ADOLESCENT MEDICINE TRIALS NETWORK FOR HIV/AIDS INTERVENTIONS

CONSENT/ASSENT

Enhancing Sexual Safety: Couples' Communication and HIV Testing Among YMSM: ATN 156

NCT04289116

Sponsor:	National Institute of Child and Human Development (NICHD) National Institute on Drug Abuse (NIDA)
Protocol Lead:	Tyrel J. Starks, PhD Hunter College, New York, NY
Protocol Lead:	Sarah W. Feldstein Ewing, PhD Oregon Health & Science University Portland, Oregon
Recruitment and Enrollment Center:	PRIDE Health Research Consortium (PRIDE), Hunter College
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Study Procedure Guide Version Date:	**May 12, 2021**

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CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Enhancing Sexual Safety: Couples' Communication and HIV Testing Among YMSM (WE TEST)- Phase 3

Principal Investigators: Tyrel Starks (Hunter College), Sylvie Naar (Florida State University), Angulique Outlaw (Wayne State University), Beth Davenport (San Diego LGBT Community Center), & Sarah Feldstein Ewing (University of Rhode Island)

Introduction

You are invited to take part in a research study that is a collaboration between Florida State University, Hunter College at the City University of New York, Wayne State University in Detroit, The San Diego LGBT Center in San Diego, and University of Rhode Island in Kingston, RI.

Key Information about the research study

Things you should know:

- Taking part in this research is entirely voluntary. You may choose not to take part, or you may withdraw from the study at any time. In either case, you will not lose any benefits to which you are otherwise entitled.
- You may receive no benefit from taking part. The research may give us knowledge that may help people in the future.
- The purpose of the study is to deliver and test a HIV testing and counseling program for young people in couples.
- Due to COVID-19, participants may complete this research study in-office face to face, in-office virtually in separate assessment rooms, or entirely virtually from home depending on the participant's preference or the study team's preference.

Also, some people have personal, religious, or ethical beliefs that may limit the kinds of research procedures they would want to receive. If you have such beliefs, please discuss them with the research team before you agree to the study.

Now we will describe this research study. Before you decide to take part, please take as much time as you need to ask any questions and discuss this study with anyone on the FSU research team, or with family, friends or your personal physician or other professional.

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Principal Investigators: Tyrel Starks (Hunter College), Sylvie Naar (Florida State University), Angulique Outlaw (Wayne State University), Beth Davenport (San Diego LGBT Community Center), & Sarah Feldstein Ewing (University of Rhode Island)

Why is this study being done?

This study is being conducted by Tyrel Starks, PhD (Hunter College), Sylvie Naar, PhD (FSU), Angulique Outlaw PhD (Wayne State University), Beth Davenport (San Diego LGBT Community Center), & Sarah Feldstein Ewing, PhD (University of Rhode Island). It is funded by the National Institutes of Health (ATN 156).

The purpose of the study is to adapt couples HIV Testing and Counseling (CHTC) for adolescents and young adults aged 15-24 years old. CHTC was created for use with adults, so it may not be suitable for younger people like you. The purpose of this study is to compare different ways to deliver the counseling intervention that may be more suited for adolescents and young adults. In total, we aim to involve 200 individuals in this project.

Why are you being asked to take part in this study?

You are being asked to take part because you have indicated that you identify as male, genderqueer, gender non-conforming, aged 15-24, and have a male, genderqueer, or gender non-conforming partner.

How many people are expected to take part in this study?

We plan to have 200 people, in total, in this project.

Study Procedures

If you agree and are eligible to participate in this study, you will be asked to participate in the following activities (all study procedures may be completed remotely online):

Baseline Appointment: At your first appointment (your baseline appointment), you will have an HIV test, an STI test and complete an online survey on a computer. With the STI testing, we are testing for chlamydia (rectal and urethral) and gonorrhea (rectal and urethral).

If you are participating with your partner, they will also receive the HIV and STI testing and complete the online survey individually, separate from you. You, and your partner if they choose to participate, can either complete testing in-person or receive a testing kit in

the mail with your consent if you are over the age of 17. Your survey and STI data are confidential. We will not inform you of your partner's responses and they will not know yours.

Intervention: You will be randomized (like flipping a coin) into one of two groups that will receive different interventions. You will either be randomized to participate in the routine HIV testing version of the project, or in the We Test version. Both versions can be done on your own as an individual and/or you can participate with your partner as well.

If you are randomized to participate in the **routine HIV testing version** of the project, you will complete a baseline appointment with HIV testing, a one-month follow-up survey, a three-month visit, and a six-month visit, as described below:

If you are randomized to participate in the **We Test version** of the project, you will complete a baseline appointment with HIV testing, a one-month follow-up survey, a three-month appointment, and a six-month follow-up appointment, as described below.

