

Evaluating the Effectiveness of an eHealth EBI for Latino Youth in Primary Care

NCT03009539

April 23, 2017

eHealth Familias Unidas Primary Care: Adolescent Assent Form

You are being asked to take part in a study by the University of Miami's Department of Public Health Sciences. We are asking you to participate because you are Hispanic, live in Miami-Dade County, and are between the ages of 12-16 years of age. We will ask approximately 456 families like yours to participate. Here are the answers to some common questions about the study:

What is the purpose of the research?

The purpose of this study is to find out whether the online intervention program, eHealth Familias Unidas, will help your family communicate more effectively about preventing substance use, HIV risks and other sexually transmitted diseases. This is important because Hispanic teens are at a greater risk for being involved in substance use and HIV risky behavior than other teens and Miami has one of the highest HIV and AIDS rates in the United States. We will try to do this by showing your family different ways of communicating with each other. Your caregiver will receive information about HIV transmission, substance use and how to talk about risky sexual behaviors.

We may ask you to complete up to four online family sessions in your home, or other private location, utilizing a web cam over the next twelve weeks. We want to find out whether the programs will help in preventing risky sexual behaviors and HIV transmission and substance use.

What will I be asked to do?

Program Options: There will be two programs. Each family in the study will be randomly assigned to one of these programs. We cannot control which program your family will be placed in, but every family will have an equal chance of being placed in each program. Each program will also consist of taking surveys and testing you for Sexually Transmitted Infections (STIs). Below we describe the programs:

Program Option 1: In this program, you will be asked to come to four online meetings with your family and one of our staff members. The four meetings, or “family sessions” will take place over the next twelve weeks and each meeting will take place using a web-app that supports video calls. Each online meeting will last about 45 minutes. In this meeting, you will be provided with information about HIV, risky sexual behaviors and how to prevent HIV-infection and substance use/abuse.

Video Recording: The family sessions for program 1 will be video recorded. If you do not wish to be video recorded you can sit outside of the site of the web-cam. If you decline video recording, your family will not be penalized in any way and will continue to receive the same medical services.

Program Option 2: In this program, you and your family will continue care as usual. You will not be receiving any services from our staff.

Surveys: Regardless of which program you are randomly assigned to, if you agree to join this study, you will be asked questions about your family and about yourself. The topics asked include basic facts about where you come from, your age, income and education. We will also ask you about your relationship with your family, whether you smoke, drink alcohol, or use illicit drugs. Finally, we will ask you questions about your sexual behavior. You do not have to answer any questions that you do not want to. You will answer these questions in private using a questionnaire provided by us. You will complete the survey 5 times, once when you first enroll, and 6, 12, 24 and 36 months after you enroll. We expect that it will take you about 30-45 minutes to finish the

survey. If you decide not to join this study, nothing bad will happen to you and you will continue to receive medical care, as usual. Also, if you want to stop, you may leave the study at any time.

STI Testing: You will be completing a urine sample at each of the 5 time points to be tested for the following STIs: gonorrhea and chlamydia. This urine sample will be collected and tested for the presence of proteins. This test will help us determine whether or not you have gonorrhea and/or chlamydia.

- If you are diagnosed with gonorrhea and/or chlamydia, you will be referred to treatment by a physician or research team member.
- You will also be encouraged to refer your sex partners for treatment.
- As required by law, the county health department will be notified of reportable STIs. We will describe your important confidentiality and privacy in the “What about my Privacy?” section of this consent form.
- Research staff will not provide your parents with any information regarding your test results.

The testing will take place on the University of Miami Medical Campus in the Miami Health District or at another pediatric clinic site in the community.

Can anything bad happen to me from being part of this study?

We do not expect that there will be any harm to you from being part of this study. But, you may be bothered by some of the topics related to sexual risks and may feel embarrassed. You might also feel tired after answering the surveys, or the questions that are asked may bother you. If any of these situations were to occur, you might feel sad, uncomfortable, and/or angry.

