NCT05215262 – TAKE Steps: Motivational Interviewing to Prevent STIs

Children's Hospital of Philadelphia ID: 19-016708

Protocol Title: Health Coaching to Improve Comprehensive HIV and Sexually Transmitted Infection Prevention in Adolescent Primary Care

Informed Consent Title: STI Health Coaching Intervention Randomized Trial

Informed Consent Date: 7/26/2023

Children's Hospital of Philadelphia

Informed Consent and HIPAA Authorization Form

Study Title: **Health Coaching to Improve Comprehensive HIV and Sexually Transmitted Infection Prevention in Adolescent Primary Care**

Version Date: July 26, 2023

Consent Name: STI Health Coaching Intervention Randomized Trial

Principal Investigator: Sarah Wood, MD, MSHP Telephone: 267-258-5894

You, or your child, may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of this research study, and the risks and possible benefits of participating.

In the sections that follow, the word "we" means the study doctor and other research staff. If you are a parent or legal guardian who is giving permission for a child, please note that the word "you" refers to your child.

Study Overview

You are being asked to take part in this research study because you are a 13 to 19-year-old who is being tested for a sexually transmitted infection (STI) at a CHOP Primary Care clinic.

The purpose of this study is to find out if a health coaching intervention increases HIV and STI prevention strategies in teens.

There are two phases of this study. The first phase of this study is the screening phase. During the screening phase, your eligibility will be confirmed, and you can agree to participate in the study's second phase, also called the intervention phase, which is described below. You will participate in the intervention phase only if you have a positive STI test result.

Participants in the intervention phase will be assigned to one of two different groups. Group one will receive their usual health care, and group two will receive four health coaching visits in addition to their usual health care. The health coaching sessions will help teens develop and meet their own HIV and STI prevention goals. Participants will be assigned to groups randomly and will not be able to choose which group they are in or change their group assignment.

If you agree to take part, your participation will last for about 6 months and will involve up to 6 study visits depending on what group you are assigned to. As a participant in the research, you will complete:

- Surveys on a computer or tablet
- Health coaching sessions (if assigned to the health coaching group) which might be recorded

- A brief feedback interview (if assigned to the health coaching group) which might be recorded

The main risks of this study are loss of confidentiality or feeling uncomfortable from the questions asked in the survey or coaching sessions.

You will not benefit directly from participating in this study.

If there is anything in this form you do not understand, please ask questions. Please take your time. You do not have to take part in this study if you do not want to. If you take part, you can leave the study at any time.

Please see below for additional details about the study.

How many people will take part?

About 150 individuals will take part in this study.

What is involved in the study?

All participants will complete surveys at the baseline, 3-month and 6-month visits. If assigned to the health coaching group, participants will receive health coaching sessions, at the baseline, 1-week, 1-month and 3-month visits, and a feedback interview at the 3-month visit. If you are assigned to the usual health care group, you will not receive health coaching sessions during the study. However, you will have the opportunity to receive one health coaching session after you have completed the study if you wish.

What are the study procedures?

Some of the procedures in this study will be repeated several times. Tests that are part of your regular, routine medical care will continue to be performed. The study involves the following procedures.

Randomization: You will be randomly assigned to a health coaching group or a standard care group. You will have a 2/3 chance of being assigned to the coaching group and a 1/3 chance of being assigned to the standard of care group.

Medical Record Review: We will collect information from your medical record such as your date of birth, diagnoses, test results, and medications.

Surveys: You will complete surveys on a computer or tablet. Some of them will contain sensitive or triggering questions. They will ask questions about 1) your age, sex and race, 2) emotions and trauma, 3) sexual behavior, 4) confidence about your behavior, 5) communication with sexual partners, 6) communication with healthcare providers, 7) health prevention goals, 8) thoughts about the coaching sessions. Both groups will complete about 40 minutes of surveys at 3 study visits. The coaching group has an additional 5 minute survey at 2 study visits.

Feedback Interview: After the 3-month health coaching session, you will complete a brief feedback interview. Your feedback will help the study team modify the study procedures for future studies.

Audio Recording: The health coaching sessions and feedback interview might be recorded. The research team and transcription service will be the only people who

hear the recordings. If someone's name is mentioned, it will not be included on any notes made by the researchers.

Experimental Procedures:

Health Coaching Intervention: You and the coach will look over the health coaching planning form and make an education plan for coaching sessions. Coaches will focus on improving your skills in prevention. Each session will include education about HIV/STI prevention topics based upon the plan you make with the coach.

