Efficacy Trial of a Brief Parent-Based Adolescent Sexual Health Intervention

NCT02600884

Version Date: 11/13/2015

UTHealth
The University of Texas
Health Science Center at Houston

INFORMED CONSENT FORM TO TAKE PART IN RESEARCH

Efficacy Trial of a Brief Parent-Based Adolescent Sexual Health Intervention

HSC-SN-15-0091

INVITATION TO TAKE PART

You are invited to take part in a research project called "Efficacy Trial of a Brief Parent-Based Adolescent Sexual Health Intervention" conducted by Dr. Diane Santa Maria, of the University of Texas Health Science Center. For this research project, she will be called the Principal Investigator or PI.

Your decision to take part is voluntary. You may refuse to take part or choose to stop taking part, at any time. You may refuse to answer any questions asked or written on any forms. This research project has been reviewed by the Committee for the Protection of Human Subjects (CPHS) of the University of Texas Health Science Center at Houston as HSC-SN-15-0091.

PURPOSE

The purpose of this research study is to evaluate a brief parent-based adolescent sexual health intervention called Families Talking Together, or FTT+ and an obesity prevention intervention. Your child is being asked to take part in this study because he/she is between the ages of 11-14 years old, the age range with the largest burden of sexually transmitted infection, HIV, and unplanned pregnancy.

This study will enroll 530 parent-child dyads. This is a local study with several sites in the Greater Houston area, and it is being conducted with funds from the National Institute of Child Health and Human Development.

PROCEDURES

Before any study-related tests and procedures are performed, you will be asked to read and sign this consent document. If you are: 1) the parent of a child between the ages of 11-14 years old who resides with you and attends a participating community center, after school program, or Boys and Girls Club; 2) are available for a face-to-face or small group

session with research personnel; and 3) speak English or Spanish, then you qualify to take part in this study.

If you agree to take part in the study you will be asked to:

- Complete a questionnaire about your demographics (age, income, family size, etc.), beliefs, and experiences regarding adolescent sexual health, parent-child communication, and parental monitoring and allow the nursing student to measure your height and weight.
- Attend a face-to-face or small group informational session.
- Designate a time to talk with your child about the content from the informational session.
- Take part in two (2) telephone-based booster sessions at one- and three-months following the informational session.
- Complete a questionnaire at one- and six-months following the informational session.

TIME COMMITMENT

The questionnaires will take about 30 minutes to complete, and the informational session will last about one hour. The entire duration of the study is 6 months.

BENEFITS

There may be no direct benefit from taking part in this study. However, information from this study may help researchers better understand the effects of a parent-based adolescent sexual health intervention, and how parents communicate with their children about sexual health topics.

RISKS AND/OR DISCOMFORTS

There are no expected risks, side effects or discomforts in participating in this study. However, you may feel uncomfortable or embarrassed by some of the questions on the questionnaire you will be asked complete. Reflecting on your feelings, emotions, thoughts, and parenting strategies may trigger concern, sadness, confusion, denial, or uncertainty.

You do not have to answer any questions you do not want to answer. Similarly, you can always take a break or leave an informational session early if you so desire.

There is a possible risk to your confidentiality. Although you will be assigned a study identification number, there is a master file where names and study numbers are listed. In order to lessen the risk to confidentiality, this master file is stored as an encrypted file on a password protected server at UTHSC.

Please know that there is certain information that if disclosed, must be reported to the appropriate agencies including law enforcement and/or child protective services. Reportable information includes rape, incest, child abuse, thought to harm oneself and/or others, and any other information that suggests harm to a minor. It is not a breach of confidentiality to report child abuse including sexual abuse or the other events listed above.

ALTERNATIVES

The only alternative is not to take part in this study.

STUDY WITHDRAWL

Your decision to take part is voluntary. You may decide to stop taking part in the study at any time.

In addition, there may be instances where the PI may withdraw you from the information sessions proposed in this study. If the PI determines that you do not meet the eligibility criteria or if the PI is unable to set up a mutually agreeable time and location for the session, you may be withdrawn from the study.

However, the information collected up to the point of your withdrawal will still be used in the study without any personal identifiers.

IN CASE OF INJURY

If you suffer any injury as a result of taking part in this research study, please understand that nothing has been arranged to provide free treatment of the injury or any other type of payment. However, all needed facilities, emergency treatment and professional services will be available to you, just as they are to the community in general. You should report any injury to Dr. Diane Santa Maria 713-500-2187 and to the Committee for the Protection of Human Subjects at (713) 500-7943. You will not give up any of your legal rights by signing this consent form.

COST, REIMBURSEMENT, AND COMPENSATION

There will be no charge to you for taking part in this study. However, each participant will receive a $20 gift card after completing the face-to-face session and the 1- and 6-month post surveys ($60 total).

CONFIDENTIALITY

You will not be personally identified in any reports or publications that may result from this study. Any personal information about you that is gathered during this study will remain confidential to every extent of the law. A special identification number will be used to identify you in the study and only members of the study team will know your name.

QUESTIONS

If you have questions at any time about this research study, please feel free to contact the PI, Dr. Diane Santa Maria, at 713-500-2187. She will be glad to answer your questions. You can contact the study team to discuss problems, voice concerns, obtain information, and offer input in addition to asking questions about the research.

AUTHORIZATION TO ACCESS IMMTRAC RECORDS/ENTER NEW IMMUNIZATIONS INTO IMMTRAC

ImmTrac, the Texas Immunization Registry, is a no-cost service offered by the Texas Department of State Health Services (DSHS). It is a secure and confidential registry available to all Texans. ImmTrac safely consolidates and stores immunization information from multiple sources electronically in one centralized system. Texas law requires written consent for ImmTrac participation and limits access to the registry to only those individuals who have been authorized by law. ImmTrac contains over 120 million immunization records and continues to rapidly grow with increased participation. The registry is a major component of the DSHS initiative to increase vaccine coverage across Texas.

_____I agree to allow research personnel to access my child's ImmTrac records.

SIGNATURES

Sign below only if you understand the information given to you about the research and choose to take part. Make sure that any questions have been answered and that you understand the study. If you have any questions or concerns about your rights as a research subject, call the Committee for the Protection of Human Subjects at (713) 500-7943. You may also call the Committee if you wish to discuss problems, concerns, and questions; obtain information about the research; and offer input about current or past participation in a research study. If you decide to take part in this research study, a copy of this signed consent form will be given to you.

_____

Printed Name of Subject

_____ _____ _____

Signature of Subject Date Time

_____

Printed Name of Person Obtaining Informed Consent

_____ _____ _____

Signature of Person Obtaining Informed Consent Date Time

CPHS STATEMENT: This study (HSC-SN-15-0091) has been reviewed by the Committee for the Protection of Human Subjects (CPHS) of the University of Texas Health Science Center at Houston. For any questions about research subject's rights, or to report a research-related injury, call the CPHS at (713) 500-7943.