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Rationale and design for eHealth Familias Unidas Primary Care: A drug use, sexual risk behavior, and STI preventive intervention for hispanic youth in pediatric primary care clinics

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Abstract

Family-based behavioral interventions are efficacious and effective in preventing drug use and sexual risk behaviors; unfortunately, they have not been evaluated and disseminated in pediatric primary care practice, where they can have a significant impact. There is an increased focus on integrating parenting interventions into primary care to reduce health disparities among ethnic minorities such as Hispanics. Although Hispanic youth demonstrate higher levels of drug use and sexual risk behaviors than their non-Hispanic counterparts, few parenting interventions are available for Hispanic youth, and none have been delivered specifically to Hispanic adolescents in primary care. Therefore, this manuscript describes the rationale and design of an Internet-based, family-centered, Hispanic-specific, evidence-based prevention intervention, *eHealth Familias*

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Unidas Primary Care. Hispanic adolescents (n = 456) and their care givers will be recruited from pediatric primary care clinics in South Florida and randomized to: eHealth Familias Unidas Primary Care or prevention as usual. The intervention will be delivered by trained interns, clinic volunteers, social workers, mental health counselors, students, and nurses. Outcomes will be measured at baseline and 6, 12, 24, and 36 months post-baseline. This study will determine whether the intervention, compared to prevention as usual, is effective in reducing drug use, unprotected sex, and STI incidence in Hispanic youth through the improvement of family functioning. Additionally, we will determine the cost effectiveness of delivering eHealth Familias Unidas within primary care settings. The effectiveness of eHealth Familias Unidas Primary Care will further inform the need to integrate effective behavioral health interventions into primary care settings.

Keywords

drug use prevention; STI prevention; family-based intervention; Hispanic; primary care; pediatrics; adolescents; eHealth intervention

1. Introduction

Behavioral health disparities persist for Hispanic youth. In a national report, Hispanic students reported higher rates of use in nearly all classes of drugs in the 8th and 10th grade, relative to non-Hispanic white and African-American students (Johnston et al., 2017). Hispanic youth also had a higher prevalence, compared to non-Hispanic white and black students, of drinking alcohol before the age of 13 (Kann et al., 2016). Hispanics are also disproportionately affected by sexually transmitted infections (STIs); they accounted for 24% of new diagnoses of HIV despite representing 18% of the US population (CDC, 2017) and, in 2016, the rate of gonorrhea and chlamydia among Hispanics was 1.9 and 1.7 times the rate among non-Hispanic whites, respectively (CDC, 2015).

Fortunately, research has documented that preventive interventions targeting family processes, such as parent-adolescent communication and parental monitoring of peers, are successful in reducing adolescent drug use and sexual risk behaviors for non-Hispanics and Hispanics alike (Jensen et al., 2014; Spoth, Randall, & Shin, 2008). However, few Hispanic families receive evidence-based preventive interventions. The unfulfilled preventive intervention need among Hispanic families is partly due to a lack of tested interventions with Hispanics (as cited in Zayas, Borrego, & Domenech Rodriguez, 2009), evidence-based interventions not reaching community settings (Nápoles, Santoyo-Olsson, & Stewart, 2013), and difficulty in engaging and retaining participants into family-based interventions (Ingoldsby, 2010). The current study addresses this need by testing a culturally specific, Internet-based intervention for Hispanics offered in an accessible, local, and trusted setting to reach participants: primary care settings (Kolko & Perrin, 2014).

Given that the fragmentation of mental health, substance use, and medical services leads to inadequate care, there has been a call for integrating behavioral health, including parenting and family-based interventions, into primary care settings (Gerrity, 2016). Primary care settings are a familiar entry point for preventive services, offer an additional access point

other than school settings, and are used by many: in 2014, approximately 80% of all youth ages 10–17 received a well-child visit within the past year (Black, Nugent, & Vahratian, 2016). Due to organizational and time barriers in clinics (Butler et al., 2008), researchers have suggested that one way to facilitate the integration of behavioral health within primary medical care is through the use of Internet-based interventions (Prado, Pantin, & Estrada, 2015). Internet-based, or “eHealth”, interventions have an impact not only family functioning (Sanders, Baker, & Turner, 2012), drug use (Palfai et al., 2014) and unsafe sexual behavior (Carpenter et al., 2010), but also lessen barriers for researchers, clinicians, and participants alike (Ahern, 2007). Furthermore, 84% of Hispanic adults in the United States use the Internet (Brown, Lopez, & Hugo Lopez, 2016).

Despite (a) the evidence that family-based interventions can help address health disparities among Hispanic adolescents; (b) the call to evaluate parenting and family-based interventions within primary care settings (Leslie et al., 2016), and (c) the widespread use of the Internet by Hispanics, there currently are no efficacious or effective, Hispanic-specific, eHealth drug use and sexual risk behavior preventive interventions in primary care or pediatric settings.

