**Official Title:**
Families Talking Together Plus (FTT+): An Online, Family-Based Approach to Promote Sexual Delay and Strengthen the Evidence-Base for Sexual Risk Avoidance Education

**NCT#:**
NCT04731649

**Informed consent document date**:
10/20/2023

Duke University Health System

**Consent to Participate in a Research Study**
**ADULT**
Families Talking Together Plus: A Family-Based Approach to Promote Sexual Delay and Strengthen the Evidence-Base for Sexual Risk Avoidance Education

CONCISE SUMMARY
The purpose of this study is to support healthy adolescent sexual behaviors, well-being, and life opportunities. Study activities occur over a period of up to 11 months, and take 3-6 hours to complete.

Parents and adolescents are asked to complete a survey at the start of the study, at 3 months and again at 9 months after the first survey. Parents and adolescents will be placed into one of two groups – intervention and non-intervention. Parents in the intervention group will be invited to complete the Families Talking Together plus (FTT +) intervention, which includes three sessions with a Life Opportunity Coach. These sessions are designed to support parent-child communication about healthy sexual behaviors. Some parents and adolescents may be asked to participate in a focus group after completing their last survey.

The main risk with this study is loss of confidentiality.

If you are interested in learning more about this study, please listen as the rest of this consent form is read to you.

You are being asked to take part in a study to learn more about how to help increase healthy adolescent sexual behaviors, life opportunities, and societal benefits. Families Talking Together Plus (FTT +) is a parent-focused intervention that promotes healthy adolescent sexual behaviors using community health workers (CHWs) as "Life Opportunity Coaches." As the community health worker discusses this consent form with you, please ask them to explain any words or information that you do not clearly understand.

The Principal Investigator for this study is Dr. Vincent Guilamo-Ramos. A grant from the Administration for Children and Families will sponsor this study. Portions of the research team's salaries will be paid by this grant.

**WHY IS THIS STUDY BEING DONE?**
The purpose of this study is to support healthy adolescent sexual behaviors, well-being, and life opportunities.
We want adolescents and their parents to be part of it. This study will see if parents can learn to support their adolescents' health and well-being using training materials that we have made.

**HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?**
Approximately 2000 residents of the South Bronx will take part in this study.

Duke University Health System

**Consent to Participate in a Research Study**
**ADULT**
Families Talking Together Plus: A Family-Based Approach to Promote Sexual Delay and Strengthen the Evidence-Base for Sexual Risk Avoidance Education

**WHAT IS INVOLVED IN THE STUDY?**
If you agree to participate in this study, we will ask:

1. All adolescents to fill out a survey that will take about 45 minutes. Your adolescent will be asked to go into a separate room to fill out a survey. There will be a staff member available to help your adolescent with any questions he or /she may have. This baseline assessment will be conducted with parents and adolescents in their homes or at a neutral site.

2. All parents to fill out a survey that will take about 45 minutes. You will be asked to go in a separate room from your adolescent to fill out their survey. There will be another staff member available to help your adolescent with any questions they might have. If your adolescent is interested in being tested for sexually transmitted diseases (STDs), we can navigate your adolescent to a local clinic for testing.

Once you have completed the first survey, you will be placed into one of two groups– intervention and non-intervention group. The decision of which group you are placed into is random, like drawing numbers from a hat, and happens completely by chance.

*Intervention group*
Adolescents and their parents that are placed into the intervention group will be asked to do the following:

1. Parent(s) will be invited to complete the Families Talking Together Plus intervention that promotes healthy adolescent sexual behavior. The intervention includes three parent activities, which will each be 60-90 minutes. These parent activities will be three remote sessions, by phone call or Zoom meeting, with the trained Life Opportunity Coach. The sessions will be designed to support parent-adolescent communication about healthy sexual behaviors.

2. We will contact you and your adolescent by phone call or Zoom meeting in order to complete a follow-up virtual survey, at 3-months after the first survey. If your adolescent is interested in being tested for STDs, we can navigate them to a local clinic for testing.

