After that, you will enroll in one of two different programs (assignment to each program is completely random). One program involves completing five online video conferencing program sessions (1 per week for 5 weeks) that total about 9 hours. The other program involves completing one online, video conferencing session that last 1-2 hours. After you complete the program, you will fill out a survey at 3-, 6-, 9- and 12-months from the date you complete the program. The surveys at 3-, 6-, and 9-months will last about 30 minutes, and the survey at 12-months will last about 60 minutes.

Your participation in this study may involve the following risks: (1) There is a chance that you may feel emotional or upset when answering some of the survey questions. Tell the study staff at any time if you wish to take a break or stop the survey. (2) You may be uncomfortable with some of the topics in the program. If you are uncomfortable, you are free to not participate in some of the program sessions. (3) It is possible that you will learn about thoughts and feelings from your partner that you did not know about. These thoughts and feelings may be uncomfortable for you to hear and may be potentially hurtful to your relationship. At any time during the study, you may contact the study staff, and they will provide you with a list of LGBT-friendly health and support resources for you and your partner. (4) You and your partner could test HIV-positive during the course of the study. If this occurs, the study staff will work to connect you with HIV care-related resources in your area. You many also call staff at Center on Halsted to address your emotional and physical health needs. The Linkage to Care telephone number at Center on Halsted is 773-472-6469, extension 448. (5) Because the program consists of 3 group sessions, it is possible that you may experience a loss of confidentiality. We will encourage all group session participants to keep information pertaining to the program, as well as information about individuals and couples, as confidential.

As a possible benefit, the programs may provide you and your partner an opportunity to discuss important issues in your relationship that may not have been previously discussed, such as dating history, thoughts on monogamy in the relationship, and HIV testing. In addition, you and your partner will be offered free, voluntary HIV testing. Your participation may also help other young people in the future as we design healthy relationships programs to promote healthy sexual behaviors, specifically for same-sex couples.

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

You are being asked to take part in a research study. The purpose of this study is to compare approaches to promoting sexual health in same-sex male couples. The first is an online healthy relationships program aimed at promoting healthy relationships and sexual behavior in male same-sex couples. The program is called “2GETHER” and consists of small group and couples-based sessions. The other is a one session program that aims to improve sexual health in same-sex male couples. This study will examine participant perceptions of each program and evaluate changes in knowledge, attitudes, and behaviors.

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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.

If you say that "Yes, you want to be in this research," here is what you will do

You will first fill out a set of online questionnaires that ask about: demographics, sexual behavior, substance use, mental health, and your relationship. You will also video-record yourself communicating with your partner about an issue in your relationship. You will also have the option to receive STI tests. It will take about 60 minutes to fill out these questionnaires, about 15 minutes to complete the communication task, and approximately 15 minutes to complete STI testing.

1. Next you will be told if you and your partner will enroll in the 2GETHER program or the one session sexual health program. Assignment to each group is completely random.
2. Participants who are asked to complete the 2GETHER program will complete each of the 5 sessions of 2GETHER over the course of 5 weeks (approximately 1 session per week).
   Session 1. First, you will watch self-paced videos that last about 1 hour in total. Next, you will participate in a group discussion session via videoconference (1 hour). The videos and group session will cover the following topics: 1) an orientation to the intervention, 2) characteristics of healthy relationships, and 3) effective communication skills.
   Session 2. You will first watch self-paced videos that last about 1 hour total. Next, you will participate in a group discussion session via videoconference (1 hour). The videos and group session will cover the following topics: 1) sexual health, and 2) relationship agreements.
   Session 3. You will first watch self-paced videos that last about 1 hour total. Next, you will participate in a group discussion session via videoconference (1 hour). The videos and group session will cover the following topics: 1) coping skills 2) social and community support; and 3) group session wrap-up.
   Session 4. The first couples session (1.5 hours) will consist of more in-depth discussion and practice of communication skills.
   Session 5. The second couples session (2 hours) will be focused on relationship sexual agreements and includes voluntary HIV counseling and testing. HIV testing is optional. Prior to this session, participants will be mailed home-based HIV tests that are conducted with an oral swab.
3. Some participants will be asked to complete the one session sexual health program for same-sex male couples. For couples where both members are HIV-negative, the couple will complete couples-based HIV testing and risk behavior counseling (1 hour). Prior to this session, participants will be mailed home-based HIV tests that are conducted with an oral swab. For couples where both members are HIV-positive, the couple will complete the Life-Steps HIV medication adherence and risk behavior counseling program (1 hour). For couples where one member is HIV-negative and the other HIV-positive, the couple will complete both programs together (2 hours). Participants may opt out of the HIV test but will still receive HIV risk reduction counseling.
4. All participants will fill out a set of online questionnaires 3-, 6- and 9-months after completing the programs that ask about: sexual behavior, substance use, and mental health. It will take about 30 minutes to fill out these questionnaires. If you do not complete one of these sets of questionnaires, you can stay in the study and complete future questionnaires.
5. All participants will fill out a set of questionnaires online 12-months after completing the program, be video-recorded communicating with your partner about an issue in your relationship, and have the option to complete urethral and rectal Chlamydia and Gonorrhea tests. HIV-negative participants will also have the option receive HIV testing and counseling at 12-months.
6. All couple sessions will be audio recorded so that we have detailed information on how to improve the program for future participants. Agreeing to the audio recording is required for participation. If you do not wish to be recorded, you cannot participate in this study.

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What happens if I do not want to be in this research or 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. You will be paid for all components of the study you completed before leaving the study.

What happens to the information collected for the research?

We will ask you for your name, address, phone number, and e-mail. We will use your email to contact you to remind you about your assessments. We will not contact you using your phone number unless you say it's OK. We will use your name and address to pay you at the end of the study. We will give you a study ID number so your name will not be connected to questionnaires. Personal information such as your name, phone number, or e-mail, will not be released to anyone without your written approval. 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 and Northwestern University. Only study staff that need this information to contact you will have access to it. Staff members may contact you to remind you about completing questionnaires. 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 one year after the completion of the study. The data that only has your ID number on it will not be destroyed. This surveys you complete as part of this study are hosted by REDCap and involves a secure connection. Terms of service, addressing confidentiality, may be viewed at https://projectredcap.org/partners/termsofuse/. The information from this study may be published in scientific journals or presented at scientific meetings, but your identity will be kept strictly confidential.

A description of this clinical trial (NCT03284541) will be available at http://www.ClinicalTrials.gov as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time. The results of the research study may be published, but your name will not be used.

What else do I need to know?

Participation in this study will involve no cost to you. You will receive $50 for completing the initial questionnaires, and $50 for completing the questionnaires at 3-, 6-, 9- and 12-months after you complete the program (up to $250 total). You will be paid with a pre-paid Visa credit card that is sent to you via email. You will be paid after you complete each set of questionnaires.

Who can I talk to?

If you have any questions about this study you may contact: Dr. Michael Newcomb is the person in charge of this research study and can be reached at 312-503-0702.

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.

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.