2. Methods

2.1 Objectives and Hypotheses

This manuscript describes the protocol for an effectiveness- implementation hybrid design randomized controlled trial to evaluate the relative effectiveness of eHealth Familias Unidas Primary Care, compared to prevention as usual, on family functioning, youth drug use, risky sexual behavior, and sexually transmitted infections (Curran, Bauer, Mittman, Pyne, & Stetler, 2013). The current study is applying a Hybrid Type 1 trial design. An effectiveness-implementation hybrid design dually focuses on assessing clinical effectiveness and implementation (Curran et al., 2013) instead of addressing them in separate stages of research. We chose the 11 pediatric primary care sites to be quite diverse but recognize that the central aim of the trial is on effectiveness. Nonetheless, even this trial with its modest number of sites, can be useful in gleaning new insights about acceptance of the intervention within pediatric primary care settings. Therefore, we will also collect data from clinic personnel on organizational climate to understand the variables associated with the implementation of an evidence-based intervention in pediatric primary care settings. Clinicians and staff surveys conducted during this trial will help us understand barriers and facilitators to wider scale implementation and sustainment. By collecting implementation level data, we position future research towards broad scale implementation, assuming the intervention is found to be effective. It is important to note that because families are randomized within each site, the design for effectiveness is a randomized block design and overall power is only minimally affected by the number of sites. Finally, an economic analysis will be conducted to estimate the cost-effectiveness of eHealth Familias Unidas Primary Care.

A unique aspect about the intervention in this study is that—unlike most youth drug use and sexual risk prevention interventions—eHealth Familias Unidas Primary Care targets the parent, instead of the adolescent, as the agent of change to reduce adolescent risk behaviors.

Further, the intervention uses the Internet as a vehicle for intervention delivery, which reduces burden for participants and researchers, and can be delivered by trained health professionals (i.e., nurses, social workers, mental health counselors) and students (i.e., master's and doctoral level psychology, social work, and public health students; volunteers; trained interns). Additionally, to date, a large majority of Internet-based efficacy or effectiveness studies for drug use and sexual risk behaviors have focused on adult populations with only a few effectiveness trials with families of Hispanic youth, none of which have been implemented into primary care settings. We hypothesize that the intervention will be more effective than prevention as usual in preventing drug use, sexual risk behaviors (condomless sex), and STIs (gonorrhea and chlamydia). Furthermore, we hypothesize that intervention effects will be partially mediated by family functioning, a mediator in previous Familias Unidas trials (Prado et al., 2007; Pantin et al., 2009; Perrino et al., 2016; Estrada et al., 2017a). To inform future implementation and dissemination efforts of eHealth Familias Unidas Primary Care, this randomized controlled trial also aims to: 1) estimate the cost-effectiveness of the intervention compared to control and STI incidence and 2) explore whether clinic level leadership, organizational context and climate, and attitudes towards evidence-based practice of the primary care clinicians, staff, and facilitators are associated with changes in the proposed outcomes.

2.2 Study design

This study uses two levels of intervention (eHealth Familias Unidas Primary Care and prevention as usual) as the between subject factor and five repeated measures assessments (T1, T2, T3, T4 and T5, corresponding to baseline, 6-, 12-, 24- and 36-months post baseline) as the within subject factor. Dyads of Hispanic adolescents ($n = 456$) and their primary caregivers (i.e., mother, father, or legal guardian; hereto forth, “parents”) are randomly assigned to eHealth Familias Unidas Primary Care or the prevention as usual condition. Participants are being randomized on a 1:1 allocation ratio.

2.3 Participants and inclusion criteria

To be included in the study, participating families need to meet the following criteria: a) the parent must be of Hispanic immigrant origin, defined by at least one parent born in a Spanish speaking country of the Americas (i.e., parent must understand Spanish given that parent sessions are viewed in this language), b) the adolescent must be between the ages of 12–16 years at enrollment, c) the adolescent lives with a parent who is willing to participate, d) the family must have broadband Internet access on a device, including (but not limited to) a smartphone, iPad, tablet, or computer at their home or other location (e.g. school, library, etc.), and e) the adolescent is willing to participate. Families will be excluded if they report plans to move out of the South Florida area during the study or if the family reports that the adolescent has a developmental delay which would preclude the adolescent from engaging in or understanding the intervention. Adolescent developmental delays will be assessed based on parental report.

2.4 Setting

Participants will be recruited from 11 pediatric care clinics in South Florida. Clinics were selected based on: a) clinic's willingness to participate in the study, b) the pool of Hispanic

patients attending the clinic, and c) the representation of different types of clinics in the study, e.g., academic, privately owned, and community. Clinics currently include an academic health clinic, six private clinics, two community health clinics, a community hospital and a pediatric mobile clinic housed within an academic hospital.

