MULTI-LEVEL INTERVENTION TO REDUCE PREGNANCY RISK AMONG ADOLESCENTS: A FEASIBILITY TRIAL IN THE EMERGENCY DEPARTMENT

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ADOLESCENT CONSENT/ASSENT TO PARTICIPATE IN A RESEARCH STUDY AT CHILDREN'S MERCY HOSPITALS

Miller R-21

SUMMARY

This research study is being done to get a better understanding of how we can make it easier to get birth control in different places, like the Emergency Room. Up to 98 female teens between the ages of 15-18 will be asked to be in this study at two different ERs. Teens may be able to be in the study if they have had sex with a male (or think they might have sex soon), do not want to get pregnant, and are not using hormonal birth control, or copper IUD. Some teens may be offered birth control today or get a referral for a specialized clinic. We are asking you to be in this research study. Being in a research study is voluntary and your choice will not affect your regular medical care.

WHO IS DOING THIS STUDY?

A study team led by Dr. Melissa Miller, MD and Dr. Cynthia Mollen, MD are doing this study with the help of other health care professionals. Funding for this study comes from The National Institutes of Health. The study team will not receive any personal payment because of your decision.

WHY IS THIS STUDY BEING DONE?

This study is being done to see what happens when teens are offered counseling about birth control in the Emergency Room (ER). We will ask teens how they feel about different birth control methods and follow-up at 30 days, 3-months, and 6-months to see what happened after the ER visit.

WHAT WILL HAPPEN TO ME IN THIS STUDY?

If you chose to be part of this study, we will ask you to take a survey on an iPad that will ask about your health behaviors (like using a condom or birth control). After the survey you will talk to a provider about different types of birth control, this will take about 10-15 minutes. Your conversation with the provider will be audio recorded. This is to make sure that we are following the proper rules of the study. Audio recordings will be de-identified, which means we will not have your personal information like your name. After talking with the provider, some teens will have the opportunity to accept birth control or a referral for follow-up care.

If you decide to participate then you will be "randomized" into one of two groups described below. This means that you are put into a group by chance (like flipping a coin).
There is no way to know which group you will be assigned to and you or your doctor cannot choose what group you will be in. Teens in both groups will receive handouts about places to go to receive health services. Parents who are present in the Emergency Department will receive an information sheet that talks about the study.

Group 1. You will talk in private with a nurse practitioner or physician assistant about birth control. After talking, you can choose to get birth control today in the ER, or a prescription sent home if you want it. Any method given during your emergency department visit will be covered free of charge. If a prescription is given, you are responsible for covering the medication using either your insurance or paying out of pocket. The nurse practitioner will first make sure it is ok for you to start a medicine today, then you could choose a birth control shot, pill/patch/ring, or implant. You can also choose to get an appointment in our clinic that specializes in birth control for teens. All teens that choose to start birth control must have a negative urine pregnancy test while they are in the ER. A member of the research team will also give you a take-home pregnancy test to take in 2 weeks after you leave the ER. You may also choose not to start any medicine and not to go to clinic. The choice is totally up to you. After your visit to the ER, you will be asked to complete 3 follow-up surveys at 30 days, 3 months, and 6 months. These can be done during a phone call or using a link to a computerized survey.

Group 2. You will talk in private with a nurse practitioner or physician assistant about birth control. After talking, you can choose to get an appointment in our clinic that specializes in birth control for teens if you do not have a preferred doctor. You may also choose not to go to clinic or get follow up care from your normal doctor's office. The choice is totally up to you. After your visit to the ER, you will be asked to complete 3 follow-up surveys at 30 days, 3 months, and 6 months. These can be done during a phone call or using a link to a computerized survey.

WHAT ARE THE RISKS OF THE STUDY?

There is minimal risk for being in this study. There is a chance that some of the questions may make you feel uncomfortable or embarrassed. You don't have to answer those questions if you don't want to and you can stop the being in the study at any time.
As part of this study, you may be offered birth control by a healthcare provider. You will also be given information sheets on the different types of birth control that will list possible risks and side effects for each medicine you might want to start. If you have any side effects from any birth control medicine, you should see a doctor right away. There may be risks to each medication offered in this study, if you are able to start one.

