Informed Consent Form

TITLE: Cross-disciplinary HIV Integrated Mental Health Support (CHIMES) Intervention

NCT NUMBER: NCT04833829

IRB APPROVAL DATE: June 1, 2020

You Are Being Asked to Be in a Research Study

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study you will be one of 75 people who are being studied, at Emory.

Why is this study being done?
This study is being done to develop, implement, and pilot test CHIMES- an intervention focused on enhancing HIV and MH care integration to improve engagement by increasing access, decreasing stigma, and prioritizing cultural competence.

Do you have to be in the study?
It is your decision to be part of this research study. You do not have to be in it. Before you make your decision, you should take time to learn about the study.

What do I have to do if I choose to participate in this study?
If you are eligible and want to be part of the study, you will participate for 12 months. The researchers will ask you to do the following: surveys and in-depth interviews (IDIs).

How is this study going to help you?
If you are in the study, you will be helping the researchers answer the study question. This study is designed to learn more about new, effective ways of delivering HIV and mental health care to help young Black MSM and others who are living with HIV. The study results may be used to help others in the future.

What are the risks or discomforts I should know about before making a decision?
The study will take time. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious – for this study, these loss of privacy, and breach of confidentiality. A full list of expected risks, their frequency and severity are in the "What are the possible risks and discomforts?" section of this document.

Alternatives to Joining This Study
Since this is not a treatment study, the alternative is not to participate.

Costs
You WILL NOT have to pay for any of the study procedures.
What Should I Do Next?

Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.) Take time to consider this, and talk about it with your family and friends.

Emory University
Consent to be a Research Subject

Title: Cross-disciplinary HIV Integrated Mental Health Support (CHIMES) Intervention

Principal Investigator: Sophia Hussen, MD MPH

Funding Source: Awaiting funding decision

Introduction

You are being asked to be in a research study. This form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study. You can skip any questions that you do not wish to answer.**

Before making your decision:

- Please carefully read this form or have it read to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. By signing this form you will not give up any legal rights.

Study Overview

The purpose of this study is to develop, implement, and pilot test CHIMES (Crossdisciplinary HIV Integrated MEntal Health) - an intervention focused on enhancing HIV and mental health (MH) care integration to improve engagement among young Black gay, bisexual, and other men who have sex with men (YB-GBMSM) through expanded screening, provider trainings, culturally tailored print materials, and multidisciplinary case review meetings.

Procedures

You will be asked to either participate in a survey, in-depth interview, or both.

The survey will take approximately half an hour to complete. It will be self-administered online. The survey will ask about your demographic information and experiences providing health care and working in this clinic.

A subset of participants will be asked to participate in one-on-one, face-to-face interviews. These in-depth interviews will take approximately one hour to complete and will be audio recorded. Interviews will be conducted in one study visit by a trained study team member. The interview will ask you more details about your experiences and thoughts about mental health and HIV care services. We will also ask you about what things might prevent or encourage people living with HIV to use the new proposed integrated HIV-mental health care services.

Risks and Discomforts

1. Potential loss of privacy and confidentiality. To minimize this risk, we will make sure that your name, contact information, and other identifying information will not be listed on the survey or transcripts from the in-depth interview. Also, we will ensure that all study documents will be locked in a filing cabinet. We will make sure study documents stored on the computer are password-protected.
2. You may experience emotional reactions such as feeling upset, uncomfortable or embarrassed. It may be difficult to speak critically about the way that services are provided at your place of employment. We will practice discretion and your feedback will never be attributed to you or shared with your supervisors.

New Information

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Benefits

This study is not designed to benefit you directly. This study is designed to learn more about new, effective ways of delivering HIV and mental health care to help young Black MSM and others who are living with HIV. The study results may be used to help others in the future.

Compensation

Survey respondents will receive a $25 gift card upon completion of each survey (at initial CHIMES implementation, and then at 6-, 12-, and 18-months post-implementation). IDI participants will receive an additional $50 gift card upon completion of each interview (6- and 12-months post-implantation).

Confidentiality

Certain offices and people other than the researchers may look at study records. Government agencies and Emory employees overseeing proper study conduct may look at your study records. These offices include the Office for Human Research Protections, the funder(s), the Emory Institutional Review Board, the Emory Office of Compliance. Study funders may also look at your study records. Emory will keep any research records we create private to the extent we are required to do so by law. A study number rather than your name will be used on study records wherever possible. Your name and other facts that might point to you will not appear when we present this study or publish its results.

Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.

Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Storing and Sharing your Information

De-identified data from this study, may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific

standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Your data from this study may be useful for other research being done by investigators at Emory or elsewhere. To help further science, we may provide your deidentified data and/or specimens to other researchers. If we do, we will not include any information that could identify you. If your data or specimens are labeled with your study ID, we will not allow the other investigators to link that ID to your identifiable information.

Once the study has been completed, we will send you a summary of all of the results of the study and what they mean. We will not send you your individual results from this study.

Withdrawal from the Study

You have the right to leave a study at any time without penalty. The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

Contact Information

Contact [redacted]

- if you have any questions about this study or your part in it,
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

If you are a patient receiving care from the Grady Health System and have a question about your rights, you may contact the Office of Research Administration at research@gmh.edu.

You can also stop the survey or interview at any time. This is completely voluntary.

Consent and Authorization

Consent and HIPAA Authorization for Optional Study/Studies:
Please initial below if you opt to participate in and authorize use and disclosure of your PHI in the optional study/studies previously described:

[Individual Interviews] _____Initials

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in this research study. By signing this consent and authorization form, you will not give up any of your legal rights.

_____
Name of Subject

_____ _____
Signature of Subject (18 or older and able to consent) **Date** **Time**

TO BE FILLED OUT BY STUDY TEAM ONLY

_____
Name of Person Conducting Informed Consent Discussion

_____ _____
Signature of Person Conducting Informed Consent Discussion **Date** **Time**