If you are participating ALONE, you will watch videos on ACT, participate in Communication Skills Training (MI-CST), and complete an individual HIV test. You and the community health worker will talk about your goals for HIV testing, STI testing, PrEP/PEP use and assertive communication, as well as role-playing so you can practice the communication skills discussed.

If you are participating ALONE today, but later decide to participate in the study together, you will need to come back in with your partner to complete the We Test intervention as a couple.

If you are participating WITH YOUR PARTNER, you will watch videos on ACT, participate in Communication Skills Training (MI-CST), and will then jointly receive couples HIV Testing and Counseling (CHTC). MI-CST involves participating alone in one 30-minute session of an interviewing and training session with a community health worker. You and the community health worker will talk about your goals for HIV testing,

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STI testing, PrEP/PEP use and assertive communication, as well as role-playing so you can practice the communication skills discussed.

One-month follow-up survey: You will complete an online survey that can be completed at home (i.e., does not require an in-office visit).

Three-month follow-up visit: You will complete an online survey (either at home or in the office based on your preference and the study team's preference), and complete STI and HIV tests. You may be asked to complete the online survey and HIV and STI testing at home, using a self-testing kit we would mail to you.

Six-month follow-up visit: You will complete an online survey (either at home or in the office based on your preference and the study team's preference) and complete STI and HIV tests. You may be asked to complete the online survey and HIV and STI testing at home, using a self-testing kit we would mail to you.

STI/HIV Testing: You can have your STI and HIV tests done at the clinic or at home. For some follow-up appointments, you may be asked to take home-based STI and/or HIV tests, or you can go to a community lab for testing, like Quest Diagnostics, at no cost to you.

If you want to use a lab or have at home test(s), you have to agree to have the research team keep a copy of your contact information, and are giving permission for study staff to contact you to complete the study. You must be 17 or older to have at-home testing kits sent to you.

At-home testing kits may be mailed to your home address, or you can have the tests mailed to a different location that is safe, such as a youth center. You will have to speak with a trained staff member at your clinic or Hunter College to ensure that the arrangements are safe and allowed.

How long will I be in the study?
In total, you will be in the study for approximately 6 months.

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Study Title: Enhancing Sexual Safety: Couples' Communication and HIV Testing Among YMSM (WE TEST)

Principal Investigators: Tyrel Starks (Hunter College), Sylvie Naar (Florida State University), Angulique Outlaw (Wayne State University), Beth Davenport (San Diego LGBT Community Center), & Sarah Feldstein Ewing (University of Rhode Island)

Risks of Study Participation

The study has the following risks:
The risks and discomfort associated with participation in this study are no greater than those ordinarily encountered in daily life, standard medical care or physical/psychological tests. However, there is some risk of emotional discomfort or distress due to the personal nature of the topics discussed in the training and counseling sessions.

In addition to the other possible harms or discomforts related to research that we told you about, there may be risks with using web-based or online programs. First, someone may try to interfere or tamper with our collection of information from you. Second, after we collect information from you, someone may see or take information about you without permission. Third, by us recording our Zoom sessions, someone outside of the study team may recognize you and know what you said or what you did as part of this study. If any of these things happen, your privacy and the confidentiality of the information that you provide to us may be violated.

In addition to other possible harms or discomforts related to research that we told you about, there may be risks by having you take part in our face-to-face study activities during this time of the Coronavirus emergency. First, face-to-face activities and contact with other persons may increase the risk of getting Coronavirus. No one is yet quite sure how easily Coronavirus passes from person to person, how to know for certain when someone has or does not have Coronavirus, or what works best at preventing Coronavirus from spreading. Second, getting Coronavirus may result in a person being isolated or quarantined at home and away from work, family and other activities. Third, Coronavirus is, a serious illness that may require medical care including hospital care, long-term disability, and even death.
Fourth, certain persons are at higher risk for severe illness from Coronavirus, and these persons are not permitted to take part in our study.

Persons thought to be at higher risk include:

- Being 65 years of age or older

- Prior or current exposure to persons that have Coronavirus whether or not they know it
- Persons of any age with serious medical conditions such as diabetes, and heart, lung, kidney or liver disease, or persons who are severely obese
- Persons who have poor immunity, such as persons under cancer treatment or who have other conditions with weakened immune systems
- People who reside in nursing homes or other long-term care facilities

We will therefore by asking some questions screen all research participants and study staff to see who may be at risk of severe illness, or who have been exposed to Coronavirus. Even after we ask these questions, if you think that at any time before or during this study you may been exposed to Coronavirus or are at risk of severe illness, then we will ask you not to take part in this study, so please let us know.