In addition, STI testing may involve minimal physical discomfort. Being tested for STIs may also cause anxiety for you regardless of test results. Receiving positive results may make you very upset. If the test is negative, there is still the possibility that you could be infected with an STI and test positive at some time in the future. Also, it is always possible that the test results could be wrong.

What do I get for being part of this study?

You may not benefit from being part of this study. However, depending on which program you are in, you and/or your family may be able to communicate better, learn about HIV and prevention and be less likely to engage in unsafe sexual behavior. In addition, being involved in this study may help you know if you have become infected with an STI.

Compensation

We will compensate you for the completion of both the survey and STI test at each time point. At the first survey (today), you will be compensated a total of \$20 cash for your time. At the second, third, fourth, and fifth survey, you will be compensated \$20 cash each time after completing the survey and STI test. You will receive your compensation after both you and your parent are done with the assessment at each time point.

Right to Decline or Withdraw

Your participation in this study is voluntary. You can refuse to participate in the study or withdraw your consent at any time during the study. There will be no negative consequences for you if you decide to withdraw from the study. The investigators reserve the right to remove you from the study without your consent at such time that they feel it is in your best interest.

What about my privacy?

What you tell us will be kept private to the extent allowed by law. We will work to protect your privacy in several ways. We will not reveal any of your answers from the survey to the medical team in the primary care setting where you receive your medical services. Also, to protect your privacy, we will not share your responses to our surveys with your parent. Nothing you tell us will appear in your medical records. Second, we will give you a code number, so that only that number connects you to your answers. We will keep a list of matching names and code numbers in secure electronic systems. Only the study staff will be allowed to look at them. Your name will not be kept with the data. Also, the staff will never put the names of you or your family members in any report on these data. The staff delivering the family sessions will not share the information learned about you in the family sessions with anyone, except to the extent required by law.

Despite taking all of the safety measures listed above, there is risk that your privacy will be broken. We cannot guarantee total privacy. Your personal information may be given out if required by law. If you test positive for a reportable STI, we are required by Florida law to report the results to state and local health departments with your name and identifying information, as needed.

Certificate of Confidentiality

We will do everything we can to keep others from learning about your participation in this study. To help further protect your privacy, the study researchers have obtained a Federal Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced, even by a court order, to share research information that may identify you in any civil, criminal, administrative, legislative, or other proceedings in any court. The researchers will use the Certificate to resist any demands for information that would identify you, except to prevent serious harm to you or others, and as explained below.

You should understand that a Certificate of Confidentiality does not prevent you, or a member of your family, from voluntarily releasing information about yourself, or your involvement in this study. If an insurer or employer learns about your participation, and obtains your consent to receive research information, then we may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy. Disclosure will be necessary, however, upon request for the purpose of audit or evaluation, and is limited only to Department of Health and Human Services employees involved in the review. You should understand that we will in all cases take the necessary action, which may include reporting to authorities, to prevent serious harm to yourself or others.

Future Studies

We may conduct additional studies related to the study we are describing in this form. If we do conduct these studies, we may contact you in the future to see if you would like to be part of the future study.

Consent Statement

I agree to take part in the study eHealth Familias Unidas Primary Care described above, which I have read and has been explained to me by _____.

I know that I have the right to ask questions at any time, and do not have to answer any questions that I don't want to answer for any reason. I know that being in this study is my choice. I know that if I choose to be in this study, I may leave at any time and nothing bad will happen to me. I also know that I will receive \$20 cash for completing both the survey and STI test.

I have been given the chance to ask questions. I also know that I will get a copy of this consent form. If I have any future questions I can call Dr. Guillermo Prado during the daytime at (305) 243-2748. If I have any questions about my rights as a research participant, I have been told that I may contact the Human Subjects Research Office at the University of Miami at (305) 243-3195.

