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Assessing the effectiveness of a patient-centred computer-based clinic intervention, *Health-E You/Salud iTu,* to reduce health disparities in unintended pregnancies among Hispanic adolescents: study protocol for a cluster randomised control trial

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ABSTRACT

Introduction Teen pregnancy rates in the USA remain higher than any other industrialised nation, and pregnancies among Hispanic adolescents are disproportionately high. Computer-based interventions represent a promising approach to address sexual health and contraceptive use disparities. Preliminary findings have demonstrated that the *Health-E You/Salud iTu,* computer application (app) is feasible to implement, acceptable to Latina adolescents and improves sexual health knowledge and interest in selecting an effective contraceptive method when used in conjunction with a healthcare visit. The app is now ready for efficacy testing. The purpose of this manuscript is to describe patient-centred approaches used both in developing and testing the *Health-E You* app and to present the research methods used to evaluate its effectiveness in improving intentions to use an effective method of contraception as well as actual contraceptive use.

Methods and analysis This study is designed to assess the effectiveness of a patient-centred computer-based clinic intervention, *Health-E You/Salud*iTu, on its ability to reduce health disparities in unintended pregnancies among Latina adolescent girls. This study uses a cluster randomised control trial design in which 18 school-based health centers from the Los Angeles Unified School District were randomly assigned, at equal chance, to either the intervention (*Health-E You* app) or control group. Analyses will examine differences between the control and intervention group's knowledge of and attitudes towards contraceptive use, receipt of contraception at the clinic visit and self-reported use of contraception at 3-month and 6-month follow-ups. The study began enrolling participants in August 2016, and a total of 1400 participants (700 per treatment group) are expected to be enrolled by March 2018.

Ethics and dissemination Ethics approval was obtained through the University of California, San Francisco Institutional Review Board. Results of this trial will be submitted for publication in peer-reviewed journals. This study is registered with the US National Institutes of Health.

Trial registration number NCT02847858.

Strengths and limitations of this study

- Integrates technology in a clinical setting to support contraceptive decision making among Latina adolescents.
- Rigorous cluster randomised control trial study design.
- Significant engagement with stakeholders in developing and implementing study.
- The study is limited to female sexually active Latina adolescents.
- Participant retention is a limitation.

INTRODUCTION

Over the past two decades, teen pregnancy rates in the USA have declined dramatically.[1] Nonetheless, US rates remain higher than any other industrialised nation,[2] and pregnancies among Hispanic adolescents are disproportionately high.[3] By 12th grade, 68% of Hispanics[i] report having had sex, and 22% report having had four or more

[i]This paper uses the term Hispanic or Latina interchangeably to refer to individuals residing in the USA who are of Mexican, Central American, South American or Caribbean origin or ancestry. Much of the published research uses the broader term, Hispanic; however, our study population prefers and uses the term Latina which is used in describing our study and population.

sexual partners.[4] Before the age of 20 years, roughly one in three Hispanic teens have been pregnant at least once—a rate that is one and a half times the national average and further exemplifies the significant disparities experienced by Hispanic adolescents.[5] Most of these pregnancies are unintended and preventable. However, Hispanic adolescents are less likely to use contraception during sex than non-Hispanics.[6–8] When contraception is used, condoms are most common, but often they are used inconsistently[9 10] or incorrectly.[11] Births to teen mothers place both young mothers and their children at a greater risk for poorer educational, economic, health and social outcomes. Given the disparities in teen pregnancies among Hispanic adolescents, this population faces a disproportionate burden of these adverse consequences.[2]

Several factors contribute to the higher unintended pregnancy rates among Hispanic adolescents. They tend to have less knowledge about reproductive health and contraceptives than their White peers.[12 13] They also tend to overestimate potential side effects associated with contraceptives such as weight gain, bleeding and method reversibility.[14] Many youth, especially Hispanic adolescents, hold ambivalent and conflicting attitudes about contraception, which contribute to the none or inconsistent use of effective contraception.[15] For example, there is a cultural expectation for Hispanic adolescent girls to delay sex until marriage, thus, actively seeking contraceptive services represents an individual's volition to have sex.[16 17] These attitudes further contribute to fear and embarrassment in accessing and using contraceptive services. Studies have found that Hispanic women, especially those born outside the USA, use reproductive health services less frequently than any other racial/ethnic group.[18 19] When they do seek care, many are uncomfortable discussing sexual health topics with clinicians and fear that their health information will not be kept confidential.[9] Concerns that health care services, especially for sensitive services such as sexual and reproductive health, have caused Hispanics, as well as other adolescent groups, to forgo needed reproductive health services.[10]