2.5 Recruitment procedures

To recruit participants for this study, trained assessors interface with the clinic staff. Clinic staff informs the research team ahead of time (e.g., a day or week before) whether there is a Hispanic youth aged 12 – 16 scheduled to come into the clinic and at what time. Several recruitment methods are utilized across the clinics to match the clinic flow or unique demands. The main recruitment method is for a recruiter to briefly introduce the study and ask if the family would like more information. If so, the family is moved to a small office space or exam room.

The recruiter screens parent and youth and obtains informed consent from the parent and assent from the youth, if the family is eligible. Additional recruitment methods include sending a letter to potential participants, from his or her physician, that describes the study and petitions parents to contact study staff if interested in participating. Potential participants who have been mailed the letter are also followed up with a call to invite them to participate. Further, flyers are posted in patient rooms with study information and contact numbers, and clinic providers endorse the program during the health visit. If a participant calls or indicates interest in the study, a recruiter meets the participant at the clinic to screen, consent and assent. Once parent and youth are consented/assented, they complete a short assessment battery on a tablet and the adolescent is asked to provide a sample of his/her urine for the baseline STI test which is processed by a qualified lab. The family is then randomized to one of the two conditions and compensated for their time. Parents are compensated \$40, \$45, \$50, \$55, and \$60 cash, for each respective assessment; adolescents receive \$20 cash at each assessment time point. Additionally, families receive \$35 to cover travel costs. The total time to recruit, assess, randomize, and compensate participants is approximately one and a half hour.

2.6 eHealth Familias Unidas Primary Care

eHealth Familias Unidas Primary Care is an Internet adaptation of the Familias Unidas face-to-face intervention. Previous publications describe the Familias Unidas program of research in detail (e.g., Prado & Pantin, 2011; Prado et al., 2012a, 2012b) and the Internet adaptation of eHealth Familias Unidas (e.g., Estrada et al., 2017b; Perrino et al., 2018). The intervention consists of 12 sessions: eight (approximately 30 minutes) e-parent group video sessions in Spanish that are accessed via a website, and four (approximately 35 to 45 minutes) family sessions delivered in Spanish and/or English by a trained facilitator via web conferencing software. Given that a full description on the development of eHealth Familias Unidas has been published (Estrada et al., 2017b), the next section will only briefly describe the intervention.

2.6.1 e-Parent Group Sessions.—The eight e-parent video group sessions contain three elements: 1) e-parent group discussions, 2) an episode of a culturally syntonic

telenovela/soap opera, and 3) interactive exercises. The e-parent group discussions are videos that recreate the topics that parents discuss in the face-to-face Familias Unidas intervention. Participants in these videos are parents from the community with an adolescent between the ages of 12 – 16. Topics are guided by the original intervention manual and include communication techniques and how parents can protect adolescents from risk behaviors, among others. The telenovela series is comprised of eight episodes which map on to the eight topics of the face-to-face intervention. The telenovela includes scenes that depict situations that take place within families and peers, including, parent-adolescent conversations, the risks of drug use and sexual risk behaviors, and ways that adolescents can respond when faced with situations to use drugs or engage in sexual risk behaviors. Lastly, the interactive exercises are used to reinforce e-parent group discussions, to adapt the participatory learning strategy that characterizes the face-to-face intervention, and to tailor the family sessions to each family's particular needs by allowing them to input responses to prompts (e.g., "What are the goals for your family?"). The intervention facilitators are able to review parent responses and use this information to facilitate discussion between parents and adolescents during the online family sessions.

2.6.2 Online Family Sessions.—The four online family sessions are delivered live via the Internet utilizing webcams and a HIPPA compliant videoconferencing software similar to Skype called VSee (2018). eHealth Familias Unidas Primary Care facilitators are responsible for scheduling and delivering the four online family sessions with each of their families. The online family sessions provide parents the opportunity to practice with their adolescent the skills learned in the e-parent group sessions. The content of each of these four family sessions is identical to that of face-to-face Familias Unidas and is described in Table 1 below.

Prevention as Usual

Prevention as usual is conceptualized as the current standard of care offered in the clinics (i.e., routine anticipatory guidance or services, that are relevant to substance use, sexual risk, and STI prevention, delivered to the patient by clinic personnel). Participants in the control condition do not receive any intervention services from the study team. These families are only asked to complete the assessments and for the adolescents to provide a urine sample for the STI test at every time point.

2.7 Training and supervision

The research team received a series of trainings before launching of the randomized trial. Study personnel were trained in study operating procedures, consenting/assenting, and the use of REDCap (a secure web application for building and managing online surveys and databases; REDCap, 2018), which was programmed on all the tablets to collect consent/assent and assessment data. All study personnel are CITI trained and are fully informed about the protocol, research procedures, and their duties and functions. Study personnel were asked to role-play all procedures. Regardless of experience, trainings are continuously held to assure all study personnel members are adherent to the study procedures. Weekly meetings are held to discuss study updates, progress, and challenges.

