



***Family-based eHealth Intervention for Hispanic Adolescents***  
**IBIS#: 20160415**

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**Confidentiality Statement**

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## CONSENT TO PARTICIPATE IN A RESEARCH STUDY

**Title of Study:** *Family-based eHealth Intervention for Hispanic Adolescents*

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**Study Contact Telephone Number:** (786) 643-4300

**Study Contact Email:** [healthyjuntos@med.miami.edu](mailto:healthyjuntos@med.miami.edu)

**Key Information** The following is a short summary of this study. It will help you decide whether or not to take part. More detailed information is given later in this form.

You and your adolescent are being asked to take part in a research study. Doing so is voluntary. The purpose of this study is to test an online program and see how helpful it is at improving physical activity, nutrition, and family functioning in Hispanic adolescents and their primary caregivers. You will spend about two months in this study. Your participation involves completing surveys, getting your height, weight, waist circumference, and body composition measurements taken, and potentially using the 8-week online program. Taking part in the study involves some risks, including feeling sad, uncomfortable, embarrassed, and/or angry during measurements or while answering the questionnaires, and experiencing some discomfort from increasing your physical activity levels or changing your eating behaviors. No direct benefit can be promised to you for being in this study. Instead of being in this research study, you may choose to decline to take part.

**Detailed Information** The rest of the form gives more detailed information.

### What is the purpose of the research?

The purpose of this study is to find out whether an online (web and mobile-phone based) program promotes health. Specifically, we are interested in learning how helpful this program is at improving physical activity levels, nutrition, and family functioning in Hispanic adolescents and their primary caregivers. The results of this study will help us to develop online health programs for Hispanic families.

### How many people will take part in the study?

We will ask about 50 families like yours to participate.

### What happens if I say yes, I want to be in this research?

If you decide to participate in this study, you and your adolescent will be in the study for about two months. **If you give permission to be in the study, you and your adolescent will be asked to complete the following measures at the beginning of the study (time 1), and 2 months after the beginning of the study (time 2):**

1. **Body Measures:** You and your adolescent will have your height, weight, waist circumference, and

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body composition measured while you wear loose clothing. These measures will be done in a private location where other participants will not overhear the results. We will not share any of this information with anyone. For example, we will not share your weight with any other families participating in the study.

2. **Questionnaires:** You and your adolescent will answer some questions about yourselves (e.g., date of birth, country of origin), your family (e.g., how you communicate), and about physical activity and nutrition. We will also ask you to estimate how much time you spend sitting (e.g., watching tv, reading). We will not share any of the information we gather from you or your adolescent with anyone. We will also not share the information your adolescent provides us with you.

**In addition to completing the measures described above, you MAY OR MAY NOT be asked to participate in an online health program for two months.** We will randomly choose whether you participate in the program (e.g., by flipping a coin). The program is described below:

**Online Program:** The online program consists of eight weekly online sessions (each lasting about 45 minutes) completed over a period of about two months. You and your adolescent will be sent text message reminders to log in to the website using your own smartphone. The website will include information on healthy lifestyle behaviors; features that will help you set weekly goals to improve your lifestyle; and strategies for parents on how to help your adolescent achieve a healthy lifestyle.

Your family will also be assigned a healthy lifestyle coach who will engage in 15-30 minutes of conversations by phone or videoconferencing software (e.g., Zoom) with you weekly throughout the two-month period about your family's progress. These sessions will focus on topics such as communication, family support, and health/wellness. Sessions may be recorded for the purposes of training and supervision. No recording will be done without your prior knowledge and consent. At the end of each week, you will be asked to complete a brief survey that asks you to rate weekly content, including what you liked/disliked and would change about each session.

You and your adolescent will wear a physical activity monitor (Fitbit) around your wrist and download the Fitbit app on your phones. You will be asked to wear the monitor all day and night for at least the first two months and log in your meals to the Fitbit app. We will collect technical data, such as how often you log-in and use the program, and any other information that is necessary to allow you to use the features of the program (e.g., steps from your Fitbit).