The process of selecting contraception is a challenge for adolescents. The number and types of methods can be overwhelming and confusing, and contraceptive knowledge is poor. In particular, most adolescents, and especially Hispanic adolescents, are not aware of the relatively new non-coitally dependent, longer-acting, reversible contraception (LARC) methods,[15] which include intrauterine devices (IUDs) and arm implants. LARCs are now recommended for use among adolescents[20] and should be routinely included among the contraceptive options for adolescents.[21] LARCs are particularly advantageous for adolescents because they are safe and effective (>99% efficacy),[22] do not require daily adherence or frequent visits for refills and are highly cost-effective.[17 18] LARCs are also undetectable to others, thus precluding inadvertent disclosure. While research is limited, one study found that only 21% of sexually active adolescents have heard of IUDs, 71% feel uncertain about IUD safety and 58% feel uncertain about IUD efficacy and as a result, LARC use among adolescents is particularly low.[23–25] These barriers are further exacerbated for youth who are English language learners and/or who have limited health literacy.[9 12 21]

In addition to patient-related barriers to contraceptive use, clinician-related barriers are common. Clinicians often lack the skills, comfort or time to provide the comprehensive education necessary for patient-centred choice.[18 26–28] Furthermore, when contraception is discussed, they do not consistently include LARCs as part of their comprehensive contraceptive counselling and care.[29 30] In recent years, under the Affordable Care Act (ACA), health plans have been required to include contraceptive services without cost sharing, which removes an important barrier for low-income adolescents.[31] Yet, there is considerable uncertainty regarding the fate of this and other provisions under and related to the ACA. However, even with healthcare coverage, traditional health education approaches are suboptimal,[32] clinical guidelines for sexual health and contraception are followed inconsistently and there are significant gaps in sexual health information and services for Hispanic adolescents.[32] Clinicians who provide family planning services face additional language or cultural barriers, time constraints and misconceptions about LARCs (such as the risk of infection from LARCs, IUD expulsion and infertility).[24 25 29 30 32] As a result, despite recommendations and clinical guidelines, many clinicians still do not offer patient-centred contraceptive counselling and services including LARCs to their teen patients.[9 24]

Computer-based interventions, including mobile health technologies and applications (apps), have an opportunity to improve access and provision of comprehensive reproductive health services, especially when integrated into the healthcare delivery system. An app can individualise the educational experience and improve the quality of reproductive health services provided. For instance, computer-based sexual health risk assessments have been found to improve teen's disclosure of sexual health risk behaviours.[24 28] Computer-based systems have been found to address psychological aspects of behaviour in ways that teens perceive to be less judgmental than advice from a health educator or clinician.[28] Interactive patient-centred systems can also respond to a patient's unique needs and risk profiles, tailor health information and messaging to meet diverse racial/ethnic backgrounds and 'activate' patients to ask about and/or advocate for services they may need. Apps can also be readily translated into different languages with culturally appropriate phrasing and imagery.[33] In addition, previous research indicates that adolescents are interested in talking about sexual health issues with their clinician, but often do not initiate such conversations.[34] Thus, computer-based

interventions could also be used to facilitate these important conversations.

While computer-based health interventions have been highly acceptable among Hispanic adult populations including those with low literacy,[35 36] there is little evidence regarding computer-based sexual health interventions for Hispanic adolescents.[37] This is despite the fact that computers, tablets and online technologies are widely used and are an especially attractive medium for delivering health information for adolescents and young adults.[38–41] A recent review of brief contraceptive interventions targeting adolescents found only one study that used a computer-based intervention modality, whereas the rest centred on variations of in-person counselling and provider training.[32] Furthermore, this one computer-based intervention resulted in only short-term improvements in knowledge and not in other, longer-term outcomes.[42] While promising, this study was limited in that it took place in family planning clinics, involved only two clinics and included few Latinas. In addition, since this study was published in 1999, there have been significant changes in both technology and contraceptive methods.[42] In another review, of school-based interventions to improve contraceptive use, none of the studies included used technology.[43] In yet a third review, focused specifically on computer-based sexual health interventions for adolescents,[44] only two studies targeted unintended pregnancy.[45 46] One was designed to increase communication about sex between teenagers and their role models (peers, teachers and/or parents),[45] and the other was a thesis study.[46] Neither of these studies were rigorously evaluated or focused on Latinas. To our knowledge, there is only one published study in the past several years that evaluated computer-based interventions to improve contraceptive use.[47] This randomised control trial found that patients at family planning clinics who used the module were significantly more likely to choose an effective contraceptive method than those who did not use the module. While many participants were Latina (70%), only 15% of the sample was between 16 and 19 years of age. Thus, despite the widespread usage of technology among adolescents, especially mobile devices such as tablets, iPads and smartphones, and the potential of technological interventions to provide adolescents with tailored health education experiences to empower their contraceptive decision-making process, there is limited research. Furthermore there is a paucity of research on how to leverage this type of technology for use as a clinician extender to enhance the delivery of health information, improve the quality of patient-centred care and reduce clinician barriers to providing evidence-based contraceptive services.