2.7.1 Facilitator training, supervision, and fidelity.—Facilitators for the eHealth Familias Unidas Primary Care study consist of social workers, mental health counselors, students, clinic staff (such as developmental therapists), volunteers and nurses. The intervention is delivered by personnel that directly work for the pediatric clinic, or by facilitators associated with the clinic (e.g., trained interns, clinic volunteers, social workers, mental health counselors, students, and nurses). Additionally, research staff receive referrals from the clinics, but only from clinics that are affiliated with the university that is conducting the research. Providers are not informed which condition families are randomized to, unless a provider is delivering the intervention. All facilitators are fluent in both English and Spanish and complete a three-day training. Training approaches include review of the intervention manual, didactic presentations, videotape reviews and role-plays between the facilitator and the clinical supervisor. Facilitators are also trained on strategies to build alliance and rapport with the families. Additionally, facilitators are trained on how to access the online intervention, troubleshoot difficulties with VSee, and how to track the parents' progress in terms of watching the online sessions. To monitor implementation fidelity, all family sessions are video recorded, and 25% of all family sessions conducted by each facilitator are randomly selected and rated by an independent adherence rater. Our lead fidelity trainer also rates 25% of those cases rated by the independent rater to obtain inter-rater reliability. Inter-rater reliability has been $> .75$ in our prior efficacy studies (e.g., Prado et al., 2007; Estrada et al., in press) and effectiveness (Estrada et al., 2017a) trials. The clinical supervisor reviews fidelity ratings with the facilitators during group supervision sessions. Specific problem areas and unique intervention or fidelity issues that need to be addressed by each facilitator are identified and problem solved. Group supervision for each of the family sessions also includes didactic presentations, case review and planning for future sessions.

2.8 Data collection and measures

2.8.1 Data collection.—Regardless of condition assignment, assessments of parents and youth occur at baseline and 6, 12, 24, and 36 months post-baseline. Trained assessors invite participants to complete the assessments at the University of Miami Miller School of Medicine campus, one of the pediatric clinics, or an assessor travels to the participant's home. All consents and measures (except for the STI tests) are administered via REDCap, which meets security requirements (Harris, 2009). Measures were programmed into REDCap and links to the assessment battery were pre-programmed onto tablets. As assessments are completed, data are stored in secure university servers. Data are protected such that participants can only view their own survey responses as they complete the assessment. To protect confidentiality, a numerical ID is assigned to each family and survey data are kept separate from identifying information, including consents and assents. Study personnel are always present to assist with any technological issues or questions.

2.9.2. Measures.—All parent and adolescent measures, except for the STI test, are self-reported. The main outcomes being examined include: parent and youth family functioning, adolescent and parent drug use, adolescent sexual risk behaviors, and adolescent STI incidence and reoccurrence. Additionally, clinic personnel and facilitators complete a self-report survey on a tablet to assess organizational context, and climate and attitudes

towards evidence-based practices. Lastly, study costs (e.g., facilitator involvement and family time) are tracked to determine the cost effectiveness of eHealth Familias Unidas Primary Care.

Family functioning (reported by both youth and parents) consists of parental involvement, positive parenting, parent-adolescent communication, and parental monitoring of peers. Two subscales of the Parenting Practices Scale (Tolan, P. H., Gorman-Smith, D., Huesmann, L. R., & Zelli, A., 1997): (a) extent of parental involvement (20 items) and (b) positive parenting (9 items) are being used. Communication is assessed via the Parent-Adolescent Communication Scale (Barnes & Olson, 1985) which determines the quality and content of parent-adolescent communication as reported by parent and youth, respectively. Parental monitoring of peers is being assessed with five-item measure used in previous Familias Unidas trials (Pantin, 1996).

Adolescent reported drug use is assessed with items from a national longitudinal survey, *Monitoring the Future* (Johnston et al., 2017). Adolescents are asked to report on lifetime and past 90-day drug use. Adolescents who endorse previous drug use, are queried on the frequency of use. Adolescent sexual risk behaviors are assessed with items from the Sexual Behavior Instrument (Jemmott, Jemmott, & Fong, 1998) which has also been used in previous trials.

Adolescents are asked whether, and the number of times, they have had sex (oral, vaginal, or anal sex) in their lifetime and in the previous 90 days. Additionally, adolescents are questioned about the occurrence and frequency of high risk situations during sexual intercourse, such as condomless sex, and being under the influence of drugs and/or alcohol during sexual encounters. A urine sample is also taken, at each time point, to test for the incidence of chlamydia and gonorrhea. The sample is collected by study personnel, examined by a qualified lab, and the results are returned to the project coordinator. During the consent/assent process, research staff explain study procedures to adolescents and parents regarding positive STI results. That is, if there is a positive result, adolescents are informed of this result via phone by the clinical supervisor; parents are not informed of the result, per Florida law. Adolescents with a positive test result are referred to treatment and encouraged to inform their sexual partner(s) and parent. Additionally, positive test results are reported to the Florida Department of Health by the study's infectious disease physician.