At the end of the eight weeks, you and your adolescent will be asked to complete a brief survey. In addition, you and your adolescent MAY or MAY NOT be asked to complete a final interview to discuss your overall experience with the entire online program. The final interview will be conducted either in person, by phone or videoconference. Each interview session will last about 1–2 hours. You will be asked questions by the interviewer about the impact the program had on you and your adolescent. You may choose to respond or not respond at any point during the discussion. Also, if you want to stop, you may end the interview at any time. The final interview will be recorded via

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videoconferencing software (e.g., Zoom) or audio-recorded and transcribed (written out word-for-word) to review at a later time. If you do not wish to be video or audio-recorded, our staff will only take notes during the interview. If you decline video or audio-recording, your family will not be penalized in any way.

If you do not get randomly assigned to participate in the online program, you will receive a list of free health apps and websites, and we will contact you when it is time for the scheduled measures. In addition to the body measures and questionnaires, you will be asked to complete a brief electronic survey about whether and how you used the health apps and websites at 2 months (time 2) after the beginning of the study.

### **What should I think about before I enroll in this research?**

This study involves an 8-month commitment for the assessments and if you are in the App Group, you will have weekly assignments. You should ask any questions you may have and obtain answers before you decide.

### **Do I have to be in this research?**

No. Your participation in this study is voluntary. You do not have to be in this study if you do not want to, and you can leave the study at any time. You will not lose any services, benefits, or rights you would normally have if you choose not to be in the study or if you leave the study early. No additional data will be collected after you withdraw but we would like to include data collected up to the point of withdrawal in our analysis. If you would like your data to be deleted, you must notify the study team in writing.

### **Can I be removed from the research without giving my OK?**

The person in charge of the research study can remove you from the research study without your approval. Possible reasons for removal include giving fake information, the study team determining from your survey responses that you no longer meet eligibility requirements to participate in the study, the study team's belief that it is in your best interest, and any other reason deemed appropriate by the person in charge of the study.

### **Is there any way being in this study could be bad for me?**

You might feel tired after completing the body measures or answering the questionnaires or the measures/questions may bother you. If any of these situations were to occur, you might feel sad, uncomfortable, embarrassed, and/or angry. If you are selected to participate in the online program, you may experience some discomfort from increasing your physical activity levels or changing your eating behaviors. The possibilities include but are not limited to some muscle and joint stiffness. This stiffness generally subsides in one or two days and is not considered to be serious. Some of the topics covered during the online sessions may bother you and may make you feel uncomfortable or embarrassed. If you have any questions, you may contact the study team for assistance.

### **What are the benefits to being in this study?**

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You may not benefit from being part of this study. However, you may learn about your health and technology. We cannot promise any benefits to others from you taking part in this research. The information you provide will be used to improve an online program for Hispanic families in the future.

### **What happens to the information collected for the research?**

What you tell us will be kept private to the extent allowed by law. To maintain your and your adolescent's privacy, we will not associate any identifying information with the responses you provide. To protect your adolescent's privacy, we will not tell you what s/he says in her/his responses. Nothing you tell us will appear in your adolescent's school records. Also, the staff delivering the final in-person interview sessions will not share the information learned with anyone. The information learned by the staff delivering the interview session will be kept completely confidential. Only the staff from the University of Miami will review the outcomes of these interview sessions. At the end of the study, we may publish the results of this research. Information will be presented in summary format and you will not be identified in any publications or presentations.

Your information may be looked at and/or copied for research or regulatory purposes by:

- The Department of Health and Human Services (DHHS);
- Other government agencies;
- Other University of Miami employees for audit and/or monitoring purposes; and
- Other investigators and/or organizations collaborating in the research

This research is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health (NIH). The researchers with this CoC may not give out or use information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding. Your information may not be used as evidence if there is a court subpoena, unless you consent to this use. Information and documents protected by this CoC cannot be disclosed to anyone else who is not connected with the research except as described below, and

- If you consent to the disclosure;
- If it is used for other scientific research as allowed by federal regulations protection research subjects.