- Yes, I agree to participate
- No, I choose not to participate

Youth Name (First, Last)

Signature of Youth

Date

Name of Person Obtaining Consent (First, Last)

Signature of Person Obtaining Consent

Date

Video Recording

The University of Miami’s Department of Public Health Sciences wants to take still photographs, video recordings, and/or sound recordings of you.

The University may use the photographs, film, video or audio recordings, in whole or in part (please read and check below on the line next to the statement(s) below that complete(s) this sentence and is (are) okay with you):

- For the purpose of research. Yes No
- For the purpose of teaching and training. Yes No
- For the purpose of presenting at scientific meetings. Yes No

Recordings may be kept indefinitely for the purpose of teaching and training. All video recordings will be electronically stored in secure University servers. Your video recordings will only be accessed by study staff. The recordings are not labeled with your name but with the identifiers assigned to you at the beginning of the study.

I agree to be video recorded for the purposes stated above. Yes No

Youth Name (First, Last)

Signature of Youth

Date

Name of Person Obtaining Consent/Assent (First, Last)

Signature of Person Obtaining Consent/Assent

Date

Future Studies

I agree to be contacted after the study ends to be asked to take part in future studies.

- Yes No

Youth Name (First, Last)

Signature of Youth

Date

Name of Person Obtaining Consent/Assent (First, Last)

Signature of Person Obtaining Consent/Assent

Date

eHealth Familias Unidas Primary Care: Primary Caregiver Consent Form

You and your adolescent are being asked to take part in a study by the University of Miami's Department of Public Health Sciences. We are asking you to participate because you are Hispanic, live in Miami-Dade County, and have an adolescent between the ages of 12-16 years of age. We will ask approximately 456 families like yours to participate. Here are the answers to some common questions about the study:

What is the purpose of the research?

The purpose of this study is to find out whether the online intervention program, eHealth Familias Unidas, will help you communicate more effectively with your child about preventing HIV risks, other sexually transmitted diseases, and the dangers of drug abuse. This is important because Hispanic teens are at a greater risk for being involved in substance use and HIV risky behaviors compared to other teens, and Miami has one of the highest HIV and AIDS rates in the United States. The sessions are intended to prevent drug use and risky sexual behavior by: (1) improving how your family functions (including how you and your child talk to each other) and (2) informing your family about risks of drug use and unsafe sexual behavior.

The program will be delivered through our website and you may be asked to access the website in the clinic today, while you and your child are waiting to see your doctor or nurse. We may ask you to complete up to four online family sessions in your home, or another private location, over the next twelve weeks. We want to find out whether the program will help prevent adolescent drug use and risky sexual behaviors associated with HIV transmission.

What will I be asked to do?

Program Options: There will be two programs. Each family in the study will be randomly assigned to one of these programs. We cannot control which program your family will be placed in, but every family will have an equal chance of being placed in each program. Each program will also consist of surveys both you and your adolescent will take, along with a Sexually Transmitted Infection (STI) test of your adolescent at each of the 5 time points. Below we describe the programs:

Program Option 1: In this program, you will watch eight videos on our website. Each video is approximately 30 minutes. Additionally, a member from our team will arrange four video calls, or "family sessions," with you and your adolescent. Each family visit will take about 45 minutes and you will have an opportunity to talk to your child about all you have learned from watching the videos on the website and how to effectively communicate with your child about the topics of the videos.

Video Recording: The family sessions for program 1 will be video recorded. If you do not wish to be video recorded you can sit outside of the site of the web-cam. If you decline video recording, your family will not be penalized in any way and will continue to receive the same medical services.

Program Option 2: In this program, you and your family will continue care as usual. You will not receive any services from our staff.

Surveys: Regardless of which program you are randomly assigned to, if you agree to join this study, you will be asked questions about your family, child, and about yourself. The topics asked include basic facts about where you come from, your age, income and education. We will also ask you about your relationship with your child.