While we will take steps to protect you from exposure to Coronavirus when you take part in our face-to-face activities, there is always the chance that you may still be exposed.

Finally, in order to reduce exposure to Coronavirus we will ask you to stay at least six feet away from anyone else, including us, during our activities; wear a special mask to cover your mouth and nose; wear gloves to cover your hands; wear other equipment to cover your head and body; sit behind a wall or in another room nearby; wash and sanitize your hands; not to touch your face or anything else during our study activities unless we say it is OK. These steps are required. Having to do these things may not be comfortable for you and may cause you to be worried or stressed.

In addition to the risks of these Coronavirus-related harms or discomforts, this research may have risks of other Coronavirus-related harms or discomforts that are unknown at this time. If in the future we become aware of any additional harms or discomforts that may affect you, we will tell you.

Benefits of Study Participation

The benefits to study participation are:

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This study can benefit you and other adolescents and young adults like you by helping develop a counseling intervention that is better suited for younger couples. Of course, because everyone responds differently, no one can know ahead of time if it will help you.

Alternatives to study participation

There are no therapeutic alternatives available at this time. An alternative is for you not to participate in this research study. Participants always have the option not to participate in this study, and referrals to other services are available to all study participants.

Ending the study

Your participation in this study is entirely voluntary. If you decide to leave the study, please contact the Site PI to inform them of your decision. Because withdrawing data threatens the scientific integrity of the study, we plan to securely store and later use all of the previously collected data in analyses to address the aims of the study. It is also important to the study that we continue collecting data at the follow-up assessment. We will ask you about whether you would be willing to continue with the follow-up assessment portion of the study, but you may choose not to continue. We will also ask you about your decision to withdraw your participation in this study in order to get your feedback about ways to help improve future studies.

We may end your participation for a number of reasons:

1. If, during the course of the assessment, it becomes clear that you do not meet study eligibility criteria,
2. If physical or psychological problems arise which would interfere with your voluntary participation in this study,
3. If we feel that it is in the best interests of your health, and/or
4. If we feel you are providing inaccurate or false information.

In addition, the research team may dismiss you if you engage in any hostile behavior toward the staff or if we find you are ineligible after completing your baseline appointment today.

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Study Costs/Compensation

There will be no cost to you for your participation in this research study.
You will be compensated for your participation in this study at the following rates:

Appointment	Study Component	Compensation Amount
Baseline	Survey	$30
	STI Testing	$10
	HIV Testing	$10
1 Month Follow-Up	Survey	$30
3 Month Follow-Up	Survey	$30
	STI Testing	$10
	HIV Testing	$10
6 Month Follow-Up	Survey	$30
	STI Testing	$10
	HIV Testing	$10

You will be paid the amounts specified above via cash or gift card. If you are participating virtually at home, the only option is to be paid via a gift card. To issue you a gift card, we may need to provide the gift card company with your email address for payment purposes only. You will have the option to decline the gift card company from receiving your email address and we would then send you the gift card anonymously.

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If you are randomized to receive the We Test version of the project, and complete the Baseline appointment, and if you and your partner come back to attend the We Test version of the project, your partner will receive the amounts listed above, while you would also receive an additional $20 for attending the second Intervention session.

Who can profit from study results?

No conflicts or gains have been identified in connection with this study. Florida State University reviews staff researchers for conflicts of interest.

Confidentiality

The records of this study will be kept private and confidential, to the extent allowed by law. In any publications or presentations, we will not include any information that will make it possible to identify you as a subject. Every effort will be made to keep all of the material related to you private and confidential. All records with personally-identifying information will be kept in a locked, limited access area (such as a locked file cabinet). All computer entry and networking programs will be done with coded numbers only.

However, research information that identifies you may be shared with the FSU Institutional Review Board (IRB) and others who are responsible for ensuring compliance with laws and regulations related to research, including people on behalf of the National Institutes of Health (NIH) and the Office for Human Research Protections (OHRP).

Your information will be kept confidential – we will only use this information to contact you for the purposes of this study. Data that cannot be linked to you individually (i.e., de-identified data) will be kept indefinitely; these data will be saved for future use and may be shared with other researchers. By participating in this study, you are agreeing to allow us to save and share your anonymous data.

The biospecimens collected for the purposes of this study will not be used to conduct any future research and will be destroyed after analysis is completed.

To help protect your confidentiality, a Certificate of Confidentiality has been obtained from the National Institutes of Health (NIH). With this Certificate, the researchers cannot

be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. A Certificate of Confidentiality does not represent an endorsement of the research study by the Department of Health and Human Services or the National Institutes of Health.