A CoC does not prevent you from saying you are in this study. If you want your research information given to anyone not part of this research, you must give consent to allow the study team to release it. The CoC cannot be used to prevent reporting information that is required by law. If we find that you are at risk to harm yourself or others, abuse or neglect a child or elderly person, or other forms of abuse, we are required by law to report this immediately to the proper authorities.

This trial will be registered and may report results on [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov), a publicly available registry of clinical trials.

It is also important to note that your participation depends on use of a third-party device which is maintained and managed by Fitbit. The University of Miami has no control over the way Fitbit maintains and manages your family's data. As a result, a loss or compromise of data caused by Fitbit is

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Fitbit's sole responsibility. In addition, we will use the third-party software Twilio to text you log-in information. The University of Miami has no control over the way Twilio maintains and manages your family's data. As a result, a loss or compromise of data caused by Twilio is Twilio's sole responsibility.

### Payment

We will also compensate you for each session of measures that you complete. You will be given a \$60 digital gift card at the beginning of the study (time 1), and \$65 digital gift card two months after the beginning of the study (time 2). Your adolescent will receive a \$20 digital gift card at time 1, and \$20 digital gift card at time 2 for completing measures. If you know of another parent who would be interested in being in this study, we will offer an extra payment of \$10 for any referrals (Maximum of three referrals). Those assigned to the online program will keep the Fitbit devices once the study is completed. Additionally, if you complete the final interview, you will be given \$40 digital gift card and your adolescent will be given \$30 digital gift card.

### Cost

We will be sending information and updates by text. If you do not have unlimited texting, messaging and service charges may apply. If you wish to stop receiving texts, please contact the study team.

### Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at (786) 643-4300. This research has been reviewed and approved by an Institutional Review Board ("IRB"). The Human Subject Research Office (HSRO) provides administrative support to the University of Miami's IRBs. Please call the HSRO at 305-243-3195 if you are a participant in any research being conducted by UM, and:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

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## PARTICIPANT'S STATEMENT/SIGNATURE

- *I have read this form and the research study has been explained to me.*
- *I have been given the chance to ask questions, and my questions have been answered. If I have more questions, I have been told who to call.*
- *I agree to be in the research study described above.*
- *I will receive a copy of this consent form after I sign it.*

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Printed Name of Child

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Printed Name of Parent/Legally Acceptable Representative

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Signature of Parent/Legally Acceptable Representative

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Date

---

Printed Name of Person Obtaining Consent

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Signature of Person Obtaining Consent

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Date

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### Authorization for Audio/Videotaping

I hereby authorize the University of Miami, Department of Public Health Sciences, to take video and/or audio recordings of me and my child. I authorize the University to use in any manner said video or audio recordings, in whole or in part as follows (Please read and check box next to appropriate permission statement):

- ☐ For the purpose of teaching, research, scientific meetings and scientific publications, including professional journals or medical books;
- ☐ For research purposes only.

I agree that the University of Miami, its Trustees, officers, employees, faculty and agents will not be responsible for any claims arising in any way out of the taking and use as described above of such recordings. I understand that I will not have an opportunity to inspect and approve such recordings prior to their use.

I agree to be ☐ video and/or ☐ audio recorded for the purposes stated above.  
☐ Yes ☐ No

I agree for my adolescent to be ☐ video and/or ☐ audio recorded for the purposes stated above.  
☐ Yes ☐ No

\_\_\_\_\_  
Printed Name of Child

\_\_\_\_\_  
Printed Name of Parent/Legally Acceptable Representative

\_\_\_\_\_  
Signature of Parent/Legally Acceptable Representative

\_\_\_\_\_  
Date

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### Future Studies

We may conduct additional studies related to the study we are describing in this form. If we do conduct these studies, we will contact you at that future time 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.

*I agree to be contacted for future studies.*

☐ Yes ☐ No

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Printed Name of Parent/Legally Acceptable Representative

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Signature of Parent/Legally Acceptable Representative

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Date

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Printed Name of Person Obtaining Consent

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Signature of Person Obtaining Consent

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Date

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