The purpose of this manuscript is to describe the development of the *Health-E You/Salud iTu* app as well as the study methods, procedures, analysis and dissemination plans for a cluster randomised clinical trial. The objective of this clinical trial is to evaluate the effectiveness of *Health-E You/Salud iTu,* a patient-centred, mobile health computer-based clinic intervention on its ability to reduce disparities in unintended pregnancies among Latina adolescents. The study aims to assess improvements in Latina adolescents' contraceptive knowledge, attitudes towards contraceptive use and access to and utilisation of effective contraceptives using a cluster randomised design.

Health-E You/Salud iTu is a novel, interactive, patient-centred, mobile clinical contraceptive health application (app), designed to be used as a clinician extender and in conjunction with a healthcare visit. It is grounded in Social Cognitive Theory (SCT),[48 49] a theoretical framework of behaviour change, and incorporates interactive technology to provide customised educational experience and support an individual's decision-making process in selecting an effective method of contraception that is responsive to their unique needs, preferences and experiences. Contraceptive method efficacy is based on the World Health Organization's (WHO) *medical eligibility criteria for contraceptive use*, which is an evidence-based and consensus-based guideline.[50] While contraceptive efficacy is a significant factor in selecting a method, it is important to note that the app is built upon a patinet-centered approach in supporting adolescents in selecting a method that is both efficacious and in-line with their preference, attitudes and needs. Because LARCs (implants and IUDs) are the most efficacious methods of contraception, have the fewest side effects, low discontinuation rates and current utilisation is extremely low, we expect the app to increase interest in and utilisation of LARCs. At the same time, we also recognise that LARCs may not be the best fit for every teen and emphasise a patient-centred approach to supporting adolescents' contraceptive decision-making process. The app aims to enhance youths' self-efficacy to select, discuss and use effective contraception that is the best fit for their personal needs. SCT posits that personal efficacy is a strong predictor of behaviour.[48 49] *Health-E You* provides a convenient, private, and self-paced learning environment that encourages learning through games and user-driven requests for information that features YouTube style videos of Latina youth and healthcare providers to support the user's decision-making process and further enhance motivation and self-efficacy to use effective contraception. Youth are supported to think about their personal timeline and goals for whether or when they would like to have a baby. Contraception selection is supported by algorithms that take into account the individual's attitudes, preferences and experiences that could affect an individual's contraceptive choice such as: need for privacy, effects on menstrual cycle and other side effects, adherence ability, past experience and method satisfaction among others (see the 'Computer application procedures' section for additional details about the algorithm).

In all phases of this project, from development to evaluation, the study team incorporated a patient-centred approach by engaging with and obtaining guidance from youth and community advisory boards as well as individuals representing the target audience of youth, clinicians and clinic staff.[51] Thus, *Health-E You* was developed in close partnership with Latina youth and

healthcare providers to ensure its salience to this specific population. The app prototype was then pilot tested with 120 patients in three SBHCs in California during a 5-month period.[52] The app was designed to be integrated into the healthcare delivery system of SBHCs and to serve as a 'clinician extender' by providing sexual health information and customised messaging in order to enhance client and clinician readiness and thus, improve the efficiency and effectiveness of the health visit.[53] These SBHCs are located on high school campuses and provide a range of confidential health services including contraceptive counselling and provision of contraceptive services. Findings from the pilot study indicated that the app is feasible to implement, acceptable to both Latina adolescents and clinic staff and provides a promising approach for improving sexual health knowledge and contraceptive use when used in conjunction with a healthcare visit.[52] Pilot tests also gathered additional feedback that was used to inform subsequent improvements in the app to further enhance the user experience. For example, our community health partners and Latina youth filmed short video clips about contraceptive methods with age-appropriate youth, the app was updated to include photos that are more representative of the targeted demographic and the design team incorporated youth-friendly graphics and colours to improve the look and feel of the app.

Objectives

The objective of the current clinical trial is to evaluate the effectiveness of *Health-E You* on its ability to reduce disparities in contraceptive knowledge and improve access to, and utilisation of, effective contraceptives among Latina adolescents. The specific aims are as follows:

Aim 1: Examine the extent to which the *Health-E You* contraceptive app supports adolescents in making decisions about an effective method of contraception.

Specifically, we will examine its effectiveness to:

A. Increase adolescents' knowledge of sexual health and contraceptive options;
B. Increase the proportion of adolescents who report being prepared to select an effective form of contraception;
C. Increase adolescents' self-efficacy to select and use an effective contraceptive method.

Aim 2: Evaluate the efficacy of the *Health-E You* contraceptive app on its ability to improve the effectiveness and efficiency of the clinical encounter.