We will keep your records private unless we are required by law to share any information. The law says confidential information you share has to be told to legal authorities if you are a minor and reveal you are experiencing a legally reportable form of sexual or physical abuse, if you might hurt yourself or someone else, or if you reveal that a child or elderly person may be the victim of abuse.

Additionally, if you test positive with HIV or an STI, you should understand that California, New York, and Michigan state laws require healthcare providers and clinical laboratories to report the test results with your personally identifying information to the local health department. The study team is required to follow these laws.

A description of this study will be available on http://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 access this website at any time.

In addition to the steps we are taking to protect your privacy and confidentiality overall, we will also take other steps to keep people from tampering with our web-based or online activities or taking information without your permission.

First, we only use web-based and online programs that follow the laws and best standards for protecting against tampering or unauthorized access. Second, we limit who may have access to our Zoom account to only persons like you who are invited to take part and to members of my study team. Once the Zoom session is closed to taking part, no one else besides the study team has access.

Despite taking all these steps to protect your privacy or the confidentiality of your identifiable information, we are not able to guarantee that people will be unable to tamper with our web-based or online activities or take information without your permission.

AUDIO RECORDING:

As part of this project, an audio recording will be made of you during your session. Only your study ID number will appear on the audio file. Audio files will be stored on password-protected computers in a locked office and only Dr. Starks and the research team will have access to them. The audio records will be transcribed word for word. In the event that you accidently tell us personally-identifiable facts (e.g., your name) during the interview, this will be removed in the transcription. The audio recordings will be kept for three years after the study is completed, at which point they will be destroyed.

By signing this form and indicating your consent to being in the study, you are agreeing to permit the recording of sessions.

Voluntary Nature of the Study

Participation in this study is voluntary. Your decision whether or not to participate in this study will not affect your current or future relations with the universities involved. If you decide to participate, you are free to withdraw at any time without affecting those relationships. You are free to not answer any particular questions or discuss any particular topics. If you decide to leave the study, please contact the Protocol Lead for this project, Dr. Tyrel Starks, at (212) 206-7919, ext. 934 to inform him of your decision. Because withdrawing data threatens the scientific integrity of the study, we plan to securely store and later use all of the previously collected data in analyses to address the aims of the study. It is also important to the study that we continue collecting data at the

follow-up assessment. We will ask you about whether you would be willing to continue with the follow-up assessment portion of the study, but you may choose not to continue. We will also ask you about your decision to withdraw your participation in this study in order to get your feedback about ways to help improve future studies.

Contacts and Questions

The researchers conducting this study are Tyrel Starks, Sylvie Naar, Angulique Outlaw, Beth Davenport, and Sarah Feldstein Ewing. You may ask any questions you have now, or if you have questions later, you are encouraged to contact them by phone: Tyrel Starks at Hunter College at (212) 206-7919, ext. 934 and/or Sylvie Naar at Florida State University College of Medicine at (850) 644-3516.

If you have any questions or concerns regarding the study and would like to talk to someone other than the researcher(s), you are encouraged to contact the FSU IRB at telephone number 850-644-7900. You may also contact this office by email at humansubjects@fsu.edu, or by writing or in person at 2010 Levy Street, Research Building B, Suite 276, FSU Human Subjects Committee, Tallahassee, FL 32306-2742.

You will be given a copy of this form for your records.

Statement of Consent

I am 15-24 years of age. Yes No [if the answer is no, the individual cannot participate and should not be allowed to proceed to the next question.]

I identify as male, genderqueer, and/or gender non-conforming. Yes No [if the answer is no, the individual cannot participate and should not be allowed to proceed to the next question.]

My partner identifies as male, genderqueer, and/or gender non-conforming. Yes No [if the answer is no, the individual cannot participate and should not be allowed to proceed to the next question.]

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Study Title: Enhancing Sexual Safety: Couples' Communication and HIV Testing Among YMSM (WE TEST)

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I want to participate in this research and I understand that my participation is voluntary and I may stop my participation at any time. Yes No [if the answer is no, the individual cannot participate and should not be allowed to proceed to the next question.]

I have read the above information, I have asked questions, and have received answers. I consent to participate in this study. Yes No [if the answer is no, the individual cannot participate and should not be allowed to proceed to the next question.]

Questions to Verify Participant Understands Consent

It is important to us that we know you understand what this study entails. Please answer the following questions:

1. **True** or False: Participating in the study is my choice and I can choose to stop participating at any time, even if I agree today.
2. **True** or False: Every participant will be asked to complete an online survey one month, three months, and six months after their baseline appointment.
3. **True** or False: I can choose to participate in this study alone, as an individual, or with my partner, as a couple.
4. **True** or False: The HIV and STI testing performed for this study is free. I am not responsible for the cost of any study-related testing.
5. **True** or False: I will receive compensation for my time if I complete appointments and their components.

