

**Brothers Building Brothers by Breaking Barriers for Telehealth
Delivery (Tele-B6)
STUDY00003404**

Date: December 16, 2021
[NCT05829759](#)

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 60 people who are being studied, at Emory.

Why is this study being done?

We have developed a group program for young HIV-positive men and will be adapting it for telehealth delivery. The purpose of this study is to determine whether or not our program can help improve social connections and the health of young men in this study for online delivery.

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. Your choice will not affect your access to medical care for your condition. 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?

You will be asked to participate in an online group program with other young men living HIV. You will be assigned to participate in the online group immediately or after a brief waiting period. The decision of the timing of which sessions you will participate in is decided at random, much like flipping a coin.

At the beginning of the study, you will be asked to complete an online survey that will take about 30 minutes. We will ask you to come back and fill out the survey again after 2, 4, 6 months, and possibly after 8 months depending on the group you are in.

Additional sub-study: you may also be asked to participate in a one-time interview at the end of the study. This interview will last about one hour and ask your opinions of the group program.

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 other young men in the group program.

The less common risks and discomforts expected in this study are: A breach of confidentiality. We will do our best to make sure that your personal information is not seen by anyone outside our team. We will use passwords and

encryption to protect study files. Any papers (including this form) will be kept in a locked file cabinet that only we can access.

If you share personal information during the group program, it is possible that others in the group may tell this information to others. For example, someone in your group could disclose your sexuality or HIV status. If you aren't comfortable with that, you should not participate in the study.

It is possible that we will learn something new during the study about the risks of being in it. If this happens, we will tell you about it. You can then 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?

We hope that participation in the study will increase your knowledge about your health and your overall sense of well-being. This study is designed to learn more about how group participation helps young men's health. We hope the study results can be used to help others in the future.

Will I be compensated for my time and effort?

We will provide gift cards as tokens of appreciation for each group session (\$25 per session for six sessions), and a \$25 gift card each for completing the five surveys and up to one interview. You will get \$25 after each survey or interview that you complete. You will get up to \$275 total over one year if you complete all survey visits. You will get \$300 total if you also participate in the additional 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?

When 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 legal request for documents.

Storing and Sharing your Information

Your survey answers and health information may be shared with other researchers *without* your personal information. By agreeing to participate in this study, you also agree 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 chart at Emory, Grady Health System, or anywhere else. Participating (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 activities.

Withdrawal from the Study

You have the right to leave the study at any time without penalty. The researchers also have the right to stop your participation in this study, 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.

Alternatives to Joining This Study

Since this is not a treatment study, the alternative is not to participate.

Costs

There is no cost for participating in the study.

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

Title: Brothers Building Brothers by Breaking Barriers for Telehealth Delivery (tele-B6)

IRB #: 00003404

Principal Investigator: [REDACTED], MD, MPH

Study-Supporter: National Institutes of Health

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 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 or have a copy provided to you electronically. 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.

A description of this clinical trial 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.

Why is this study being done?

We have developed a group program for young men living with HIV and will be adapting it for telehealth delivery. The purpose of this study is to determine whether or not our program can help improve social connections and the health of young men in this study for online delivery.

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. Your choice will not affect your access to medical care. 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?

You will be asked to participate in an online group program with other young men living HIV. You will be assigned to participate in the online group immediately or after a brief waiting period. The decision of the timing of which sessions you will participate in is decided at random, much like flipping a coin.

At the beginning of the study, you will be asked to complete an online survey that will take about 30 minutes. We will ask you to come back and fill out the survey again after 2, 4, 6 months, and possibly after 8 months depending on the group you are in.

Additional sub-study: you may also be asked to participate in a one-time interview at the end of the study. This interview will last about one hour and ask your opinions of the group program.

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 other young men in the group program.

The less common risks and discomforts expected in this study are: A breach of confidentiality. We will do our best to make sure that your personal information is not seen by anyone outside our team. We will use passwords and encryption to protect study files. Any papers (including this form) will be kept in a locked file cabinet that only we can access.

If you share personal information during the group program, it is possible that others in the group may tell this information to others. For example, someone in your group could tell others that you are HIV-positive or that you are gay. If you aren't comfortable with that, you should not participate in the study.

It is possible that we will learn something new during the study about the risks of being in it. If this happens, we will tell you about it. You can then 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?

We hope that participation in the study will increase your knowledge about your health and your overall sense of well-being. This study is designed to learn more about how group participation helps young men's health. We hope the study results can be used to help others in the future.

Will I be compensated for my time and effort?

You will be paid to join the online group sessions. We will provide electronic gift cards as tokens of appreciation for completing the surveys and interview. You will get \$25 after each session and after each survey or interview that you complete. You will get up to \$275 total over one year if you complete all survey visits. You will get \$300 total if you also participate in the additional 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?

When 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 legal request for documents.

Storing and Sharing your Information

Your survey answers and health information may be shared with other researchers *without* your personal information. By agreeing to participate in this study, you also agree 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 chart at Emory, Grady Health System, or anywhere else. Participating (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 activities.

Withdrawal from the Study

You have the right to leave the study at any time without penalty. The researchers also have the right to stop your participation in this study, 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.

Alternatives to Joining This Study

Since this is not a treatment study, the alternative is not to participate.

Costs

There is no cost for participating in the study.

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 laboratory tests you have before and during the study.

Purposes for Which Your PHI Will be Used/Disclosed:

We will use and share your PHI only when necessary for the conduct and oversight of the research study. We may share your PHI with other people and places that help us carry out the study. Outside of a few key members of our research team ([REDACTED] and our study coordinator), this includes our analyst on the Emory Institutional Review board (IRB) as well as a university official who may come to audit our research project. If we lose contact with you, we may use your PHI to determine your health 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. If you do not sign this form, you will 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 ([REDACTED]), research coordinators, and research assistants will use your PHI in this study. We will keep a file with your name and contact information so that we can reach you to remind you of study visits. We will also use your name and date of birth to look at your medical records and determine how well you are doing with your HIV care.
- The research team may share your PHI with a few other people to make sure the research is done correctly and safely:
 - Our assigned analyst or the chair of the Emory IRB
 - The Grady Research Oversight Committee, the Emory Research and Compliance Offices, and the Emory Office for Clinical Research.
- Sometimes a research team moves to a different university. If this happens, your PHI may be shared with similar research offices in that new school. PHI will be shared under a legal agreement to ensure it continues to comply with the Privacy Rules.

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.

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: [REDACTED].

At that point, the researchers would not collect any more of your PHI. But we 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 study.

Other Items You Should Know about Your Privacy

We may remove personal information like your name and birthdate from your record. Once we do this, the remaining information will not fall under the Privacy Rules. Information without identifiers may be used or shared with other people for purposes besides this study.

Contact Information

Contact Dr. [REDACTED] at [REDACTED]:

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

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 complaints about the research or an issue you rather discuss with someone outside the research team.

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:

Optional Sub-Study: Post-Participation Interview _____ **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, and any optional studies you initialed above. 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