For emergency contraception (to prevent pregnancy after sex has happened), you might be offered Plan B (Levonorgestrel)

Plan B (also called levonorgestrel) is taken by mouth by a woman to prevent pregnancy after she has already had unprotected sex. Plan B has no serious or lasting side-effects and leaves the body within a few days. Some women (fewer than one in five) have mild and short-term side-effects, including irregular bleeding from the vagina, belly pain, being tired, nausea (feeling like you might throw up). To prevent pregnancy, you might be able to start birth control:

- Sprintec: (ethinyl estradiol and norgestimate) is a birth control pill that contains female hormones that prevent ovulation (the release of an egg from an ovary)/Hormonal Pills. This medication (and similar medications) also causes changes in your cervical mucus and uterine lining, making it harder for sperm to reach the uterus and harder for a fertilized egg to attach to the uterus. Side effects may include: nausea, vomiting; breast tenderness; freckles or darkening of facial skin, loss of scalp hair; headache, dizziness, nervousness; problems with contact lenses; changes in weight or appetite; irregular menstrual bleeding or spotting; vaginal itching or discharge; or rash. Taking birth control pills can increase your risk of blood clots, stroke, or heart attack which is more common if have high blood pressure, diabetes, high cholesterol, obesity, or if you smoke.
- Depo-Provera or "The shot": (Depot medroxyprogesterone acetate) is a birth control shot for women that contains the hormone progestin. Depo is given once every three months. It stops your ovaries from releasing an egg and also thickens the cervical mucus to keep sperm from getting into the womb. Research has shown that Depo-Provera may cause a loss of bone mineral density and it's not clear whether or not this possible bone loss is completely reversible. Other side effects of Depo-Provera may include: abdominal pain, acne, breast soreness, decreased interest in sex, depression, dizziness, headaches, irregular periods and breakthrough bleeding, nervousness, fatigue, and weight gain.
- Ortho Evra and Xulane: (Norelgestromin/ethinyl estradiol) is birth control patch that works by stopping ovulation. It may also change cervical mucus to prevent the sperm from reaching the egg and change the lining of the uterus to prevent a fertilized egg from implanting in the uterus. Side effects can include: breast tenderness or enlargement; headache; menstrual cramps; mild fluid retention or weight gain; mild skin irritation at the application site; nausea; stomach pain, cramps, or bloating; vaginal spotting or breakthrough bleeding; vomiting.
- NuvaRing: (ethinyl estradiol and etonogestrel) is a birth control vaginal ring that contains female hormones that stop ovulation (the release of an egg from an ovary). This medicine also causes changes in the cervical mucus and uterine lining, making it harder for sperm to reach the uterus and harder for a fertilized egg to attach to the uterus. Side effects may include: headache; vaginal irritation or discharge, cervical pain; menstrual cramps; mood changes, decreased sex drive; nausea, vomiting, stomach pain; breast pain or tenderness; acne; or weight gain.
- Nexplanon: The implant is a small rod that goes under the skin of your arm and releases a hormone that stops ovulation (the release of an egg from an ovary). The main side effect is a change in your bleeding with your periods. Some people have off-and-on spotting. If the bleeding is a problem, your doctor may add another medicine to make it better. Spotting may last until the implant is removed. A few people have: mood changes, weight gain, headache, acne, and/or skin changes in the upper arm. Most side effects go away when the implant is removed.
- Phexxi/Non-Hormonal Contraception: Side effects can include irritation, dryness and/or allergic reactions.

WHAT ABOUT EXTRA COSTS?

You will not have to pay anything extra if you are in this study. The Study sponsor will pay for any tests and medications given to you today that are a part of this study. If you are in the study group that is able to start birth control today, that will be provided to you at no charge if you

want it. Your insurer will be responsible for all other costs related to participation in this study. You will be responsible for any costs your insurer does not cover. If you have any questions about these costs, or what out-of-pocket expenses you may be responsible for, contact your insurer.

WHAT ABOUT CONFIDENTIALITY?

If you decide to be in this study, your contact information will be collected. This includes your name, email, and phone number. We will use a study number (instead of your name) to help protect your privacy. If you choose to start a birth control medicine, your health information will stay within Children's Mercy Hospital medical record system like normal. We may take general notes about the visit that will not have any personal health information (PHI). Audio recordings will be transcribed, and any names will be removed. Your confidentiality will be protected to the greatest extent possible. To help minimize the risk to privacy, all information collected will be kept confidential among the study team and be recorded on an encrypted secure server through password-protected computers. There also is a risk to confidentiality when using the internet. By providing your email or phone number, the study team may communicate with you regarding setting up appointments, sending copies of permission/assent forms and any other non-clinical, study related communication. Please be aware of the following:

- Corresponding through electronic communication methods is not a secure method of sending information and others may be able to access the information sent.
- The information may not be secure if storing or viewing the permission/assent document on a personal electronic device (PED), especially if that PED is shared with other users or is lost, hacked, or subject to a search warrant or subpoena.
- Information that is sent electronically may be kept on the Hospital's or your service provider's (Google, Yahoo, MSN, etc) network servers. Unlike paper copies, e-copies delivered directly to your PED may not be able to be permanently removed.