[IF AN INCORRECT ANSWER IS INDICATED ABOVE, THE CORRECT RESPONSES [BOLDED ABOVE] WILL BE PROVIDED TO THE PARTICIPANT.]

_____ _____

Signature of Research Subject Date

_____

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Printed Name of Research Subject

_____ _____

Signature of Person Obtaining Consent Date

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- You may receive no benefit from taking part. The research may give us knowledge that may help people in the future.
- The purpose of the study is to deliver and test a HIV testing and counseling program for young people in couples.
- Due to COVID-19, you may be asked to complete portions of the study or the entire study virtually from home.

Also, some people have personal, religious, or ethical beliefs that may limit the kinds of research procedures they would want to receive. If you have such beliefs, please discuss them with the research team before you agree to the study.

Now we will describe this research study. Before you decide to take part, please take as much time as you need to ask any questions and discuss this study with anyone on the FSU research team, or with family, friends or your personal physician or other professional.

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Why is this study being done?

This study is being conducted by Tyrel Starks, PhD (Hunter College), Sylvie Naar, PhD (FSU), Angulique Outlaw PhD (Wayne State University), Beth Davenport (San Diego LGBT Community Center), & Sarah Feldstein Ewing, PhD (University of Rhode Island). It is funded by the National Institutes of Health (ATN 156).

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Why are you being asked to take part in this study?

You are being asked to take part because you have indicated that you identify as male, genderqueer, and/or gender non-conforming, aged 15-24 and have a male, genderqueer, and/or gender non-conforming partner.

How many people are expected to take part in this study?

We plan to have 200 people, in total, in this project.

Study Procedures

If you agree and are eligible to participate in this study, you will be asked to participate in the following activities. All study procedures (including testing) may be completed remotely online.

Baseline Appointment: At your first appointment (your baseline appointment), you will have an HIV test, an STI test and complete an online survey on a computer. With the STI testing, we are testing for chlamydia (rectal and urethral) and gonorrhea (rectal and urethral).

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If you are participating with your partner, they will also receive the HIV and STI testing and complete the online survey individually, separate from you. You, and your partner if they choose to participate, can either complete testing in-person or receive a testing kit in the mail with your consent if you are over the age of 17. Your survey and STI data are confidential. We will not inform you of your partner's responses and they will not know yours.

Intervention: You will be randomized (like flipping a coin) into one of two groups that will receive different interventions. You will either be randomized to participate in the routine HIV testing version of the project, or in the We Test version. Both versions can be done on your own as an individual and/or you can participate with your partner as well.

If you are randomized to participate in the **routine HIV testing version** of the project, you will complete a baseline appointment with HIV testing, a one-month follow-up survey, a three-month appointment, and a six-month appointment, as described below:

If you are randomized to participate in the **We Test version** of the project, you will complete a baseline visit with HIV testing, a one-month follow-up survey, a three-month visit, and a six-month follow-up visit, as described below.

If you are participating ALONE, you will watch videos on ACT, participate in Communication Skills Training (MI-CST), and complete an individual HIV test. You and the community health worker will talk about your goals for HIV testing, STI testing, PrEP/PEP use and assertive communication, as well as role-playing so you can practice the communication skills discussed.

If you are participating ALONE today, but later decide to participate in the study together, you will need to come back in with your partner to complete the We Test intervention as a couple.

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If you are participating WITH YOUR PARTNER, you will watch videos on assertive communication training (ACT), participate in Communication Skills Training (MI-CST), and will then jointly receive CHTC. MI-CST involves participating alone in one 30-minute session of an interviewing and training session with a community health worker. You and the community health worker will talk about your goals for HIV testing, STI testing, PrEP/PEP use and assertive communication, as well as role-playing so you can practice the communication skills discussed.

One-month follow-up survey: You will complete an online survey that can be completed at home (i.e., does not require an in-office visit).

Three-month follow-up appointment: You will complete an online survey (either at home or in the office) and come to the office to receive STI and HIV tests. If you do not attend the in-office appointment, you may elect to complete the online survey at home.

Six-month follow-up appointment: You will complete an online survey (either at home or in the office) and come to the office to receive STI and HIV tests. If you do not attend the in-office appointment, you may elect to complete the online survey at home.

STI/HIV Testing: You can have your STI and HIV tests done at the clinic. If you relocate during the study or are unable to attend an ATN clinic after your baseline visit and intervention visits, you can take home-based STI and/or HIV tests, or you can go to a community lab for testing, like Quest Diagnostics at no cost to you.