Visit Schedule

The tables below provides a brief description of the purpose and duration of each study visit for each group of the study. If you are in the standard of care group, the visit schedule will look like Table 1.

Table 1. Standard of Care group		
Visit	**Main Procedures**	**Duration**
Screening/ Enrollment	Eligibility review, Informed Consent	1 hour
Baseline	Randomization, Surveys, Medical record review	1 hour
3 Months	Surveys, Medical record review	1 hour
6 Months	Surveys, Medical record review	1 hour

Table 2. Health Coaching Intervention group		
Visit	**Main Procedures**	**Duration**
Screening/ Enrollment	Eligibility review, Informed Consent	1 hour
Baseline	Randomization, Surveys, Medical record review, Health coaching intervention	1-2 hours
1 Week	Health coaching intervention, Survey	½ hour
1 Month	Health coaching intervention	½ hour
3 Months	Surveys, Medical record review, Health coaching intervention, Feedback interview	1-2 hours
6 Months	Surveys, Medical record review	1 hour

What are the risks of this study?

Taking part in a research study involves inconveniences and risks. The main risks of taking part in this study are discussed below:

- Some of the questions asked may be personal or uncomfortable. You do not have to answer any question that you do not want to, and you can end your participation at any time if you do not want to continue.

  You are able to inform the study team at any time if you are feeling distress. The study team member or study investigator (Dr. Wood) can provide you with resources.

- It is possible for those in the intervention group to experience discomfort with some of the questions. You are able to stop the coaching sessions at any time. You do not have to answer any question that makes you uncomfortable during the intervention. Coaching sessions will be done with trained coaches in a private setting to avoid emotional discomfort and keep them as confidential as possible.

- As with any study involving data collection, there is the possibility of loss off confidentiality of data. Every precaution will be taken to keep your personal information safe and ensure confidentiality. When you enter the study, you will be given a study identification number. This number will be used with your data.

- Risks associated with audio recording: The main risk to you is that someone could find out you were in this study. But we will do our best to keep your information confidential, so we think this risk is very low. Some people may feel uncomfortable having the interview recorded. You may skip any question or stop the interview or session at any time.

Are there any benefits to taking part in this study?

If you are in the intervention group, you may benefit if the health coaching intervention helps you to learn more about preventing STIs. However, we cannot guarantee that you will receive any benefit. The knowledge gained from this study may help determine the best strategies for HIV/STI prevention care for adolescents.

Do you need to give your consent in order to participate?

If you decide to participate in this study, you must sign this form. A copy will be given to you to keep as a record.

What are your responsibilities?

Please consider the study time commitments and responsibilities as a research subject when making your decision about participating in this study.

What happens if you decide not to take part in this study?

Participation in this study is voluntary. You do not have to take part in order to receive care at CHOP.

If you decide not to take part or if you change your mind later there will be no penalties or loss of any benefits to which you are otherwise entitled.

Can you stop your participation in the study early?

You can stop being in the study at any time. You do not have to give a reason. If you wish to stop being in the study, you will need to inform a member of the study team, either in writing or verbally.

What about privacy, authorization for use of Personal Health Information (PHI) and confidentiality?

As part of this research, health information about you will be collected. This will include information from medical records, interviews, and questionnaires. Information related to your medical care at CHOP will go in your medical record. Medical records are available to CHOP staff. Staff will view your records only when required as part of their job. Staff are required to keep your information private. Information that could identify you will not be shared with anyone - unless you provide your written consent, or it is required or allowed by law. We will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

The results of this study may be shown at meetings and published in journals to inform other doctors and health professionals. We will keep your identity private in any publication or presentation.

Several people and organizations may review or receive your identifiable information. They will need this information to conduct the research, to assure the quality of the data, or to analyze the data or samples. These groups include:

- Members of the research team and other authorized staff at CHOP;
- People from agencies and organizations that perform independent accreditation and/or oversight of research; such as the Department of Health and Human Services, Office for Human Research Protections;
- The National Institutes of Health who is sponsoring this research;
- Audio transcription agency specializing in health-related research (not including your name);
- Public health authorities that are required by law to receive information for the prevention or control of disease, injury, or disability.

By law, CHOP is required to protect your health information. The research staff will only allow access to your health information to the groups listed above. By signing this document, you are authorizing CHOP to use and/or release your health information for this research. Some of the organizations listed above may not be required to protect your information under Federal privacy laws. If permitted by law, they may be allowed to share it with others without your permission.

The identifiable information from this study will be destroyed six years after the study is completed.