Specifically, we will evaluate its effectiveness to:

A. Improve adolescents' and clinicians' perception of the quality and efficiency of the visit;
B. Increase the proportion of visits where adolescents and clinicians discussed contraception.

Aim 3: Evaluate the effectiveness of the *Health-E You* contraceptive app to reduce the incidence of unprotected sexual intercourse (and associated unintended pregnancies) among Latina adolescent girls.

Specifically, we will evaluate its effectiveness to:

A. Increase the proportion of sexually active adolescents who receive an effective contraceptive at their clinic visit;
B. Increase the proportion of sexually active adolescents who adhere to an effective contraceptive method over time—at 3 and 6 months after their clinic visit.

Aim 4: Disseminate the *Health-E You* intervention: If proven effective, we will work with our collaborative partners and stakeholders to disseminate findings and the app to control clinics and through community-based, state and national associations.

METHODS AND ANALYSIS

Study design

A total of 18 SBHCs in the Los Angeles Unified School District (LAUSD) were randomly assigned to either the intervention (*Health-E You/Salud iTu* app) or control group (standard of care, no app). This design allows our analyses to isolate the effect of the app and determine whether the app increases adolescent sexual health and contraceptive knowledge, self-efficacy in selecting an effective method, satisfaction with the visit and contraceptive use and adherence over time.

Clinics were randomised to either control or intervention group using computer-generated random number assignment. Following randomisation, our local partners from the Los Angeles Trust for Children's Health (LA Trust) notified the SBHCs of their assignment and provided the necessary training around the study aims, use of the iPad and integration into the unique workflow at each SBHC (determined in partnership with our community outreach staff and clinic staff, providers and managers). The LA Trust also provided technical support to ensure that all sites had a reliable internet connection to be able to use the app as intended and to securely transmit data gathered from the app to the University of California, San Francisco (UCSF). These initial activities took place from June to October 2016. To monitor study implementation, the LA Trust staff conducts monthly site visits with each SBHC. In addition, the principal investigator (PI), LA Trust staff and project director conduct two monthly quality improvement calls with the intervention and control SBHC champions from each of the SBHCs. The purpose of the calls are to review iPad utilisation, study enrolment and retention numbers and discuss implementation challenges and successes.

LAUSD is the second largest school district in the USA and is an ideal setting to conduct this cluster randomised control trial. It has a large number of SBHCs, serve a large proportion of Latina adolescents and have high rates of unintended pregnancies and sexually transmitted infections (STIs) (reflecting unprotected sex).[54 55] In addition, these sites expressed a willingness and commitment to participating in a rigorous, randomised control trial.

Procedures

Recruitment procedures

Participant recruitment began in August 2016 and will continue through March 2018. All adolescent girls between the ages of 14 and 18 years who come to any of the participating SBHCs, regardless of reason for visit, are invited to use an iPad. They are given disposable earbuds to maintain privacy while using the iPad. The computer identifies teens who are eligible to participate in the study. The baseline sample goal for this study is 1400 (700 per treatment group) sexually active, Latina adolescents.

Inclusion criteria

Adolescents are eligible to participate in the study if they are:

- Women
- Aged 14–18 years
- Hispanic/Latina
- Served in an SBHC
- English-speaking or Spanish-speaking
- Sexually active (have had sexual intercourse)
- Not currently pregnant or not sure that they are pregnant (adolescents with a previous pregnancy and who are not currently pregnant are eligible)
- Not currently using an LARC method of contraception.

Computer application procedures

The app first asks the user to select their language preference (English or Spanish). Next, it provides a brief explanation of the study, informs them of their confidentiality rights and protections and obtains voluntary consent (see online supplementary appendix 1). It then collects basic demographic and health history information that is part of the routine adolescent healthcare visit. Prior to the face-to-face encounter with the clinician, participants at the control clinics complete a computerised questionnaire to assess their baseline knowledge of contraception and their self-efficacy to obtain sexual healthcare and use/nonuse of contraception. Participants in the intervention clinics continue to the *Health-E You* contraceptive intervention app before they see the clinician (which gathers the same baseline information as the controls, plus provides youth with the opportunity to go through the app for contraceptive information and decision-making support). After using the iPad, participants proceed directly to their visit with the clinician.

The contraceptive recommendation algorithm developed for the *Health-E You* app is based on adolescents' preferences and attitudes that could affect their choice and use of contraception as well as their concerns for potential side effect (see box 1). Users are asked to respond to a series of questions and rate the extent to which they agree or disagree with each statement using a 4-point Likert agreement scale where 4=strongly agree, 3=agree a little, 2=disagree a little and 1=strongly disagree. In addition, the algorithm incorporates the adolescent's responses to their contraceptive use history, satisfaction with their prior and current contraceptive method(s) and their ability to adherence to the contraceptive method(s) used. The final component of the algorithm includes potential medical contraindications. Based on all of the youth's responses, the *Health-E You* app determines which method(s) are considered to be a 'top choice(s)' for the individual.