If you want to use a lab or have at home test(s), you have to agree to have the research team keep a copy of your contact information and are giving permission for study staff to contact you to complete the study. You must be the 17 or older if you wish to have at home testing kits sent to you.
At-home testing kits may be mailed to your home address, or you can have the tests mailed to a different location that is safe, such as a youth center. You will have to speak with a trained staff member at your clinic or Hunter College to ensure that the arrangements are safe and allowed.

FLORIDA STATE UNIVERSITY

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ASSENT TO PARTICIPATE IN A RESEARCH STUDY

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How long will I be in the study?

In total, you will be in the study for approximately 6 months.

Risks of Study Participation

The study has the following risks:
The risks and discomfort associated with participation in this study are no greater than those ordinarily encountered in daily life, standard medical care or physical/psychological tests. However, there is some risk of emotional discomfort or distress due to the personal nature of the topics discussed in the training and counseling sessions.

In addition to the other possible harms or discomforts related to research that we told you about, there may be risks with using web-based or online programs. First, someone may try to interfere or tamper with our collection of information from you. Second, after we collect information from you, someone may see or take information about you without permission. Third, by us recording our Zoom sessions, someone outside of the study team may recognize you and know what you said or what you did as part of this study. If any of these things happen, your privacy and the confidentiality of the information that you provide to us may be violated.

In addition to other possible harms or discomforts related to research that we told you about, there may be risks by having you take part in our face-to-face study activities during this time of the Coronavirus emergency. First, face-to-face activities and contact with other persons may increase the risk of getting Coronavirus. No one is yet quite sure how easily Coronavirus passes from person to person, how to know for certain when someone has or does not have Coronavirus, or what works best at preventing Coronavirus from spreading. Second, getting Coronavirus may result in a person being isolated or quarantined at home and away from work, family and other activities. Third, Coronavirus is, a serious illness that may require medical care including hospital care, long-term disability, and even death.
Fourth, certain persons are at higher risk for severe illness from Coronavirus, and these persons are not permitted to take part in our study.

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Persons thought to be at higher risk include:
• Being 65 years of age or older
• Prior or current exposure to persons that have Coronavirus whether or not they know it
• Persons of any age with serious medical conditions such as diabetes, and heart, lung, kidney or liver disease, or persons who are severely obese
• Persons who have poor immunity, such as persons under cancer treatment or who have other conditions with weakened immune systems
• People who reside in nursing homes or other long-term care facilities

We will therefore by asking some questions screen all research participants and study staff to see who may be at risk of severe illness, or who have been exposed to Coronavirus. Even after we ask these questions, if you think that at any time before or during this study you may been exposed to Coronavirus or are at risk of severe illness, then we will ask you not to take part in this study, so please let us know.

While we will take steps to protect you from exposure to Coronavirus when you take part in our face-to-face activities, there is always the chance that you may still be exposed.

Finally, in order to reduce exposure to Coronavirus we will ask you to stay at least six feet away from anyone else, including us, during our activities; wear a special mask to cover your mouth and nose; wear gloves to cover your hands; wear other equipment to cover your head and body; sit behind a wall or in another room nearby; wash and sanitize your hands; not to touch your face or anything else during our study activities unless we say it is OK. These steps are required. Having to do these things may not be comfortable for you and may cause you to be worried or stressed.

In addition to the risks of these Coronavirus-related harms or discomforts, this research may have risks of other Coronavirus-related harms or discomforts that are unknown at this time. If in the future we become aware of any additional harms or discomforts that may affect you, we will tell you.

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Benefits of Study Participation

The benefits to study participation are:
This study can benefit you and other adolescents and young adults like you by helping develop a counseling intervention that is better suited for younger couples. Of course, because everyone responds differently, no one can know ahead of time if it will help you.

Alternatives to study participation

There are no therapeutic alternatives available at this time. An alternative is for you not to participate in this research study. Participants always have the option not to participate in this study, and referrals to other services are available to all study participants.

Ending the study

Your participation in this study is entirely voluntary. If you decide to leave the study, please contact the Site PI to inform them of your decision. Because withdrawing data threatens the scientific integrity of the study, we plan to securely store and later use all of the previously collected data in analyses to address the aims of the study. It is also important to the study that we continue collecting data at the follow-up assessment. We will ask you about whether you would be willing to continue with the follow-up assessment portion of the study, but you may choose not to continue. We will also ask you about your decision to withdraw your participation in this study in order to get your feedback about ways to help improve future studies.