Data from physicians, facilitators, and clinic staff are also being collected to assess the clinics' organizational leadership, context, and climate. Organizational-level factors are assessed with the Implementation Leadership Scale (ILS; Aarons, Ehrhart, & Farahnak, 2014) as well as the Implementation Climate Scale (ICS; Ehrhart, Aarons, & Farahnak, 2014). The ILS assesses the degree to which organizational leaders support their staff in the implementation of evidence-based interventions through four subscales that measure level of proactiveness, knowledge, support, and perseverance (Aarons et al., 2014). The ILS consists of one version for staff to evaluate their leader and a version for leaders to evaluate themselves. The ICS examines the level of a strategic organizational climate within an organization (Ehrhart et al., 2014). It consists of six sub-scales that assess: focus on evidence-based practice, educational support for evidence-based practice, recognition for

evidence-based practice, rewards for evidence-based practice, selection for evidence-based practice, and selection for openness. The Evidence-Based Practice Attitude Scale (EBPAS; Aarons, 2004), is used to assess provider attitudes toward adopting evidence-based practices. Finally, the Multifactor Leadership Questionnaire is administered to clinic leaders/physicians to assess leadership style and behavior (Bass & Avolio, 2017).

For the economic analyses, we have established a cost-tracking protocol to estimate the value of personnel and other resources that will be invested to implement eHealth Familias Unidas. The core economic analysis is framed from the provider perspective (i.e., costs incurred by the primary care providers), but also includes information on the costs incurred by families who participate in the intervention. We will calculate the total annual cost of eHealth Familias Unidas (e.g., staff training), total cost over the duration of the intervention (e.g., facilitator time to deliver and schedule families), and average per family cost (e.g., time to participate in sessions, transportation). We will also estimate capital (e.g., office space) and recurrent (e.g., salaries, supplies) costs to operate eHealth Familias Unidas Primary Care. To highlight the relative contribution of the various cost components, we will also calculate the percentage of total annual cost accounted for by each resource category (e.g., personnel and family time). Cost data collection will occur throughout the study, concurrent with all other data collection activities.

3.0 Data analysis plan

3.1. Data preparation and preliminary analyses.—Testing of distributional assumptions will include statistical tests for univariate and multivariate normality (tests of skew & kurtosis) as well as visual inspections of the empirical distributions for the data at each time point. Should deviations be deemed sufficient for concern, transformation of variables will be attempted where possible. Based on previous studies, the distribution of our outcomes is likely to be skewed, and methods specifically used for such data will be used. Often such data follow a Poisson distribution, and a Poisson regression would be the appropriate way to handle these analyses in the event of positively skewed distributions (Koch et al., 1986). Methods for zero-inflated Poisson, which allows for a preponderance of zeros, will also be used (Afifi et al., 2007; Angers & Biswas, 2003; Kreuter & Muthén, 2008), as will two-part modeling (Olsen & Schafer, 2001). Reliability estimates of internal consistency (Cronbach's alpha) will be generated for all scale scores. If reliability estimates are found to be below .80, item total correlations and factor analyses will be employed to diagnose and correct psychometric problems (cf. Nunnally, 1978; Ford, MacCallum, & Tait, 1986).

3.2 Measurement modeling.—Some hypotheses are based on latent constructs. For each latent construct, multiple individual scales or indicators will be used to create a measurement model based on a confirmatory factor analysis using SEM techniques (Bollen, 1989). For example, for family functioning, the multiple available indicators include parental involvement, positive parenting, parent-adolescent communication, and parental monitoring of peers. We will attempt to fit a confirmatory factor analysis with all available indicators. However, if latent variables do not emerge neatly from the measurement modeling procedures using all available indicators (determined by a Comparative Fit Index < .95 or a

standardized root mean squared residual $>.06$; Hu & Bentler, 1999; Kline, 1998), we will trim the measurement model by eliminating non-significant (i.e., $p > .05$) indicators or by correlating appropriate residual (error) terms. If these efforts are unsuccessful, and if latent variables do not emerge neatly from the measurement modeling procedures, we will select the individual measure that is best supported in the empirical literature and that satisfies distribution and measurement requirements.

To test for differences in drug use and sexual risk behaviors between eHealth Familias Unidas Primary Care and prevention as usual, we will use latent growth modeling (LGM; Preacher, Wichman, MacCallum, & Briggs, 2008). As recommended by Raudenbush & Bryk (2002), we will use 2-level analysis to determine whether the mean trajectories of drug use and sexual risk behaviors (condomless sex) for eHealth Familias Unidas Primary Care and prevention as usual differ significantly over time (i.e., 5 assessment time points). There are several advantages to using LGM when investigating the trajectory of change. First, LGM handles missing at random data well (Preacher et al., 2008), and hence all participants are retained in the analyses. Second, LGM provides hypotheses testing of specific trajectories with the incorporation of time varying and time invariant variables (Preacher et al., 2008). Further, its power is often much greater than ANOVA methods because the unit of analysis is the slope trajectory, and we have 5 time points to measure the growth trajectory of drug use (Gueorguieva & Krystal, 2004). Data analyses for these hypotheses will be conducted using Mplus (v 7.2) (Muthén & Muthén, 1998–2012).

