Title: A Pragmatic Trial of Two Strategies for Implementing an Effective eHealth HIV Prevention Program (Keep It Up! 3.0)

NCT Number: NCT03896776

Informed Consent Forms

- DTC Staff Consent Form – last approved 11/14/2022

Date Uploaded to ClinicalTrials.gov: 11/15/24

Consent to Participate in Research

Title of Research Study: ***A pragmatic trial of two strategies for implementing an effective eHealth HIV prevention program (Keep It Up! 3.0)***

Principal Investigator: ***Brian Mustanski***

Supported By: This research is supported by Northwestern University and the National Institute of Mental Health (NIMH).

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. Information that is more detailed is listed later on in this form.

The purpose of this study is to compare and evaluate two strategies for carrying out an online HIV prevention intervention for young men who have sex with men (YMSM). Our primary outcomes of interest for the study are public health impact (for example, reducing HIV risk) and comparative implementation-effectiveness of the two strategies for carrying out the intervention. We expect that you will spend no more than two hours participating in this research study. The primary risks of participation are breaches of confidentiality and the subsequent potential for negative impacts on your relationship with your supervisor. The main benefits are primarily conferred on society-at-large, as your participation will help expand scholarship on implementation of e-health interventions in community-based and other social service settings. If you agree to be in this study, we will ask you to participate in a brief online survey and a video-recorded interview. Participating in this research study is not a part of your job responsibilities – it is entirely up to you whether you want to participate in a survey and interview for this research study. The research team will not inform your employer whether you decided to be in this study or not.

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

We are asking you to take part in this research study because you have been identified by your employer as a staff member with decision making power over the implementation of Keep It Up! (KIU!) 3.0, an effective e-health HIV prevention program for young men who have sex with men (YMSM). Your participation will help us learn more about how community-based and other social service settings implement and integrate new programs, in particular e-health programs, into their existing offerings. Further, your participation will help us study the pros and cons of implementing KIU! into community-based and other social service settings vs a direct-to-consumer marketing and delivery approach.

How many people will be in this study?

We expect about 50 community-based and other social service setting staff members in 22 counties across the United States will be in this research study. We also expect approximately five staff members working on KIU! 3.0 at Northwestern University to be in this research study.

What should I know about participating in a research study?

- 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.
- You don't have to answer any survey and interview questions you do not want to answer.

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

If you consent to participate, you will be asked to complete a quantitative survey and qualitative interview to assess constructs related to implementation-effectiveness in the final year of the study grant. The quantitative survey will take approximately 5 minutes. The qualitative interview will be approximately 60-90 minutes. Qualitative interviews will be conducted remotely utilizing an online meeting software and will be audio and video recorded. Audio/video recording are required in order to participate in this study.

Should you agree to participate in the qualitative interview, research staff will work with you to schedule your qualitative interview at the time of your choosing to protect your privacy and confidentiality. Should you opt to complete your interview during work hours at the organization which employs you, research staff will strongly encourage you to reserve a private room or office wherein you may complete the interview privately. Should you prefer to complete the interview during non-work hours, away from your employer, as a strategy to protect your privacy, research staff will work with you to identify a time to do this. Note: if you elect to complete your interview at your work place, your employer may know that you are participating in this study. The research staff with Keep It Up! will maintain confidentiality of your data and never share your responses with your employer to the quantitative survey and/or qualitative interview you complete.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include feeling good about contributing to scholarship and providing an innovative service to your clients. Society will benefit from expanding scholarship on e-health implementation at community-based and other social service settings as well as the scaling out of an effective eHealth intervention that reduces risk behavior and STI incidence among YMSM, limiting the spread of HIV, and addressing health disparities.

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

While we will do our best to protect all of the information you provide us, with any study there is always the risk of loss of confidentiality. If responses your supervisor finds objectionable should become known to your supervisor, your participation could have negative consequences on your relationship with your supervisor. Further, while participation in research cannot be compelled by researchers, choosing not to participate in the research could have potential negative consequences for your relationship with your supervisor. KIU Project staff will never disclose the individual responses you provided to your employer or supervisor.

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

Participation in research is voluntary. You can decide to participate or not to participate. We will contact you for the duration of the study unless you tell us that you wish to withdraw from the study.

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. 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. No additional data will be collected after you withdraw but we would like to include data

collected up to the point of withdrawal in our analysis. You must notify the study team if you would like your data to not be included in analysis.

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.

A description of this clinical trial (NCT03896776) will be available on 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.

If identifiers are removed from your identifiable private information that is collected during this research, that information could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

The video-recordings of your qualitative interviews will only be used for data analysis.

Any reports about this study's findings will not identify you or quote you in a way that could identify you.

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.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

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 giving my OK?

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

the study team's belief that it is in your best interest, and any other reason deemed appropriate by the person in charge of the study.

Who can I talk to?

If you have questions, concerns, or complaints talk to the Principal Investigator Dr. Brian Mustanski by calling (312) 503-5421 or emailing him at brian@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 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.

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

I agree	I disagree	
_____	_____	The researcher may contact me in the future to see whether I am interested in participating in other research studies by the principal investigator of this study.

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.

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