Box 1 Assessment of contraceptive preferences and attitudes

'How much do you agree or disagree with the following statements?'

- When I have sex, it is important for me to use the most effective method for preventing pregnancy.
- It is important for me to use a method that is safe and has the fewest side effects.
- I do not want others (such as my partner or family members) to be able to know that I am using birth control.
- I do not want a birth control method that increases my risk of gaining weight.
- I am concerned about birth control methods that use hormones.
- I would like less pain or cramping when I have my period.
- I would like to have lighter periods (less bleeding) less often or possibly no periods at all.

The 'top choice(s)' is presented using the WHO's efficacy chart with the app-determined 'top choice' being highlighted (see figure 1). In this way, the youth can see the efficacy for each contraceptive method; however, as indicated previously, the youth's desire for contraceptive efficacy is just one of many considerations used in the algorithm for recommending a particular method(s). For example, if a user indicates that they are currently using birth control pills, are satisfied with this method and reports that they have not missed any pills (is adhering to the method), then the *Health-E You* app will suggest that the user continue with that method. However, if that same user reports that she was not satisfied with birth control pills and/or has missed pills in the last 3 months, the app would use that information in combination with their other responses to identify a different contraceptive method that may be a better fit for that youth. The app also provides youth the opportunity to obtain additional, self-directed, information about any contraceptive method regardless of the app's recommendation by touching any method on the list. Throughout the app, users are encouraged to use barrier contraception (condoms) to provide dual protection to reduce the risk of STIs and HIV and are informed about emergency contraception.

When app users are finished reviewing the various contraceptive methods, they are then asked to select the method(s) they are most interested in using. If they are not interested in any method, there is an option to select 'none'. The app then generates a 'print preview' screen that includes the users confidential ID, the contraceptive methods that the user is interested in, the contraceptive method(s) that the app recommended and any potential contraindications that the user reported so that the clinician is alerted to have

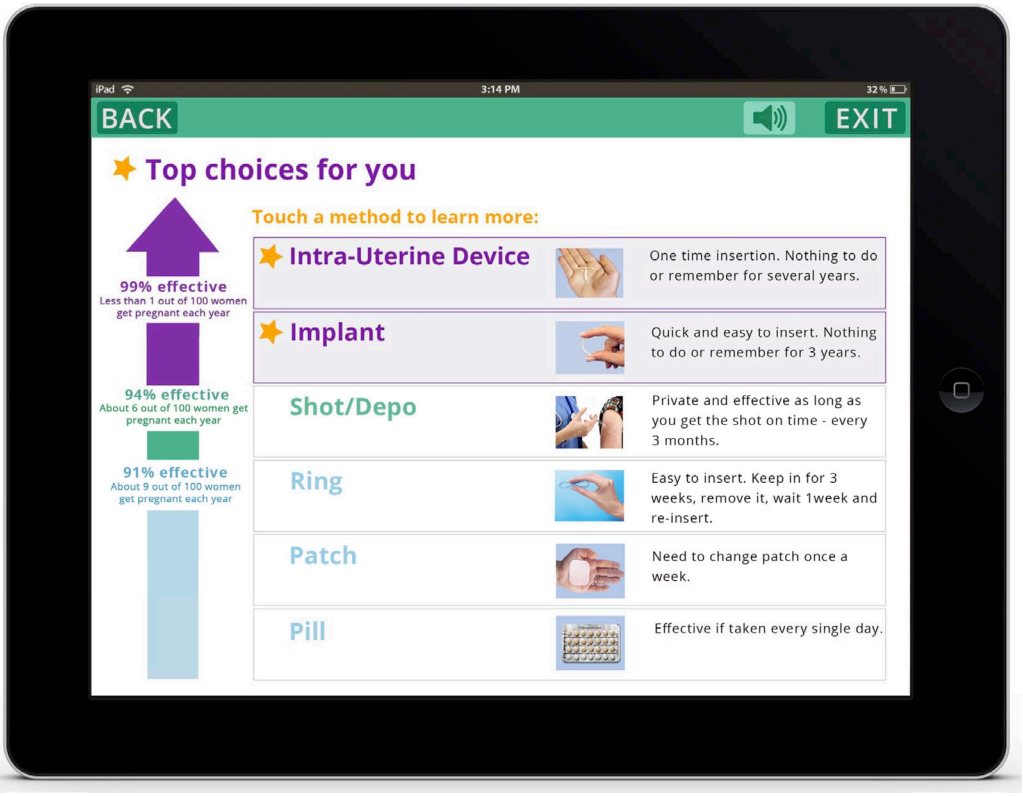

Figure 1 Health-E You application contraceptive recommendations sample screenshot.