While nesting of youth/families within sites is fully balanced across intervention condition by our randomization procedure – and therefore of limited concern other than inclusion of site as a blocking factor, there is some potential that nesting within providers could contribute a source of variation, therefore, we plan to conduct analyses that include provider as a random factor. We also plan to include measured attributes of providers, including Evidence-Based Practice Attitude Scale scores, for example, to assess whether physician's general attitudes about evidence-based interventions have an impact on child outcomes. The analysis plan will follow that presented in Brown et al. (2008 & 2013), which decomposes effects of nesting factors into those with measured site and provider level covariates (e.g., EBPAS) and remaining contribution due to unmeasured factors at these levels.

In terms of power analyses for drug use and sexual risk behaviors, Mplus Monte Carlo simulation with 10000 replications was used to calculate power using a latent growth curve model framework with one covariate (i.e., condition assignment) and missing data (Muthén & Muthén, 2002). With 5 time points (0, 6, 12, 24 and 36 months) and assuming a 5% attrition rate at each assessment (also assuming equal sample size across both conditions), with 228 cases in each condition at baseline (or 185 at the final assessment time point in each condition), we have 80% power to detect a regression coefficient equal to 0.09 (effect size = 0.3) in the regression of the slope growth factor on intervention condition. This is considered slightly over a small (0.2) effect size (Cohen, 1998).

To test for the mediating effects of family functioning, we will use the product of coefficients test described by MacKinnon and colleagues (2002), which is based on the distribution of the indirect effect of the intervention through the mediator. This procedure

tests whether the product of the coefficients from the intervention to the mediator (a) and from the mediator to outcome (b) is significantly different from zero. We will be testing whether the product $(a) \times (b)$ is statistically significantly different from zero, by comparing the observed value of $(a) \times (b)$ to the empirical distribution calculated using the bias-corrected bootstrap (MacKinnon, Lockwood, & Williams, 2004). Additionally, we will include in our analysis an interaction model involving baseline, 6-month family functioning, and intervention. As we have previously noted in Familias Unidas trials, only when baseline family functioning was poor did the intervention have definitive mediation through improved family functioning (Perrino et al., 2014). We will also conduct mediational sensitivity analyses as described by VanderWeele & Chiba (2014) in order to assess the potential effects of an unobserved confounder. We aimed to identify the minimal detectable regression coefficient for the mediator based on Vittinghoff and colleagues' methodology (2009). The results show that we have 80% power to detect a mediating effect if the logistic regression coefficient for the mediator is 0.63, which is equal to an OR of 1.88, corresponding to an effect size of $d = 0.35$. According to Cohen, this is considered a small ($d = 0.2$) to medium ($d = 0.5$) effect size (Cohen, 1998).

To analyze differences in STI incidence between eHealth Familias Unidas Primary Care participants and prevention as usual, we will use a univariate logistic regression for the binary outcome, new diagnoses of STIs (Yes/No). Sexually transmitted infection incidence will be defined as a positive laboratory test result for a new chlamydia or gonorrhea infection at any of the follow up assessment time points. In this analysis, condition will predict STI diagnosis. The test of the hypothesis will be based on a Wald test comparing the intervention regression coefficient to its standard error. Additionally, the time of STI diagnosis will be included as a covariate in the logistic regression to test the robustness of the intervention's effect. Mediation effects for this outcome will be conducted using the MacKinnon and colleagues (2004) method described above with the exception that the outcome for this hypothesis is binary. The Weighted Least Squares Means and Variance adjusted (WLSMV) estimator in Mplus will be used to estimate the indirect effect. With WLSMV, a continuous latent response variable (y^*) underlying the observed dichotomous variable is used to test for the mediated or indirect effect. In terms of power, according to CDC national statistics, the annual STI incidence rate is 3.16% for Hispanic adolescents aged 15 to 19 (Gavin et al., 2009). Thus, we expect the 3-year STI incidence rate in the control group to be approximately 9.2%. Using a one-sided Z test with pooled variance to test the difference between two independent proportions (assuming the same 5% attrition rate at each assessment time point), the study has over 80% power to detect a difference of 6.1% in STI incidence between the two conditions. This difference in proportions translates to an effect size of Cohen's $h = 0.26$, considered a small ($h = 0.2$) to medium ($h = 0.5$) effect size (Cohen, 1998).

To assess the data from the clinic personnel and facilitators, we will explore whether the clinic and facilitator level data have a moderating effect on intervention outcomes. Through Wald-type tests of the interaction (Brown et al., 2018) between the intervention condition and the 1) clinic personnel's leadership, 2) clinic personnel's organizational context and climate, and 3) facilitator attitudes towards evidence-based practice, we will explore if these data have an impact on proposed outcomes.

