Information Statement

Aim 3 Information Statement (Version 2023.11.08)

Title of the Research Study: Mitigating sexual stigma within healthcare interactions to improve engagement of MSM (men who have sex with men) in HIV prevention

KEY INFORMATION

The information below tells you about our study. At the bottom, you can tell us whether or not you want to participate. If you consent to participate, we may contact you to participate in an in-person workshop, coaching sessions, surveys, and hourlong interviews to assess the implementation of an intervention to improve communication about anal pleasure and health during healthcare encounters. Discussing this topic may make you feel uncomfortable. There is no personal benefit to participating. Your responses may help us learn how to engage people on the topic of anal health during their healthcare encounters.

PURPOSE AND OVERVIEW

We want to learn how to reduce stigma toward anal sex. We are building and testing an anti-stigma program to help healthcare providers discuss anal sex with healthcare consumers, including gay and bisexual men, and thereby to improve HIV-related healthcare outcomes. This study is funded by a grant from the National Institute of Mental Health (Grant #K23MH124569). A description of this clinical trial will be available on 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.

VOLUNTARY

Participation in this research is voluntary. You do not have to complete any procedures or answer any questions you do not want to answer. You are free to withdraw from the study at any time without penalty or loss of benefits to which you are otherwise entitled. A decision not to participate or withdraw your participation will not affect your current or future treatment at Albert Einstein College of Medicine or Montefiore Medical Center.

PROCEDURES

Today we will ask for a name and an email address or phone number so that we may contact you for participation in an educational program that will include an in-person workshop, coaching sessions, surveys, and, for some participants, video or telephone interviews. You may choose an alias other than your legal name. We will ask questions about your background (for example, your age, sexual orientation, race and ethnicity, your role in relation to healthcare, and your experience and comfort discussing anal sex). We will ask you to create a unique identification code so that we can match today's survey responses with your later interview. You may opt-in to be emailed if and when we publish our research findings or conduct future research on this topic. Today's remaining questions will take 10-15 minutes to complete. Interviews will be approximately 60 minutes long and future surveys will be 10-15 minutes long.

To schedule a video or telephone interview, we may email, call or text you, depending on your preference. During the interview, we will ask about your thoughts about discussing anal pleasure and health during healthcare encounters and your observations of the acceptability, feasibility, and appropriateness of the educational program and how the program affected your perspective on and communication about anal pleasure and health (for example, your knowledge, skills, intentions, and resources).

AUDIO RECORDING

Not everyone will be selected for an interview, but if you are selected, you can only participate if you give permission to audio record the interview. We record audio in order to document accurately what you share with us. Only study staff and a third-party transcription service will have access to recordings. Any identifying information in audio files will be removed from the written transcripts. All audio files will be permanently deleted immediately after the study team finalizes the accuracy of the transcription. The third-party transcription service will not have access to your contact information or background information from today's online survey. You may withdraw consent for audio recording at any time, and at your request we will delete recordings permanently either during or after the interview.

RISKS AND INCONVENIENCES
In this study you will be asked about anal sex, including ways you have seen, experienced or perpetuated stigma toward this topic in healthcare settings. For some people, these subjects are sensitive. You may become uncomfortable with the questions you will be asked. We will take every precaution to ensure your privacy and the confidentiality of the information you share with us. However, no system for protecting your confidentiality can be completely secure.

BENEFITS
There is no personal benefit to participating in this study. You will have resources and learn skills to communicate about anal sex at a healthcare setting during the implementation of a program to improve patient-provider communication. Your responses may help us learn how to engage people on the topic of anal health during their healthcare encounters.

CONFIDENTIALITY
To protect your confidentiality, all study questionnaire responses, audio-recordings, transcripts, and any other data will be coded only with a unique study identification number. We will use HIPAA-compliant videoconferencing and web-based platforms and encrypted email communication. Any personal identifying information will be stored in an electronically secure database at Albert Einstein College of Medicine. Your private information may be used for future research studies by the Principal Investigator but will not be distributed to another investigator.

Records will be available to research staff, and to Federal, State and Institutional regulatory personnel who may review records as part of routine audits.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

STUDY COMPENSATION
You will be compensated for your participation in our research assessment of the program. Your compensation will vary depending on how many interviews and surveys you complete. Not everyone will be selected for an interview, but if you are selected then we will compensate you $50 after you complete each interview. (The maximum number of interviews per person will be two.) After you complete each of the three surveys, we will compensate you $30. Your total compensation will therefore range between $90 to $190. **We will send your compensation after you complete each assessment, but the first compensation will occur once you arrive for the in-person workshop. To compensate you, we will need you to share with us a physical mailing address.**

IN CASE OF INJURY
If you believe that you have sustained an injury as a result of participating in this research study, you may contact the Principal Investigator, Bryan Kutner, PhD, MPH, at (415) 596-9179 so that you can review the matter and identify the medical resources that may be available to you.

QUESTIONS
If you have questions after reading this information, please contact the Principal Investigator, Bryan Kutner, PhD, MPH, (415) 596-9179, bryan.kutner@einsteinmed.edu. You may ask about the study's purpose, procedures, risks and benefits, your rights, and anything else that is not clear. If you have questions about your rights as a research subject, you may additionally call the Institutional Review Board at (718) 430-2237.

Please download a copy or email yourself a link a copy of this Information Statement for your own records.

Would you like to join this research study?
- ○ Yes
- ○ No
- ○ I'm not sure (please contact me)