a further discussion about the youth's medical history. The user has an opportunity to review this information before it is sent to the clinic's wireless printer located in a private area of the clinic (behind the front desk). The clinician receives this information prior to the face-to face portion of the visit. The app concludes with postapp knowledge assessment questions, which are framed as 'let's review what you've learned'. They are given a reminder that they will receive a follow-up survey within 48 hours after the visit and two subsequent surveys at 3 and 6 months. The patient then proceeds to the face-to-face encounter with the clinician. In this way, the app serves as a clinician extender by providing adolescents with individually tailored information prior to the visit along with evidence-based sexual health and contraceptive information which enhances the quantity and quality of health education prior to the visit; primes both the youth and provider for the face-to-face encounter to better prepare them about what to expect and discuss with regards to contraception; and improves the clinician's ability to provide patient-centred care and better meet the individual needs of their patient.

Data collection procedures

Baseline data

As previously mentioned, baseline data are collected directly from the app or baseline questionnaire on the iPad, in the clinic, prior to the face-to-face encounter.

Follow-up surveys (postvisit; 3 and 6 months)

To evaluate the effectiveness of the app, differences between the intervention and control group prior to the intervention (at baseline), within 48 hours of the visit and at 3-month and 6-month follow-up periods will be compared. These follow-up time points were selected for a number of reasons. Oral contraceptives are the most commonly used non-barrier contraceptive, and they have high rates of discontinuation within the initial 3-month period.[56] In addition, unprotected sex among adolescents, including use of the withdrawal method, is high.[57] Furthermore, while there is little research on discontinuation rates for LARCs, a recent study (among women 25 years and younger) found that discontinuation rates are generally low and do not vary much between 6 and 12 months, thus a 6-month follow-up was deemed adequate.[58]

To receive follow-up surveys, participants are asked to select their preference on how they would like to receive the survey. They can choose to receive a link sent to their email account and/or a text message to their cell phone. Approximately 5 days before the 3-month or 6-month survey is due, participants receive a reminder (via the youth's preferred reminder method: text and/or email). To improve participant retention during the follow-up period, as part of the consent process, the questionnaire gathers the names and contact information for two close friends and/or family members that may be contacted in the event there are changes to the participant's cell phone,

email and/or school. This approach has been successfully used in prior longitudinal studies of high-risk adolescents, including those in pregnancy prevention interventions.[59–62] This study does not collect patient information from other data sources such as school or clinical records. All information collected by study researchers is gathered directly from participants. Data are encrypted and transmitted securely to the UCSF secure database and deidentified prior to analyses. While participant self-reporting is a potential limitation of the study, it protects participants' confidentiality and increases their comfort in disclosing sensitive health information.

Incentive structure

Follow-up procedures are designed to maximise participant retention over time and minimise bias due to attrition. Study participants can receive up to US$70 for completing all surveys. The following is the incentive structure:

- US$10 for completing the baseline information and immediate follow-up survey,
- US$20 for completing the 3-month follow-up assessment,
- US$20 for completing the 6-month follow-up,
- US$20 bonus for completing all surveys.

Analyses

Sample size estimates and power analyses

In designing this study, we adhered to the criteria of the Patient-Centred Outcomes Research Institute (PCORI) methodology principals that pertain to the development of research questions and study designs.[63] According to our preliminary studies, approximately 80% of the eligible adolescents will agree to participate. A target sample of 1400 sexually active Latina girls aged 14–18 years will be enrolled in the study (700 per treatment group). Although we have instituted a graduated incentive structure in an attempt to minimise attrition, clinics do not have the staffing capacity to contact participants and call them from class in order to complete follow-up surveys which could impact retention rates. Sample size estimates and power analyses are based on a 40% attrition rate by the 3-month follow-up (840 total, 420 per treatment group) and another 10% by the 6-month follow-up (700 total, 350 per treatment group).

As shown in table 1, assuming power=0.80 and alpha=0.05, the minimum detectable difference in the primary behavioural outcome at each time point between the intervention and the control condition is 11%–13%, 16%–18% or 21%–22% points depending on whether the intraclass correlation (ICC) assessing the clustering effect of clinics is low, moderate or high. Estimated prevalence of outcomes in the control condition comes from preliminary data collection, and the ICC range is suggested by data from Reading *et al*.[64] The calculated differences in proportions translate into an effect size (Cohen's h) falling between a small (h=0.20) and medium (h=0.50) effect size for all three levels of ICC. Specifically regarding evaluation of the intervention condition, the minimum achievable precision for point estimates of proportions is a CI width of 12% points for visit data, 10% points for 3-month data and 11% points for 6-month data.[65]

