A text message intervention to improve the reproductive health of adolescent females in the emergency department

Part 2: Reducing Teen Pregnancy in the Emergency Department (ERICA)

NCT03866811

Informed Consent Form

Document date: April 1, 2020

Columbia University Consent Form

Protocol Information

Attached to Protocol: IRB-AAAR6781
Principal Investigator: Lauren Chernick (lc2243)
IRB Protocol Title: A text message intervention to improve the reproductive health of adolescent females in the emergency department

General Information

Consent Number: CF-AABG6750
Participation Duration: 12 weeks
Anticipated Number of Subjects: 100
Research Purpose: The purpose of this study is to understand if text messaging from the emergency department can improve adolescent sexual health.

Contacts

Contact	Title	Contact Information
Lauren Chernick	Principal Investigator	Phone: 212-305-9825 Email: lc2243@cumc.columbia.edu

Information on Research

Introduction

The purpose of this form is to give you information to help you decide if you want to take part in a research study. This consent form includes information about:

- why the study is being done;
- the things that you will be asked to do if you are in the study;
- any known risks involved;
- any potential benefit;
- options, other than taking part in this study, that you have.

The principal investigator (the lead researcher for this project) Dr. Lauren Chernick or a trained researcher will discuss the study with you. If at any time you have questions about the study, please ask a member of the study team. Take all the time you need to decide whether you want to take part in this research study.

What information is on this form?

We are asking you to take part in a research study. This form explains why we are doing this study and what you will be asked to do if you choose to be in this study. It also describes the way we (Researchers) would like to use and share information about you.

Please take the time to read this form. You should ask us any questions you have about this form and about this research study. You do not have to participate if you don't want to.

Why is this study being done?

We are doing this research study to find out how text messaging can affect the reproductive health choices of adolescent female patients. We also want to learn if it is feasible to send messages from the emergency department and if you like receiving them. You are being asked to take part in this texting study because you are a teenage female. About 50 females are expected to be enrolled in this study.

What will I be asked to do if I choose to be in this study?

If you agree to be in this study, you will receive text messages over the next 10 weeks. Many of these messages will be interactive, meaning you can write back and get a response back from us. Messages will come at a time you choose. At any point, you can "opt out" and can stop receiving messages. However, there will not a "live" person at the other end. If you text us, we will reply within 24 hours.

After you get all the texts, we will call you for follow up to get your opinions on the text messages and to also understand how the texts affected the sexual health choices you made.

Today, we will collect some information about you, including information about your demographics, prior use of medical care, and sexual behaviors. In 12 weeks, we will review your Columbia University Medical Center (CUMC) and/or NewYork-Presbyterian Hospital (NYPH) electronic medical records and collect information, such as if you saw a doctor and what happened during that visit. We will ask you today to sign a separate authorization form so that we can obtain your medical records in case your receive care outside CUMC or NYPH. We will also call you to ask you some questions.

Risks

Confidentiality

A risk of taking part in this study is the possibility of a loss of confidentiality. Loss of confidentiality includes having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. We will do everything we can to keep your data secure, however, complete confidentiality cannot be promised. Despite all of our efforts, unanticipated problems such as a stolen computer may occur, although it is highly unlikely.

Benefits

Are there benefits to taking part in this study?

You may receive personal (direct) benefit from taking part in this study. The possible benefits of taking part in this study include learning about different methods of birth control and how to protect yourself from infections.

Alternative Procedures

What other options are there?

You may choose not to take part in this research study. Whether or not you are a part of this study will not affect the medical care you receive today.

Confidentiality

What about confidentiality?

Access to your health information is required to be part of this study. If you choose to take part in this study, you are giving us the authorization (i.e. your permission) to use the protected health information and information collected during the research that can identify you. The health information that we may collect and use for this research may include medical history. However, this project does not involve collecting health information that may be considered sensitive.

Any research information that is shared with people outside of Columbia University Medical Center and NewYork-Presbyterian Hospital will not include your name, address, or any other direct identifier unless disclosure of the information is required by law or you have authorized the disclosure. Your phone number will be shared with a secure mobile platform company, who has committed to keep your number confidential.

Your information will be assigned a code number, and separated from your name or any other information that could identify you. The research file that links your name to the code number will be kept in a locked file cabinet and only the investigator and authorized study staff will have access to the file.

The following individuals and/or agencies will be able to look at, copy, use, and share your research information:
- The investigator, Columbia University Medical Center and NewYork-Presbyterian Hospital study staff and other medical professionals who may be evaluating the study
- Authorities from Columbia University, including the Institutional Review Board ('IRB')
- The Office of Human Research Protections ('OHRP')
- The National Institute of Health (NIH)
- Our data and safety monitoring board

Your authorization to use and share your health information will expire when the research is completed. Once your health information has been disclosed to a third party (for example, a mobile platform company participating in a study), federal privacy laws may no longer protect it from further disclosure.

You may change your mind and revoke (take back) this consent and authorization at any time and for any reason. To revoke this consent and authorization, you must contact the Principal Investigator, Dr. Lauren Chernick. However, if you revoke your consent and authorization, you will not be allowed to continue taking part in the Research. Also, even if you revoke this consent and authorization, the Researchers and the Sponsor (if applicable) may continue to use and disclose the information they have already collected.

Compensation

Will I get paid or be given anything to take part in this study?

We will give you a $10 gift card to pay you for your time. You will also be entered into a raffle to receive a $200 gift card if you complete follow up. If you are one of the first 10 participants enrolled, and receive weekly follow up calls, you will also receive $40 at the end of all 10 weeks to earn a total of $50.

Voluntary Participation

Do I have to be in the study?

Taking part in this study is voluntary and your choice. You can decide not to take part in or stop being in the study at any time. Your choice will not affect the treatment you receive from doctors and staff at Columbia University Medical Center and NewYork-Presbyterian Hospital.

Additional Information

Whom may I call if I have questions?

You may call Dr. Lauren Chernick at telephone (212) 305-9825 if you have any questions or concerns about this research study.

If you have any questions about your rights as a research participant, or if you have a concern about this study, you may contact the office below.

Human Research Protection Office
Institutional Review Board
Columbia University Medical Center

154 Haven Avenue, 1st Floor
New York, NY 10032
Telephone: (212) 305-5883
Email: irboffice@columbia.edu

An Institutional Review Board is a committee organized to protect the rights and welfare of human subjects involved in research. More information about taking part in a research study can be found on the Columbia University IRB website at: http://www.cumc.columbia.edu/dept/irb.

Statement of Consent

Statement of Consent and Signatures

Statement of consent and HIPAA authorization
I have read this consent form and HIPAA authorization. The research study has been explained to me. I agree to be in the research study described above.

A copy of this consent form will be provided to me after I sign it.
Another copy will be placed in my medical record.
By signing this consent and HIPAA authorization form, I have not given up any of the legal rights that I would have if I were not a participant in the study.

Signatures

_____

Research Participant Date

_____

Print Name of Research Participant

_____

Person Obtaining Consent Date

_____

Print Name of Person Obtaining Consent