To assess the cost-effectiveness of eHealth Familias Unidas Primary Care, we will collect cost data as described above in the measures section. Cost effectiveness analysis (CEA) is critically important for implementation research as stakeholders must weigh the expected benefits of an intervention or new practice with the required resources and costs associated with the implementation process. Successful translation and dissemination of new practices depends on demonstrating financial viability throughout implementation phases. CEA is inherently an incremental analysis that compares doing a little more or a little less of something to capture marginal variations in costs and effectiveness across interventions (Gold, Siegel, Russell, & Weinstein, 1996). Differences in intervention cost are divided by differences in intervention effectiveness to calculate incremental cost-effectiveness ratios (ICERs). One can then compare the ratios of cost to outcome for two or more alternative programs to determine which programs are relatively more cost-effective (i.e., have a lower cost-effectiveness ratio).

We will examine whether eHealth Familias Unidas Primary Care is more cost effective than prevention as usual in reducing drug use, unprotected sexual behavior, and STI incidence. The main outcomes of the parent study will be used as the measures of intervention effectiveness. Specifically, we will estimate the incremental cost of eHealth Familias Unidas to achieve reduced frequency of drug use, reduced frequency of unprotected sex, and reduced STI incidence. The ICER will describe the marginal cost of achieving (for example) one fewer unprotected sex act for participants in eHealth Familias Unidas relative to participants in the prevention as usual condition. As part of our cost effectiveness analyses of eHealth Familias Unidas Primary Care, we must determine the best way to characterize and adjust for uncertainty in the calculation of cost-effectiveness ratios for which various methods have been proposed (Glick, Briggs, & Polsky, 2001). We will conduct sensitivity analyses to carefully evaluate the F distributions of intervention cost and outcome measures. We will employ a nonparametric (bootstrapping) method to compute accurate confidence intervals for assessing uncertainty in the cost-effectiveness ratios (Doshi, Glick, & Polsky, 2006; Fenwick, Claxton, & Sculpher, 2001).

3. Discussion

Given (a) the disproportionate rates of drug use, unprotected sexual behavior, and STIs among Hispanic adolescents; (b) that U.S. Hispanics are a young population (32% are under 18 years old compared to 19% for whites and 26% for African Americans; Patten, 2016); (c) the Hispanic population accounted for half of the U. S. population growth since 2000 (Flores, 2017); and (d) the rise of primary care sites in underserved areas to increase access to underserved communities (Ortega, Rodriguez, & Bustamante, 2015), expanding contexts in which to implement evidence-based drug use and sexual risk behavior preventive interventions, such as primary care settings, for Hispanic adolescents is an urgent public health issue (Bustamante, Chen, Rodriguez, Rizzo, & Ortega, 2010).

This manuscript described an effectiveness study of eHealth Familias Unidas in pediatric primary care settings. eHealth Familias Unidas Primary Care is an Internet adaptation of Familias Unidas, an evidence-based, family-based preventive intervention found to reduce youth problem behaviors through improving family functioning. As stated in the 2009 IOM

report on Preventing Mental, Emotional, and Behavioral Disorders among Young People (IOM and National Research Council, 2009), although there is a wide range of preventive intervention programs with evidence of efficacy, there is a need to disseminate these programs more widely in innovative settings and to increase knowledge regarding the effective dissemination of these prevention programs. Therefore, the rationale and design of eHealth Familias Unidas Primary care is promising as we move towards an integrated care model that can potentially facilitate the accessibility of evidence-based interventions, while maintaining intervention fidelity in broad dissemination.

Providing mental and behavioral prevention services in primary care settings is intended to increase access to care by creating a single source of integrated care (Hawkins et al., 2015). Delivery through primary care settings is an actionable goal (Hawkins et al, 2015) that uses existing infrastructure to support high-quality implementation of evidence-based interventions. This capitalizes on the understanding that pediatric care is a critical intervention point, in which acute care can shift to a culture of prevention (IOM, 2011). Additionally, integration of behavioral preventive interventions, for example, programs such as CATCH-IT (Van Voorhees et al, 2009) into primary care have been successful in the past. Features such as shifting the focus to the patient (Internet-based self-management) and minimizing changes in practice work flow, have helped to overcome barriers in the implementation of interventions within primary care settings. This parallels the goals of an accountable care organization of patient empowerment and use of lower-cost approaches to modify and prevent disease course (Eisen et al., 2013) and demonstrates the potential for eHealth Familias Unidas Primary Care to be successfully integrated into primary care.