Finally, we will ask you whether you drink alcohol or use illicit drugs. Your child will be asked about the relationship he or she has with his/her family, and yourself. Your child will also be asked whether he or she smokes, drinks alcohol, or uses drugs. Finally, we will also ask your child questions about his or her sexual behavior. You/your child do not have to answer any questions that you do not want to. You will answer these questions in private using a tablet provided by us. You and your child will complete the surveys 5 times, once when you first enroll, and 6, 12, 24 and 36 months after you enroll. We expect that it will take you about 30-45 minutes to finish the survey, and about the same for your child. The surveys will take place on the University of Miami Medical Campus in the Miami Health District or at another clinic site in the community. If you decide not to join this study, nothing bad will happen to you or your child and you will continue to receive medical care, as usual. You or your child do not have to answer any questions that you do not want to. If you or your child decide not to answer questions, nothing bad will happen to you. Also, if you want to stop, you may leave the study at any time.

STI Testing: Your adolescent will be completing a urine sample to be tested at each of the 5 time points for the following STIs: gonorrhea and chlamydia. This test will help us determine whether or not the adolescent has gonorrhea and/or chlamydia.

- If your child is diagnosed with gonorrhea and/or chlamydia, they will be referred to treatment by a physician or research team member.
- Youth will also be encouraged to refer sex partners for treatment.
- As required by law, the county health department will be notified if your adolescent has reportable STIs. We will describe your important confidentiality and privacy in the “What about my Privacy?” section of this consent form.
- Research staff will not provide you with any information regarding your adolescents’ test results.

The testing will take place on the University of Miami Medical Campus in the Miami Health District or at another pediatric clinic site in the community.

Can anything bad happen to me from being part of this study?

We do not expect that there will be any harm to you or your child for being part of this study. But, you may be bothered by some of the topics related to sexual risks and may feel embarrassed. You might also feel tired after answering the surveys, or the questions that are asked may bother you. If any of these situations were to occur, you or your child might feel sad, uncomfortable, and/or angry.

In addition, STI testing involves minimal physical discomfort for your adolescent. Being tested for STIs may also cause anxiety for you and/or your adolescent regardless of test results. Receiving positive results may make you and/or your adolescent very upset. If the test is negative, there is still the possibility that your adolescent could be infected with an STI and test positive at some time in the future. Also, it is always possible that the test results could be wrong.

What do I get for being part of this study?

You may not benefit from being part of this study. However, depending on which program you are in, you, your child, and/or your family may be able to communicate better about HIV prevention and less likely to engage in

unsafe sexual behavior. In addition, being involved in this study may help your youth know if they have become infected with an STI.

Compensation

We will compensate you for each survey that you complete. At the first survey (today), you will be compensated \$40 for your time. At the second, third, fourth, and fifth survey, you will be compensated \$45, \$50, \$55, and \$60, respectively, for your time. Your adolescent will receive \$20 cash for completing both the survey and STI test at each time point. You will receive your compensation after both you and your adolescent are done with the assessment at each time point.

Right to Decline or Withdraw

You and your child's participation in this study are voluntary. You and your child can refuse to participate in the study or withdraw your or his/her consent at any time during the study. There will be no negative consequences for you or your child if you and/or your child decide to withdraw from the study. The investigators reserve the right to remove you and your child without your or your child's consent at such time that they feel it is in the best interest for you and your child.

What about my privacy?

What you tell us will be kept private to the extent allowed by law. We will work to protect your privacy in several ways. We will not reveal any of your survey answers to the medical team in the primary care setting where you receive your medical services. Also, to protect your child's privacy, we will not tell you what he or she says in his or her responses to our surveys. Nothing you tell us will appear in your child's medical records. We will give you a code number, so that only that number connects you to your answers. We will keep a list of matching names and code numbers in secure electronic systems. Only the study staff will be allowed to look at them. Your name will not be kept with the data. The staff will never put the names of you or your family members in any report of these data. Also, the staff delivering the family sessions will not share the information learned about you in the family sessions with anyone except as required by law.