Assessment of the implementation of the intervention

The research team will examine qualitative data gathered from regulary (monthly) site monitoring visits to examine how the app is being implemented, identify factors that may bias or contaminate an arm, and to gather information about implementation barriers and facilitators. We assess participants' satisfaction with and reaction to the app and the subsequent clinical visit during the postvisit survey which gathers responses to a short series of user experience and satisfaction statements in the form of Likert-type items employing 5-point agreement response scales. We will use descriptive statistics (eg, mean, mode, SD, minimum and maximum) to analyse the ratings of the app. We will report a point estimate and 95% CI for the per cent of respondents who agree with each satisfaction statement. We will also examine if per cent agreement varies according to key demographic variables (such as, age, gender, race/ethnicity and language spoken) using a cross-tabulation procedure and χ^2 statistics.

Assessment of perceived visit quality and efficiency

To assess the extent to which the *Health-E You* app improves Latina adolescents' and clinicians' perception of the quality and efficiency of the visit, adolescent participants are asked about their visit experiences at the immediate follow-up survey. Staff and clinicians' from all of the participating SBHCs will complete a retrospective

Table 1 Power analysis

Outcome	Baseline sample, % (n)	Control proportion, %	Minimum detectable change if ICC=0.01 change, % (h)	ICC=0.05 change, % (h)	ICC=0.09 change, % (h)
Receive effective method at visit*	40 (560)	42	+13 (0.269)	+18 (0.370)	+22 (0.446)
Use effective method at 3 months	60 (840)	27	+11 (0.232)	+16 (0.346)	+21 (0.428)
Use effective method at 6 months	50 (700)	27	+12 (0.246)	+17 (0.356)	+21 (0.436)

*Method efficacy is based on WHO criteria.
ICC, intraclass correlation coefficient.

Box 2 Study measures

Primary outcome measures
- Current contraceptive use
- Contraceptive use during past 3 months
- Condom use

Secondary outcome measures
- Compliance/adherence to method(s) used
- Satisfaction with contraceptive method(s) used
- Knowledge of contraception (assessed via seven items)
- Attitudes towards contraception and potential side effects (see box 1)
- Condom use at last sex
- Contraceptive receipt at visit
- Self-efficacy in choosing and using contraception (four items)
- Client and provider satisfaction with the app
- Client and provider satisfaction with the clinical encounter

Demographics
- Age
- Clinic site
- Language spoken at home
- Sexual activity (current and in past 3 months)
- Desire to become pregnant right now
- Contraindications for contraception
- Number of partners

pre–post survey regarding their experiences with the app in clinic, impact on clinic workflows and on the quality and efficiency of the visit (especially regarding the extent to which it enhances conversations around sexual health and provides patient-centred contraception for their Latina adolescent patients).

Assessment of *Health-E You/Salud iTu's* effectiveness

The effectiveness of the app will be assessed by analysing differences between the control and intervention group's knowledge of and attitudes towards contraception, receipt of effective contraception at the clinic visit and self-reported use of contraception at 3-month and 6-month follow-ups (see box 2 for study measures). To assess for non-comparability between intervention and controls despite random assignment, the groups will be compared on all non-outcome measures. If substantial differences are observed between study group participants at baseline, we will perform a statistical balancing approach by computing a weight for each participant equivalent to the inverse probability of having been assigned to the intervention condition, as estimated by regressing the condition on those same non-outcome measures.

For outcomes that are assessed at more than one time point (ie, baseline, postvisit and 3-month and 6-month follow-ups), we will assess the effect of the intervention using generalised mixed-effects models estimated by maximum likelihood. These models include the repeated outcome measure as the response variable, as well as terms for the intercept, an indicator of treatment group (intervention vs control), a time effect, the time-by-group interaction and demographic covariates. We will fit models with random intercepts and time effects to accommodate the repeated measures gathered from each subject and to allow subject-specific changes in the responses over time. We will fit linear mixed-effects models (normal distribution and identity link function) to continuous responses such as measured knowledge and binary mixed-effects models (binomial distribution and logit link function) to dichotomous responses such as use of effective contraception. If knowledge scores are generally high, we may rescore the scale as number of errors and employ a Poisson distribution and log link function to accommodate the positively skewed measure. Analysis of other count-based outcomes (eg, number of vaginal intercourse partners and number of times had vaginal intercourse) will use the same approach. Our analyses will focus on the time-by-group interaction term that assesses differences in changes in response over time between subjects in the intervention and control groups. We will also include random effects for clinic in the mixed-effects models to allow for baseline differences in responses.