We may end your participation for a number of reasons:

1. If, during the course of the assessment it becomes clear that you do not meet study eligibility criteria,
2. If physical or psychological problems arise which would interfere with your voluntary participation in this study,
3. If we feel that it is in the best interests of your health, and/or
4. If we feel you are providing inaccurate or false information.

In addition, the research team may dismiss you if you engage in any hostile behavior toward the staff or if we find you are ineligible after completing your baseline appointment today.

Study Costs/Compensation

There will be no cost to you for your participation in this research study.
You will be compensated for your participation in this study at the following rates:

Appointment	Study Component	Compensation Amount
Baseline	Survey	$30
	STI Testing	$10
	HIV Testing	$10
1 Month Follow-Up	Survey	$30
3 Month Follow-Up	Survey	$30
	STI Testing	$10
	HIV Testing	$10
6 Month Follow-Up	Survey	$30
	STI Testing	$10
	HIV Testing	$10

You will be paid the amounts specified above via cash or gift card. If you are participating virtually at home, the only option is to be paid via a gift card. To issue you a gift card, we may need to provide the gift card company with your email address for payment purposes only. You will have the option to decline the gift card company from receiving your email address and we would then send you the gift card anonymously.

If you are randomized to receive the We Test version of the project, and complete the Baseline appointment, and if you and your partner come back to attend the We Test version of the project, your partner will receive the amounts listed above, while you would also receive an additional $20 for attending the second Intervention session.

Who can profit from study results?

No conflicts or gains have been identified in connection with this study. Florida State University reviews staff researchers for conflicts of interest.

Confidentiality

The records of this study will be kept private and confidential, to the extent allowed by law. In any publications or presentations, we will not include any information that will make it possible to identify you as a subject. Every effort will be made to keep all of the material related to you private and confidential. All records with personally-identifying information will be kept in a locked, limited access area (such as a locked file cabinet). All computer entry and networking programs will be done with coded numbers only.

However, research information that identifies you may be shared with the FSU Institutional Review Board (IRB) and others who are responsible for ensuring compliance with laws and regulations related to research, including people on behalf of the National Institutes of Health (NIH) and the Office for Human Research Protections (OHRP).

Your information will be kept confidential – we will only use this information to contact you for the purposes of this study. Data that cannot be linked to you individually (i.e., de-identified data) will be kept indefinitely; these data will be saved for future use and may be shared with other researchers. By participating in this study, you are agreeing to allow us to save and share your anonymous data.

The biospecimens collected for the purposes of this study will not be used to conduct any future research and will be destroyed after analysis is completed.

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To help protect your confidentiality, a Certificate of Confidentiality has been obtained from the National Institutes of Health (NIH). With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written assent to receive research information, then the researchers may not use the Certificate to withhold that information. A Certificate of Confidentiality does not represent an endorsement of the research study by the Department of Health and Human Services or the National Institutes of Health.

We will keep your records private unless we are required by law to share any information. The law says confidential information you share has to be told to legal authorities if you are a minor and reveal you are experiencing a legally reportable form of sexual or physical abuse, if you might hurt yourself or someone else, or if you reveal that a child or elderly person may be the victim of abuse.

Additionally, if you test positive with HIV or an STI, you should understand that California, New York, and Michigan state laws require healthcare providers and clinical laboratories to report the test results with your personally identifying information to the local health department. The study team is required to follow these laws.

A description of this study will be available on http://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 access this website at any time.

In addition to the steps we are taking to protect your privacy and confidentiality overall, we will also take other steps to keep people from tampering with our web-based or online activities or taking information without your permission.

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First, we only use web-based and online programs that follow the laws and best standards for protecting against tampering or unauthorized access. Second, we limit who may have access to our Zoom account to only persons like you who are invited to take part and to members of my study team. Once the Zoom session is closed to taking part, no one else besides the study team has access.

Despite taking all these steps to protect your privacy or the confidentiality of your identifiable information, we are not able to guarantee that people will be unable to tamper with our web-based or online activities or take information without your permission.

AUDIO RECORDING:

As part of this project, an audio recording will be made of you during your session. Only your study ID number will appear on the audio file. Audio files will be stored on password-protected computers in a locked office and only Dr. Starks and the research team will have access to them. The audio records will be transcribed word for word. In the event that you accidently tell us personally-identifiable facts (e.g., your name) during the interview, this will be removed in the transcription. The audio recordings will be kept for three years after the study is completed, at which point they will be destroyed.

By signing this form and indicating your assent to being in the study, you are agreeing to permit the recording of sessions.