The Hospital is not liable for any security breaches of your information sent electronically.

There are a few situations where confidentiality would not be kept (if you verbally tell us that you or another teen/child has been hurt or is in danger). This includes sexual abuse or other abuse you may have experienced. If you choose to talk to me about an unsafe or abusive situation, this information will be reported to the appropriate organizations and hospital personnel.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide you as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.
There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT

stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your child's information from being used for other research if allowed by federal regulations.
Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

WHAT ARE THE ALTERNATIVES TO BEING IN THIS STUDY?

Instead of being in this study, you may choose not to be in the study. Whatever you choose will not affect your care today in the ER. If you want to get more information about your sexual health or birth control, you could choose to talk with your regular doctor.

WHAT WILL I RECEIVE FOR BEING IN THIS STUDY?

There is no cost to you to be in this study. The maximum compensation for being in Group 1 of this study is $225. The maximum compensation for being in Group 2 of this study is $195. If you decide to be in this study, you will receive a gift card that can be used nearly anywhere.

Today's visit	2 weeks	30 days	3 months	6 months
Be randomized into study group 1 or 2, take computerized survey, meet with the Nurse Practitioner	Submit results of pregnancy test (Group 1 only)	Take survey online or by phone	Take survey online or by phone	Take survey online or by phone
$75.00	$30.00	$50.00	$30.00	$40.00

WHO SHOULD I CALL IF I HAVE QUESTIONS OR PROBLEMS?

Dr. Melissa Miller oversees this study. You may call her at (816) 302-3142 with questions at any time during the study. You may also call Weston Kraly, the study coordinator, at (816) 802-1487 with any questions you may have.

You should call Dr. Miller if you believe that you have suffered injury of any kind or are sick as a result of being in this research study.

You may also call Children's Mercy Hospitals' Pediatric Institutional Review Board (IRB) at (816) 731-7474 with questions or complaints about this study. The IRB is a committee of physicians, statisticians, researchers, community advocates, and others that ensure that a research study is ethical and that the rights of study participants are protected.
You may withdraw from the study at any time without penalty.

SPONSOR AND INSTITUTIONAL RESPONSIBILITIES

As detailed in the "What About Confidentiality?" section, your PHI will be kept safe to the greatest extent possible. Possible risks may be the unintentional use of your PHI. This could be

by any of the parties listed in the "What About Confidentiality?" section above. If an unintentional use of PHI occurs by Children's Mercy Hospitals, there are no funds set aside to pay you. By signing this form, you are not giving up any legal rights to seek damages for harm.

If you have an illness, adverse event, or injury that is the result of a medication you are prescribed during this study, you will need to pay usual and customary medical fees for reasonable and necessary treatment. You should seek treatment, then notify the study doctor as soon as possible when you believe that an illness, adverse event, or injury has occurred. The study doctor will decide if the adverse event or injury was a result of your participation in the study. The sponsor is not responsible for expenses that are due to medical conditions you had before the study, or intentional wrongdoing by any person.

If you choose to start a subdermal implant (Nexplanon) during this study and have side effects prompting early removal of the implant within one year of placement, the costs of subdermal implant removal will be covered by the maker of the implant, Merck & Co Inc. Providing this treatment or care is not an admission by the Hospital or the Sponsor that they are responsible for such injury or illness. No funds have been set aside by Children's Mercy Hospitals to pay research participants if the research results in injury. You do not give up any legal rights as a research participant by signing this form.

CONSENT/ASSENT OF PARTICIPANT

The purposes, procedures, and risks of this research study have been explained to me. I have had a chance to read this form and ask questions about the study. Any questions I had have been answered to my satisfaction. I assent to be in this research study. A copy of this signed form will be given to me.

_____ _____

Signature of Participant Consent/Assent Date

_____

Name of Participant

STUDY PERSONNEL

I have explained the purposes, procedures, and risks involved in this study in detail to the participant listed above:

_____ _____ _____

Signature of Person Obtaining Consent/Assent Date Time

Print Name of Person Obtaining Consent/Assent_____