3. We will contact you and your adolescent by phone call or Zoom meeting in order to answer a survey, at 9 months after the first survey. If your adolescent is interested in being tested for STDs, we can navigate them to a local clinic for testing.

4. You and your adolescent may be invited to participate in a 1 to 1.5 hour focus group discussion that will be held via phone call or Zoom meeting. If you and your adolescent agree to participate, you will be remotely assigned with other individuals and a trained focus group facilitator. The parents that are selected to participate in the focus group will be placed with other parent participants, and the adolescents that are selected will be placed with other adolescent

Duke University Health System

**Consent to Participate in a Research Study**
**ADULT**
Families Talking Together Plus: A Family-Based Approach to Promote Sexual Delay and Strengthen the Evidence-Base for Sexual Risk Avoidance Education

participants. In both focus groups, the facilitator will ask parents and adolescents to offer their opinions about the importance of delaying sex and to elicit perspectives regarding virtual delivery of our program: Families Talking Together Plus.

*Non-intervention group*
Adolescents and their parents that are placed into the non-intervention group will be asked to do the following

1. We will contact you and your adolescent by phone call or Zoom meeting to complete a follow-up virtual survey, at 3-months after the first survey. If your adolescent is interested in being tested for sexually transmitted diseases (STDs), we can navigate them to a local clinic for testing. We will contact you and your adolescent by phone or Zoom meeting in order to complete a follow-up survey, at 9 months after the first survey. If your adolescent is interested in being tested for STDs, we can navigate them to a local clinic for testing.

2. You and your adolescent may be invited to participate in a 1 to 1.5 hour focus group discussion that will be held via phone call or Zoom meeting. If you and your adolescent agree to participate, you will be remotely assigned with other individuals and a trained focus group facilitator. The parents that are selected to participate in the focus group will be placed with other parent participants, and the adolescents that are selected will be placed with other adolescent participants. In both focus groups, the facilitator will ask parents and adolescents to offer their opinions about the importance of delaying sex, condom use, and to elicit perspectives regarding virtual delivery of our program: Families Talking Together Plus.

Virtual attendance at all survey assessments and requested activities is important so we can better understand how to help increase healthy adolescent sexual behaviors and life opportunities.

**Participant Counseling and Referral**
Some of the questions we ask on the survey may be sensitive. If any of the questions we ask make you upset or embarrassed, you can decide not to answer the question. If you feel that you need to talk about any discomfort you may experience, you should tell a staff member so that we may help you. We can talk to you about how you are feeling and answer any questions you may have. If you need more support, a staff member can refer you to a counselor. If needed, we can also remotely navigate your adolescent to a local clinic to be tested and/or treated for STDs.

**HOW LONG WILL I BE IN THIS STUDY?**
If you and your adolescent do choose to join, you both will be in the study for a total of up to 11 months. Participation in this study will involve between 3 to 6 hours for you to complete all the research activities.

Duke University Health System

**Consent to Participate in a Research Study**
**ADULT**
Families Talking Together Plus: A Family-Based Approach to Promote Sexual Delay and Strengthen the Evidence-Base for Sexual Risk Avoidance Education

## WHAT ARE THE RISKS OF THE STUDY?

If any of the questions we ask in the research activities make you upset or embarrassed, you can decide not to answer. If at any time during your participation in an activity you should feel uncomfortable, you may choose not to participate in the activity. If you want to stop, you can just let us know. We do not want to make you feel upset. A staff member can also refer you to a counselor if you need more support. There are no physical risks associated with this study. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

## ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

Participants in the data collection may directly or indirectly benefit from the Families Talking Together Plus intervention. These activities are designed to inform, evaluate, and improve community-based prevention and infrastructure development activities. Through participating in this study, you may have a better relationship with your adolescent and learn more about sexual health. Participants assigned to the non-intervention group may not experience these benefits until they participate in the intervention after the 9-month survey. We cannot guarantee that any participant will benefit from the Families Talking Together Plus intervention.