Your permission to use and share the information and data from this study will continue until the research study ends and will not expire. Researchers continue to analyze data for many years, and it is not possible to know when they will be completely done.

Certificate of Confidentiality (CoC)

A Certificate of Confidentiality (CoC) covers this research. A CoC helps protect your identifiable information and biological samples.

A CoC protects your private information from all legal proceedings. Unless you consent, information from this research study that identifies you will not be shared outside this research.

- No one can be forced to share your identifiable information or biological samples for a lawsuit.
- Your information can't be used as evidence even if there is a court subpoena.

The CoC does not prevent some disclosures.

- The researchers can't refuse requests for information from those funding this research. The National Institute of Health may need information to assess this project.
- You can still share information about yourself. You can also freely discuss your involvement in this research.
- The researchers must disclose things required by law. This includes suspected child abuse and neglect, harm to self or others, or communicable diseases.

Can you change your mind about the use of personal information?

You may change your mind and withdraw your permission to use and disclose your health information at any time. To take back your permission, it is preferred that you inform the investigator in writing.

Dr. Sarah Wood
The Children's Hospital of Philadelphia
Craig Dalsimer Division of Adolescent Medicine
2716 South St
Roberts Center for Pediatric Research 11th Floor
Philadelphia, PA 19146

In the letter, state that you changed your mind and do not want any more of your health information collected. The personal information that has been collected already will be used if necessary for the research. No new information will be collected. If you withdraw your permission to use your personal health information, you will be withdrawn from the study.

Financial Information

While you are in this study, the cost of your usual medical care – procedures, medications, and doctor visits – will continue to be billed to you or your insurance.

Will there be any additional costs?

There will be no additional costs to you by taking part in this study.

Will you be paid for taking part in this study?

Participants in both groups will be paid $40 dollars each at the baseline, 3-month, and 6-month visits. Participants will be paid an additional $10 for completing baseline surveys within 3 business days of enrollment.

Participants in the health coaching group will be paid an additional $5 at the 1-week and 3-month visits if they complete a feedback survey or feedback interview after their health coaching sessions. Participants in the health coaching arm who completed a baseline coaching session but have missed subsequent visits, including a missed 3-month coaching session, will be offered $15 compensation for completing a feedback survey at the 3-month time point.

The maximum amount you can receive in the standard of care group will be $130 and the maximum amount you can receive in the health coaching group will be $140.

If you receive payment using a bankcard, the bank will have access to some personal information to process your payment. The bank will not have access to any medical information.

Who is funding this research study?

The National Institutes of Health is providing funding for this study.

Please ask Dr. Wood if you have any questions about how this study is funded.

What if you have questions about the study?

If you have questions about this study or how your samples/data are going to be used, call the study doctor, Dr. Wood at 267-258-5894. You may also talk to your own doctor if you have questions or concerns.

The Institutional Review Board (IRB) at The Children's Hospital of Philadelphia has reviewed and approved this study. The IRB looks at research studies like these and makes sure research subjects' rights and welfare are protected. If you have questions about your rights or if you have a complaint, you can call the IRB Office at 215-590-2830.

What will be done with my data and specimens when this study is over?

We may use and share data for future research. They may be shared with researchers/institutions outside of CHOP. This could include for profit companies. We will not ask for your consent before using or sharing them. We will remove identifiers from your data, which means that nobody who works with them for future research will know who you are. Therefore, you will not receive any results or financial benefit from future research done on your data.

Consent to Take Part in this Research Study and Authorization to Use and Disclose Health Information for the Research

The research study and consent form have been explained to you by:

Person Obtaining Consent	Signature of Person Obtaining Consent
	Date

By signing this form, you are indicating that you have had your questions answered, you agree to take part in this research study and you are legally authorized to consent to your child's participation. You are also authorizing the use of your/your child's health information as discussed above. If you don't agree to the collection, use and sharing of health information, you cannot participate in this study. **NOTE:** *A foster parent is not legally authorized to consent for a foster child's participation.*

Name of Subject	
Signature of Subject (18 years or older or minor who may consent for themselves)	Date
Name of Authorized Representative (if different than subject)	Relation to subject: ☐ Parent ☐ Legal Guardian
Signature of Authorized Representative	Date

Minor Assent to Take Part in this Research Study

For minors providing assent:

I have explained this study and the procedures involved to _____ in terms he/she could understand and that he/she freely assented to take part in this study.

_____
Person Obtaining Assent

_____ _____
Signature of Person Obtaining Assent Date

This study has been explained to me and I agree to take part.

_____ _____
Signature of Subject (optional) Date