For outcomes assessed at a single time point, analyses will compare data between the intervention and control groups for the follow-up surveys, using linear regression for continuous outcomes, Poisson or negative binomial regression for counts and logistic regression for dichotomous outcomes. Robust variance estimation will be used to adjust for clustering by clinic. Models will contain an indicator of treatment group (intervention vs control) plus demographic covariates. All intervention by covariate two-way interactions will be tested for statistical significance. Non-significant interactions and main effects for covariates will be deleted to obtain the most parsimonious final models.

Heterogeneity of treatment effects across SBHCs

A concern in any cluster randomised control trial is whether or not the treatment effect is robust across sites. However, small per site sample sizes preclude direct comparisons between sites because of a lack of statistical power. Instead, sensitivity and heterogeneity in the treatment effect due to recruitment/treatment site (SBHC) will be assessed using a jackknife technique in which we compute the intervention effect while leaving out one of the intervention sites. The variability of the results of these analyses will be compared with the overall treatment effect to examine how sensitive the results are to recruitment/treatment site.

Missing data

Our approach to handling missing data meets the PCORI methodology standards. Information on potential sources of bias such as non-response and patient dropout will be collected throughout the study. Since we are using relatively brief self-administered instruments, the amount of missing data due to item non-response is likely to be minimal. However, the anticipated substantial dropout rate will necessitate employing multiple imputation of missing data in order to reduce bias caused by attrition. The imputation model will be supplemented with

auxiliary variables (eg, demographic and health characteristics) identified in preliminary analyses to be related to attrition. Multiple imputation, which allows analytic models to be fit to all available data while invoking the mild assumption that the data are missing at random, has proven efficacious in simulation studies with as much as 50% of data missing, even when sample sizes are small.[65]

CONCLUSION

Health-E You/Salud iTu is a web-based mobile health application that provides interactive, individually tailored sexual health information and patient-centred contraceptive decision support and is designed to serve as a clinician-extender to improve the quality and delivery of patient-centered contraceptive care. The aim of this study is to improve contraceptive use and reduce disparities in pregnancy rates among Latina adolescents. The pilot study of *Health-E You* found that it was acceptable to Latina adolescents, clinicians and clinic staff, feasible to implement in SBHCs and improved knowledge, attitudes and intentions to use effective methods of contraception.[52] To assess the effectiveness of the app on improving contraceptive use, the current study is using a cluster randomised trial of 18 SBHCs with an initial sample of 1400 sexually active Latina adolescents between 14 and 18 years of age. Analyses will examine differences between the control and intervention group's knowledge of and attitudes towards contraceptive use, receipt of contraception at the clinic visit and self-reported use of contraception at 3-month and 6-month follow-ups.

This study has many strengths and limitations. First, this study is designed to reduce disparities in contraceptive knowledge and use among sexually active Latina adolescents using a rigorous research design. Second, Latina adolescents and healthcare providers/staff have been actively engaged in and informed all phases of the study design and implementation efforts. Third, it is one of few studies that integrates mobile health technology in "real-world" clinical settings. The app serves as a clinician extender by providing individually tailored sexual health information and patient-centred contraceptive decision support for Latina adolescents and to improve the quality of the face-to-face encounter between the adolescent and healthcare provider. There are a few noteworthy limitations. This study is limited to women who are sexually active and Latina between the ages of 14 and 18 years. Older women at risk of unintended pregnancy, men and other racial/ethnic groups are outside of the scope of the current study. Furthermore, despite efforts to retain participants over a 6-month follow-up period, attrition is a significant challenge. An additional limitation is that all data are self-reported. Despite these limitations, this study addresses a significant gap in the field by addressing disparities of contraceptive knowledge and use among Latina adolescents using novel, interactive mobile health application.

Ethics and dissemination

This study was approved by the Institutional Review Board (IRB) for Protection of Human Subjects of the UCSF (IRB approval no 10-02730).

The app will be made available to all LAUSD SBHCs that serve adolescents as part of the dissemination efforts at the final phase of this study. We will also disseminate it to SBHCs across the nation and to other clinical settings that serve Latino adolescents. The app will be made available free of charge. We will disseminate research findings indicating clinical and policy implications through traditional dissemination activities (eg, adolescent health/quality improvement conferences and peer-reviewed publications). We will also work with patients and organisations to report results in a manner understandable to and appropriate for each target audience. Beyond traditional dissemination activities, we will use our existing professional networks to disseminate the intervention and facilitate training through professional organisations and will make training resources more widely available through online portals to major health organisations, again with specific attention so that the information is presented in a way that is understandable to each target audience.

This study is registered at ClinicalTrials.gov as required by US law. As required, a summary of study results will also be submitted to ClinicalTrials.gov. ClinicalTrials.gov is a registry and results database of publicly and privately supported research studies. Any important protocol modifications (eg, changes to eligibility criteria, outcomes and analyses) will be reported for approval to the UCSF IRB and to ClinicalTrials.gov.

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