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April 23, 2019

Descriptive Title: Testing a Latino web-based parent-adolescent sexual communication intervention  
Agency Name: National Institutes of Health  
Protocol #: 820216  
ClinicalTrials.gov ID: NCT03063385

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Latino adolescents are at high risk for HIV/AIDS, other sexually transmitted infections (STIs), and unintended pregnancies. Puerto Rican adolescents, in particular, experience disparities in these areas, yet few adolescent and even fewer parent interventions have been developed to address these important issues with this underserved population. Parent-adolescent programs are an effective approach to reduce adolescent sexual risk behavior and associated negative consequences. A web-based parent communication intervention provides an opportunity to strengthen and enhance programs that are designed for adolescents by providing additional support for safer sex decisions, and to increase parents' access to sexual health education programs by decreasing barriers that keep them from participating in these interventions (e.g., low cost, can be viewed privately, at parents convenience, minimizes competing time with work and family). The purpose of this proposed study is to evaluate a brief theoretically informed (i.e., Ecodelopmental Theory, Theory of Reasoned Action/Planned Behavior, Social Cognitive Theory 1-6), culturally appropriate, and linguistically tailored web-based parental communication program, *Cúdalos* ("Take care of them"), designed to improve parent-adolescent sexual communication and reduce adolescent sexual risk behavior. Recent findings from an NIH funded R21 randomized control trial (RCT) testing a brief computer-based version of the *Cúdalos* program indicated that the program increased parent-adolescent general communication and sexual risk communication with English and Spanish speaking U.S. Latinos. <sup>7</sup> Further, despite limited or no previous computer use, parents reported they liked and learned from the program, and that it was easy to use and accessible.

In this proposed RCT, and based on recommendations from parents who participated in the initial *Cúdalos*<sup>7</sup> intervention trial, we plan to modify the program by: 1) increasing the amount of content related to sexual communication (e.g., more case studies and interactive activities); 2) adding a module on stigma (towards HIV/AIDS); 3) increasing access by moving from a computer-based to a web-based platform; and 4) increasing the flexibility in how the program is used (e.g., ability to view the entire program or specific modules more than once). In order to examine the efficacy of the program, we will recruit 680 parents and one of their adolescents from schools, community-based and governmental organizations in Puerto Rico, and will randomly assign parents to receive: 1) the *Cúdalos* intervention; or 2) a web-based health promotion control intervention focused on the prevention of diabetes and cardiovascular disease. Parents and adolescents will complete measures at pre-intervention and at 3- (parents only), 6-, and 12 month follow-ups.

We will address the five following specific aims:

- 1: Determine whether the *Cúdalos* intervention increases parents' comfort with, as well as the amount of, general and sexual risk-specific communication with adolescents and whether it decreases stigma (towards HIV/AIDS) at 3-, 6-, and 12- month follow-ups as compared to the general health promotion control intervention.
- 2: Determine whether the *Cúdalos* intervention decreases self-reported adolescent intercourse and unprotected intercourse at 6-, and 12- month follow-ups as compared to the general health promotion control intervention.
- 3: Identify theory-based variables (e.g., attitudes, subjective norms, perceived behavioral control, and intentions) that mediate the intervention effects of *Cúdalos* on parents' self-reported comfort with and amount of communication with their adolescents.

4: Determine whether the effects of the Cuídalos intervention on adolescents sexual behavior and parent-adolescent communication are moderated by individual (adolescents: sexual experience, gender, age, stigma; parents: gender, age, computer access and experience, frequency and time engaged in the program), and microsystem (adolescents: parent-adolescent communication) factors.

5: Examine the cost-effectiveness of the web-based Cuídalos intervention on adolescent sexual behavior.

Results from this study will inform the use and efficacy of a web-based Cuídalos program for Puerto Rican parents. This study is an innovative and timely effort given the existing disparities in sexual health outcomes among Latino youth, the lack of culturally and linguistically effective interventions for Latino parents and adolescents, and the absence of web-based interventions with Latinos. If the program is efficacious, the web-based format will accelerate the translation of this program into public health practice and will be an important contribution in supporting adolescent sexual health behaviors.

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03-Jun-2015

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REVIEW BOARD : IRB #8

Dear Dr. Villarruel:

The documents noted below submitted as modification to the above-referenced protocol, were reviewed and administratively incorporated to the regulatory file on 01-Jun-2015.

The following documents were included in the review:

- HS ERA Modification, confirmation code: biajbdei, submitted 5.26.15
- Puerto Rican IRB Approval Letter, dated 6.17.14
- Grant Transfer Request and Progress Report, uploaded 5.4.15
- CITI Training Report of Completion for Antonia Villarruel, passed on 5.2.15

If you have any questions about the information in this letter, please contact the IRB administrative staff. Contact information is available at our website: <http://www.upenn.edu/IRB/directory>.

Thank you for your cooperation.

Sincerely,

IRB Administrator