The study may also improve your engagement in and use of existing community services and resources that actively promote positive youth development and life opportunities. Lastly, your participation is helping to develop a program that can help others in your community. We want to come up with the best program possible and you can help us do that.

## WILL MY ADOLESCENT CHILD'S INFORMATION BE KEPT CONFIDENTIAL?

You and your adolescent's answers and anything either of you write will be kept private. If you and your adolescent participate in the focus-group, we will combine what you say or write with what other individuals say or write, which will lower the chance that any participant can be identified by what you say or write. For some project activities, we will take notes and tape record the activities so that we have an accurate record of what was said. Only the project team will have access to the notes, recordings, and surveys. Notes, recordings, and surveys that can be traced back to you will be retained in your research record for six years after the study is completed or until your adolescent reaches the age of 21, whichever is longer. At that time either the research information will be destroyed or information identifying you will be removed from such study results at DUHS.

To protect the safety and well-being of minors, we are required under NY law to report any information to authorities (police and/or child protection services) if we think a minor has been or is in immediate danger of being abused or neglected.

Duke University Health System

**Consent to Participate in a Research Study**
**ADULT**
Families Talking Together Plus: A Family-Based Approach to Promote Sexual Delay and Strengthen the Evidence-Base for Sexual Risk Avoidance Education

You and your adolescent's responses will be kept confidential by project staff, but we cannot guarantee that other participants in the focus-group will do the same. However, trained facilitators will reinforce the importance of confidentiality during the activities. If you are navigated to outside health services, we will adhere to NY State law regarding patient confidentiality. If you decide to share your adolescent's private information with anyone not involved in the study, the federal law designed to protect your adolescent's health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

Your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives from Duke University, ACF representatives and affiliates, the Duke University Health System Institutional Review Board, and others as appropriate.

This information may be further disclosed by the sponsor of this study. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations. While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your adolescent's name or other personal information will not be revealed.

**WHAT ARE THE COSTS TO YOU?**
There are no costs to you to be in the study.

**WHAT ABOUT COMPENSATION?**
If you agree to be part of the study, you will fill out 3 surveys. We will give you a $20 gift card for the first survey you complete, and a $50 gift card for each additional survey that you complete as part of our project. You may get a total of $120 in gift cards. If you are asked to participate in the focus groups, and you agree to participate, you will be eligible to receive a $20 gift card. At the end of the project, we will enter your family into a raffle system to earn an additional $50 gift card for completing all project activities within the 9-month window allotted. About 1 in every 3 families will win the raffle. In addition, our team will offer you additional project items, such as tote bags and t-shirts, as part of your ongoing participation in our project. We appreciate that you have given your time to the FTT project.

**WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?**
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal. All data that have already been collected for study purposes will be sent to the study sponsor.

Duke University Health System

**Consent to Participate in a Research Study**
**ADULT**
Families Talking Together Plus: A Family-Based Approach to Promote Sexual Delay and Strengthen the Evidence-Base for Sexual Risk Avoidance Education

If you do decide to stop participating in the study, we ask that you contact Dr. Guilamo-Ramos in writing and let him know that your adolescent is withdrawing from the study. His mailing address is Duke University School of Nursing, Box 3322, Durham, NC 27708, or email: Vincent.ramos@duke.edu.

Your data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name, are removed. If your identifying information is removed from your data, we will no longer be able to identify and destroy them.

A description of this clinical trial will be available on https://www.clinicaltrials.gov/ as required by U.S. Law. This Web site will not include information that can identify you or your adolescent. At most, the Web site will include a summary of the results. You can search this Web site at any time.

**WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?**
For questions about the study, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Vincent Guilamo-Ramos at (919) 684-9444 during regular business hours, and at (984) 243-7141 after hours and on weekends and holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

**STATEMENT OF CONSENT**
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

| | | |
|---|---|---|
| _____ | _____ | _____ |
| Signature of Person Obtaining Consent | Date | Time |
| _____ | _____ | _____ |
| Signature of Witness | Date | Time |