While we argue that primary care is an innovative setting to implement evidence-based interventions, there are some challenges that should be noted (Bitar, Springer, Gee, Graff, & Schydlower, 2009). One challenge is the availability of evidence-based preventive interventions for providers to offer to their patients (i.e., limited programs have been tested in connection to primary care), and needed resources and personnel to implement interventions into regular clinic activities (Bitar, et al., 2009). Another challenge is the acceptability of EBIs in pediatric primary care by clinic personnel and agency administrators. Physicians and staff have constraints on time and space that must be addressed to maintain clinic flow (Bitar et al., 2009). The organizational context and climate data that we will be collecting could help identify the aforementioned challenges of acceptability in pediatric primary care settings and illuminate whether leadership and/or organizational climate can impede or facilitate EBI adoption. Adequate funding is also a challenge when it comes to implementing effective prevention strategies. To seamlessly integrate EBIs into pediatric primary care, reimbursement of preventive services through insurance (e.g. Medicaid) could be a long-term and continual funding stream. The cost-tracking analysis that we will be completing can help further inform whether insurance reimbursement would be fiscally possible.

4. Conclusion

We have chosen diverse primary care pediatric settings (academic practice, public health clinic, mobile clinic, private practice), so that our findings can be immediately disseminated

to a broad range of primary care settings. We hope that using an Internet-based program will enable greater dissemination, while maintaining intervention fidelity and minimizing disruption to clinic activities. Prevention researchers can use our future findings to answer important implementation and sustainability questions for behavioral health prevention interventions in pediatric primary care settings.

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Table 1.

eHealth Familias Unidas Primary Care Session Overview

Family Session #1 – Engagement Family Session: Facilitator begins engagement with both parent and youth and encourages both to participate in all subsequent family sessions and watch all videos. Facilitator completes family needs assessment and problem-solves family's perceived barriers to participation.
Parent Session #1 – Parental Investment in Adolescent Worlds: Parents watch a video which reviews adolescent risk factors in the various contexts in which adolescents are embedded (i.e., family, peer, and schools). Parents engage in an interactive exercise to set goals in each of the adolescent's worlds.
Parent Session #2 – Enhancing Communication Skills: Parents watch a video which reviews characteristics of effective family communication, including effective co-parenting and parent adolescent communication skills. Parents engage in an interactive exercise to reinforce key communication skills.
Family Session #2 - Family Communication: Facilitator meets with family so that the parents can exercise newly learned communication skills and practice with adolescents by discussing a relevant issue in the youth's life.
Parent Session #3 – Family Support and Behavior Management: Parents watch a video on the significance of parental support, behavior management, and effective discipline to manage adolescent behavior problems, including sexual risk behaviors. Parents complete an interactive exercise that reinforces behavior management strategies.
Parent Session #4 – Parental Monitoring of Peer World: Parents watch a video which highlights the role of prosocial and antisocial peers in youth development. The video also discusses the protective effects of parental monitoring of adolescents' peer activities. Parents complete an interactive exercise that reinforces parental monitoring strategies.
Parent Session #5 – Adolescent Drug Use: Attitudes, Beliefs, Intentions & Peer Pressure : Parents watch a video that discusses the prevalence and consequences of adolescent drug use. In this video, they also observe other parents identify their own attitudes and beliefs regarding substance use and what they currently do to influence their adolescents. Parents complete an interactive exercise on strategies to prevent adolescent drug use.
Family Session #3 – Parental Monitoring of Peer World and Adolescent Drug Use: Facilitator covers family conversations about adolescent's peers and provides ways to troubleshoot interactions between parents and the youth's peer world. Parents teach youth the skills necessary to effectively manage peer pressure to engage in drug use.
Parent Session #6 – Parental Investment in Adolescent's School: In this video, parents address the role of school in the adolescent's life. Parents watch a discussion on how parental connections to school can serve as a protective mechanism. Parents engage in an interactive exercise that emphasizes how parents can become involved in the adolescent's school world.
Parent Session #7 – Adolescent Sexual Risk Behaviors: Attitudes, Beliefs, Intentions & Peer Pressure: Parents watch a video that lists risks for STIs, discusses the effects of adolescent sexual risk behaviors, and covers parent-adolescent conversations about sexual risk behaviors and STIs. Parents watch a discussion on attitudes and beliefs regarding adolescent sexual risk behaviors and what parents are currently doing to influence adolescent behavior. Parents learn about safe sexual practices. Parents complete two interactive exercises to reinforce correct information regarding sexual risk behaviors.
Family Session #4 – Adolescent Sexual Risk Behaviors: With the Facilitator present, parents communicate the dangers and consequences of risky sexual behavior. Parents guide their adolescent in developing safety skills.
Parent Session #8 – Prevention Has to Be Achieved All Over Again Everyday: In this video, parents review the content of eHealth Familias Unidas and process experiences in the program. Parents highlight parents' role as lifetime educators of their adolescent and the importance of daily implementation of skills to improve family functioning in order to prevent drug use and sexual risk behaviors. Parents watch a review of the interconnectedness among these behaviors and the importance of parental involvement, family communication, family support, and parental monitoring in combating these risks.