Study Name: Digital Initiative for Youth: An Innovative Youth-Centered Initiative to Improve the Sexual Health and Socio-Economic Well-Being of Youth in Fresno County,

California

Principal Investigator: Mara Decker, DrPH

NCT number: NCT03765255

Initial Consent Form IRB Approval Date: September 3, 2017



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IN THE KNOW PRINCICPAL INVESTIAGTOR: MARA DECKER, DrPH UNIVERSITY OF CALIFORNIA SAN FRANCISCO (UCSF)

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What is In the Know?

In The Know is a program that combines in-person sexual health education with a mobile application. This study is funded by the Family and Youth Services Bureau. It will be carried out by Fresno EOC with youth in Fresno County. Dr. Mara Decker and her research team from the University of California, San Francisco will evaluate the study. Your participation in this study can help us understand if this program helps youth learn about sexual health, relationships, and educational and career opportunities. We want you to know that participation in this study is voluntary and no one will get angry with you if you choose not to participate.

How many people will take part in this study?

About 1400 youth in the state of California will participate in this study.

What will happen if you decide you want to participate in this study?

- If you agree to participate in this study, you will be asked to complete a short, private survey. The survey will ask you about your background, sexual activity, personal relationships, contraceptive/birth control use, and technology use. The survey should take about 15 minutes to complete. We will also ask you to complete similar surveys two more times (in about 6 months and 9 months). If you are selected to participate in the program, we will also ask you to complete a short survey asking you what you think of the program. For each survey you complete, you will receive a gift certificate. If you complete all the surveys, you will receive up to \$60 total.
- Once you complete the survey, we will let you know if you and your group have been assigned to participate in the program immediately or after the study is over. All youth who want to participate in the program will be able to participate. However, some youth will go through the program first and others will begin the program later. We will collect your contact information to let you know when you can start the program and so that we can follow up with you to complete the other surveys.
- If you are assigned to participate in the program, you will attend three two-hour sessions (six hours total) that cover topics including sexual health, healthy relationships, and educational and career success. You will also gain access to an app that has games, resources, and other related information.
- You also will receive motivational Short Message Service (SMS) messages twice a week to support what you have learned in the workshops. The messages will also provide you information about safe sex, healthy living, career and educational goal setting, and life skills (e.g. budgeting). Message and data rates may apply and you can opt-out of these messages at any time, by replying STOP to any message.

Can I stop being in the study?

Yes. Participation is voluntary and you can decide to stop at any time. Just tell us right away if you wish to stop participating. Also, we may stop you from taking part in this program at any time we believe it is in your best interest, if you do not follow the program rules, or if the program is stopped for another reason. If you do not want to participate in the study, you can call the numbers listed below or email us at ITK@ucsf.edu.

Will any parts of this study or program have risks?

- Some of the questions on the surveys or activities in the program may make you feel uncomfortable or sad, but you may refuse to answer any questions or to participate at any time.
- To protect your privacy, you may use a different name than your real name. All information is confidential (private). Your name, if you use it, will not be connected to what you say, nor will it be listed anywhere or written into any report. However, we cannot guarantee total privacy.
- In order to reach you to complete the follow-up surveys, we will ask you to share your email address, cell phone number, and other contact information. This will be stored in a separate location and will be destroyed at the end of the study period (in about 9 months).
- Some questions might ask you about illegal behavior such as your drug and alcohol use. This information will remain confidential. As with any question, you do not need to answer if it makes you uncomfortable.

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- Health educators are required to report any information about imminent danger to self or others and
 ongoing child abuse to the appropriate authorities. Neither the survey nor the study ask questions related
 about imminent danger to self or others and ongoing child abuse.
- Although every reasonable effort has been taken, confidentiality during Internet communication procedures cannot be guaranteed and it is possible that additional information beyond that collected for research purposes may be captured and used by others not associated with this study.

Are there any benefits to taking part in this study?

Youth who receive the program content may experience positive health and lifestyle changes and increased knowledge about different health topics. Additionally, the information that you provide may help us better understand what types of sexual health programs and services for youth are needed.

What are your choices?

If you decide to participate in this study, we will let you know when you can start the program. However, you don't have to participate if you don't want to. Nobody will get mad at you if you don't want to do this and it will not impact your participation in other programs or activities at this site.

Are there costs or payments connected with this study?

You will not have to pay to participate in this study.

After finishing the first survey today, you will receive a \$20 gift card to thank you for your participation. You will receive a \$10 gift card for finishing a follow-up survey online in about 6 months and \$20 for finishing a final online survey in about 9 months. If you participate in the program, you will also receive a \$10 gift certificate for filling out a survey about your opinions of the program. If you complete all the surveys, you will receive up to \$60 in gift certificates.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in it. If you decide to take part in this study, know that you may leave the study and the program at any time. No matter what decision you make, there will be no penalty to you in any way.

Will information about me be kept private?

We will do our best to make sure that the information gathered for this program is kept private. Information that identifies you will be kept safe. The survey itself will not include details that directly identify you, such as your name or address, but instead will focus on your background, views, and opinions. The completed surveys will be kept safe and separate from information that identifies you. Only a small number of researchers will have access to these surveys or your contact information. If we published or presented at meetings, names and other information that might identify you will not be used. However, we cannot promise total privacy. Participants' personal information may be given out if needed by law.

Organizations that may look at and/or copy your research records for research, quality assurance, and data analysis include:

- UCSF Human Research Protections Program
- UCSF Philip R. Lee Institute for Health Policy Studies
- US Department of Health & Human Services, Family & Youth Services Bureau

What if you have questions?

You can talk directly to one of the people leading the classes or you can contact In The Know program lead, Julio Romero, at (559) 265-5504. You can also talk to the researcher(s) who made this program about any questions or worries you may have about the program. Please call Dr. Mara Decker at (415) 476-3095 or Abigail Gutmann-Gonzalez at (415) 476-9507.

If you have any questions, comments, or worries about taking part in this program, first talk to the researchers (above). If for any reason you do not wish to do this, or you still have concerns after doing so, you may contact the office of the **Committee on Human Research**, UCSF's Institutional Review Board. You can reach their office at **415-476-1814**, 8 am to 5 pm, Monday through Friday or you may write to: Committee on Human Research, Box 0962, 3333 California Street, Suite 315, University of California, San Francisco (UCSF), San Francisco, CA 94143.

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Do you agree to participate in this study?

CONSENT

You have been given a copy of this consent form to keep.

PARTICIPATION IN THIS STUDY IS VOLUNTARY. You have the right to decline to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled.

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