Despite taking all of the safety measures listed above, there is risk that your privacy will be broken. We cannot guarantee total privacy. If your adolescent tests positive for a reportable STI, we are required by Florida law to report the results to state and local health departments with their name and identifying information, as needed.

Certificate of Confidentiality

We will do everything we can to keep others from learning about your participation in this study. To help further protect your privacy, the study researchers have obtained a Federal Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced, even by a court order, to share research information that may identify you in any civil, criminal, administrative, legislative, or other proceedings in any court. The researchers will use the Certificate to resist any demands for information that would identify you, except to prevent serious harm to you or others, and as explained below.

You should understand that a Certificate of Confidentiality does not prevent you, or a member of your family, from voluntarily releasing information about yourself, or your involvement in this study. If an insurer or employer learns about your participation, and obtains your consent to receive research information, then we may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy. Disclosure will be necessary, however, upon request for the

purpose of audit or evaluation, and is limited only to Department of Health and Human Services employees involved in the review. You should understand that we will in all cases take the necessary action, which may include reporting to authorities, to prevent serious harm to yourself or others.

Future Studies

We may conduct additional studies related to the study described in this form. If we do conduct these studies, we will contact you in the future to see if you would like to be part of the future study. Your participation in this study does not depend in any way on your participation on any future study. If we have difficulty finding you, we may call your contact persons to find out where you are.

Consent Statement

I agree to take part in the study eHealth Familias Unidas Primary Care described above, which I have read and has been explained to me by _____.

I know that I have the right to ask questions at any time, and do not have to answer any questions that I do not want to answer for any reason. I know that being in this study is my choice. I know that if I choose to be in this study, I may leave at any time and nothing bad will happen to me or my child. I also know that I will be compensated for completing the surveys.

I have been given the chance to ask questions. I also know that I will get a copy of this consent form. If I have any future questions I can call Dr. Guillermo Prado during the daytime at (305) 243-2748. If I have any questions about my rights as a research participant, I have been told that I may contact the Human Subjects Research Office at the University of Miami at (305) 243-3195.

- Yes, I agree to participate
- No, I choose not to participate

Youth Name (First, Last)

Name of Parent or Primary Caregiver (First, Last)

Signature of Parent or Primary Caregiver

Date

Name of Person Obtaining Consent (First, Last)

Signature of Person Obtaining Consent

Date

Video Recording

The University of Miami’s Department of Public Health Sciences wants to take still photographs, video recordings, and/or sound recordings, of you and your child.

The University may use the photographs, film, video or audio recordings, in whole or in part:

For the purpose of research Yes No

For the purpose of teaching and training. Yes No

For the purpose of presenting at scientific meetings Yes No

Recordings may be kept indefinitely for the purpose of teaching, research, and training. All video recordings will be electronically stored in secured University servers. Your video recordings will only be accessed by study staff. The recordings are not labeled with your name but with the identifiers assigned to you at the beginning of the study.

I agree to be video recorded for the purposes stated above. Yes No

I agree for my child to be video recorded for the purposes stated above. Yes No

Youth Name (First, Last)

Name of Parent or Primary Caregiver (First, Last)

Signature of Parent or Primary Caregiver

Date

Name of Person Obtaining Consent/Assent (First, Last)

Signature of Person Obtaining Consent/Assent

Date

Future Studies

I agree to be contacted after the study ends to be asked to take part in future studies.

Yes No

I agree to allow my child (if he/she is under the age of 18) to be contacted after the study ends to be asked to take part in future studies.

Yes No

Youth Name (First, Last)

Name of Parent or Primary Caregiver (First, Last)

Signature of Parent or Primary Caregiver

Date

Name of Person Obtaining Consent/Assent (First, Last)

Signature of Person Obtaining Consent/Assent

Date