Voluntary Nature of the Study

Participation in this study is voluntary. Your decision whether or not to participate in this study will not affect your current or future relations with the universities involved. If you decide to participate, you are free to withdraw at any time without affecting those relationships. You are free to not answer any particular questions or discuss any particular topics. If you decide to leave the study, please contact the Protocol Lead for this project, Dr. Tyrel Starks, at (212) 206-7919, ext. 934 to inform him of your decision. Because withdrawing data threatens the scientific integrity of the study, we plan to securely store and later use all of the previously collected data in analyses to address the

aims of the study. It is also important to the study that we continue collecting data at the follow-up assessment. We will ask you about whether you would be willing to continue with the follow-up assessment portion of the study, but you may choose not to continue. We will also ask you about your decision to withdraw your participation in this study in order to get your feedback about ways to help improve future studies.

Do My Parents or Guardians Need to Know About This?

[DISPLAY FOR YOUTH UNDER 18 WHOSE PARENTS DO NOT KNOW THEIR SEXUAL IDENTITY OR SEXUAL BEHAVIOR OR WHO WILL BE PLACED AT RISK OF HARM FROM PARENTAL KNOWLEDGE OF STUDY PARTICIPATION AND NEED WAIVER OF PARENTAL CONSENT]

You do not need consent or permission from a parent or guardian to be a part of this study, but you are welcome to share with your parents that you are participating in this study, if you feel comfortable doing so. This will not impact your participation in this study, nor is this inconsistent with state law in Michigan, California, or New York.

[DISPLAY FOR YOUTH UNDER 18 WHOSE PARENTS KNOW THEIR SEXUAL IDENTITY AND SEXUAL BEHAVIORA AND WHO WILL NOT BE PLACED AT RISK OF HARM DUE TO PARENTS' KNOWLEDGE OF STUDY PARTICIPATION]

For youth under 18 who will not be placed at risk of harm, parental permission is required to take part in the study.

Does the parent or legal guardian grant permission for your participation in the study?
Only by clicking on a "Yes" response will you be permitted to take part in the study.

Yes No [If the answer is no, the individual cannot participate.]

Please indicate how you obtained parental permission.

My parent checked the "Yes" box. My parent told me to check the "Yes" box.

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Contacts and Questions

The researchers conducting this study are Tyrel Starks, Sylvie Naar, Angulique Outlaw, Beth Davenport, and Sarah Feldstein Ewing. You may ask any questions you have now, or if you have questions later, you are encouraged to contact them by phone: Tyrel Starks at Hunter College at (212) 206-7919, ext. 934 and/or Sylvie Naar at Florida State University College of Medicine at (850) 644-3516.

If you have any questions or concerns regarding the study and would like to talk to someone other than the researcher(s), you are encouraged to contact the FSU IRB at telephone number 850-644-7900. You may also contact this office by email at humansubjects@fsu.edu, or by writing or in person at 2010 Levy Street, Research Building B, Suite 276, FSU Human Subjects Committee, Tallahassee, FL 32306-2742.

You will be given a copy of this form for your records.

Statement of Assent

I am 15-24 years of age. Yes No [if the answer is no, the individual cannot participate and should not be allowed to proceed to the next question.]

I identify as male, genderqueer, and/or gender non-conforming. Yes No [if the answer is no, the individual cannot participate and should not be allowed to proceed to the next question.]

My partner identifies as male, genderqueer, and/or gender non-conforming. Yes No [if the answer is no, the individual cannot participate and should not be allowed to proceed to the next question.]

I want to participate in this research and I understand that my participation is voluntary and I may stop my participation at any time. Yes No [if the answer is no, the individual cannot participate and should not be allowed to proceed to the next question.]

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I have read the above information, I have asked questions, and have received answers. I assent to participate in this study. Yes No [if the answer is no, the individual cannot participate and should not be allowed to proceed to the next question.]

Questions to Verify Participant Understands Consent

It is important to us that we know you understand what this study entails. Please answer the following questions:

1. **True** or False: Participating in the study is my choice and I can choose to stop participating at any time, even if I agree today.
2. **True** or False: Every participant will be asked to complete an online survey one month, three months, and six months after their baseline appointment.
3. **True** or False: I can choose to participate in this study alone, as an individual, or with my partner, as a couple.
4. **True** or False: The HIV and STI testing performed for this study is free. I am not responsible for the cost of any study-related testing.
5. **True** or False: I will receive compensation for my time if I complete appointments and their components.

[IF AN INCORRECT ANSWER IS INDICATED ABOVE, THE CORRECT RESPONSES [BOLDED ABOVE] WILL BE PROVIDED TO THE PARTICIPANT.]

_____ _____
Signature of Research Subject Date

_____
Printed Name of Research Subject

_____ _____
Signature of Person Obtaining Assent Date

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_____

Printed Name of Person Obtaining Assent