

Social Capital and Engagement in Care Among Young Black Men who have Sex with Men Living with HIV

NCT03664817

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You Are Being Asked to Be in a Research Study

What Is a Research Study?

The main purpose of research studies is to gain knowledge. This knowledge may be used to help others. Research studies are not intended to benefit you directly, though some might.

Do I Have to Do This?

No. Being in this study is entirely your choice. If you decide to join this study, you can change your mind later on and withdraw from the research study.

Taking part in a study is separate from medical care. The decision to join or not join the research study will not affect your status as a patient.

What Is This Document?

This form is an informed consent document. It will describe the study risks, procedures, and any costs to you.

This form is also a HIPAA Authorization document. It will describe how your health information will be used and by whom.

Signing this form indicates you are willing to take part in the study and allow your health information to be used.

What Should I Do Next?

1. Read this form, or have it read to you.
2. Make sure the study doctor or study staff explains the study to you.
3. Ask questions (e.g., time commitment, unfamiliar words, specific procedures, etc.)
4. If there will be medical treatment, know which parts are research and which are standard care.
5. Take time to consider this, and talk about it with your family and friends.

**Emory University and Grady Health System
Consent to be a Research Subject / HIPAA Authorization**

Title: Social Capital and Engagement in Care Among Young Black Men who have Sex with Men Living with HIV

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Hubert Department of Global Health, Emory University School of Public Health

Study-Supporter: Centers for Disease Control and Prevention

Introduction

You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of 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.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:

- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study 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. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

What is the purpose of this study?

The purpose of this study is to determine whether or not a group-based intervention can help increase social connectedness and HIV-related outcomes among young HIV-positive black gay, bisexual and other men who have sex with men.

What will I be asked to do?

You will be asked to participate in either one ten-hour session or two six-hour sessions with a group of other young men. This is a research study, so you will either go through an established program (the “control”) or our newly developed program (the “intervention”). The decision of which type of sessions you will participate in is decided at random, much like flipping a coin or like drawing straws. One month later, you will be asked to come in again for a brief follow-up session which will last approximately two hours. You will not find out which program you were in (“control” or “intervention” group) until the end of the study, but we hope that you will have a good experience either way.

At the beginning of the study, you will be asked to complete an online survey lasting approximately 30-45 minutes. We will ask you to do a similar survey after 3 months, and again after 9 months. These can be done online or in person.

Finally, we are also asking for your consent to look at your medical records from your HIV clinic (if you are in care), to see if our program has any impact on your appointment attendance or viral load, and to see how you are doing with your HIV care in general.

Qualitative Interview sub-study: you may also be asked to participate in a one-time interview after your participation, which will last approximately one hour and will gauge your opinions of the sessions you participated in and how helpful you found them.

Who owns my study information and samples?

If you join this study, you will be donating your study information (your answers to the survey questions). If you withdraw from the study, data that were already collected may be still be used for this study.

What are the possible risks and discomforts?

There may be side effects from the study procedures that are not known at this time.

The most common risks and discomforts expected in this study are: Unpleasant or uncomfortable experiences working with others in the group-based interventions.

The less common risks and discomforts expected in this study are: A breach of confidentiality relating to your personal health information. The study team will take many precautions to ensure that your name or other identifying information is not linked to your health information or other data. If you disclose personal information during the course of the group intervention, it is possible that others in the group may disclose this information to others. For example, there is the possibility that others in the group may discuss outside the group that you are HIV+ and that you have sex with men. If you aren't comfortable with that, you should not participate in the study.

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.

Will I benefit directly from the study?

It is our hope that participation in the study will increase your knowledge relating to your health conditions as well as your overall sense of well-being. This study is designed to learn more about how group participation influences healthcare outcomes. The study results may be used to help others in the future.

Will I be compensated for my time and effort?

You will be compensated for the group session(s) (\$75), and we will provide MARTA cards if needed to facilitate transportation to and from session(s). You will be compensated \$25 for each survey (and interview, if you participate in that substudy) that you complete—at baseline, 3 months and 9 months after enrollment. If you do not finish the study, we will compensate you for the visits you have completed. You will get \$150 total, if you complete all study visits, and \$175 if you also participate in the additional qualitative interview.

What are my other options?

If you decide not to enter this study, this will not affect your medical care. You do not have to be in this study to be treated for HIV.

How will you protect my private information that you collect in this study?

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents.

Storing and Sharing your Information

Your survey answers and health information will be stored and may be shared with other researchers, without your identifying information. The data will be available for any research question, such as research to understand what causes certain diseases (for example heart disease, cancer, or psychiatric disorders), or development of new scientific methods. By consenting to participate in this study, you are also consenting for us to share de-identified data with other researchers. We will never share any information that could be traced back to you, with anyone outside our research team.

Medical Record

No information from the study will go into your medical record at Emory, Grady Health System, or anywhere else. Also, if you decide to be in this study, it is up to you to let your other health providers know. We will not inform your healthcare providers and participation (or the decision not to participate) will not impact your medical care.

Costs

There will be no costs to you for participating in this study. You will not be charged for any of the research activities.

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.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your “protected health information” or “PHI.” To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the “Privacy Rules.” Here we let you know how we will use and disclose your PHI for the main study and for any optional studies in which you may choose to participate.

Main Study**PHI that Will be Used/Disclosed:**

The PHI that we will use or share for the main research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.

Purposes for Which Your PHI Will be Used/Disclosed:

We will use and share your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study related treatment and for payment for such treatment. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information.

Use and Disclosure of Your Information That is Required by Law:

We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

Authorization to Use PHI is Required to Participate:

By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your PHI. If you do not sign this form, then you may not participate in the research study.

People Who will Use/Disclose Your PHI:

The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study.
- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
 - Emory and Grady Health System offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRBs, the Grady Research Oversight Committee, the Emory Research and Compliance Offices, and the Emory Office for Clinical Research.
 - Government agencies that regulate the research including: [Office for Human Research Protections; Food and Drug Administration; Veterans Administration].
 - Public health agencies.
 - Research monitors and reviewer.
 - Accreditation agencies.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

Optional Study: Post-participation Interview**PHI That Will be Used/Disclosed for Optional Study:**

We will not collect any new PHI as a part of this interview, however, your responses may be linked to the PHI described above from the main part of the study.

Purposes for which your PHI will be Used/Disclosed for Optional Study:

We will use and disclose your PHI for the conduct and oversight of the qualitative interview study

People Who Will Use/Disclose Your PHI for Optional Study:

- The same people and groups who will use and disclose your PHI for the Main Study will also do so in connection with the optional research study/storage of PHI for future research.

Expiration of Your Authorization

Your PHI will be used until this research study ends.

Revoking Your Authorization

If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team at:

Sophia Hussen



At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the main study.

Other Items You Should Know about Your Privacy

Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information

Contact [study contact person(s)] at [telephone number(s)]: Sophia Hussen [REDACTED]

[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 [REDACTED] or [REDACTED] or [REDACTED]

- 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 [REDACTED]

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 [REDACTED]

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:

Qualitative Interview Study _____ **Initials**

TO BE FILLED OUT BY SUBJECT ONLY

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

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