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Native IYG: Improving Psychosocial Protective Factors for HIV/STI and Teen Pregnancy Prevention among Youth in American Indian/Alaska Native Communities

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INTRODUCTION

The federal government recognizes 567 distinct American Indian/Alaska Native (AI/AN) tribes, which represent 2% of the US population.[1] The AI/AN population is young, with 30% younger than 18 years of age, compared with 24% of the total US population.[2] AI/AN youth experience sexual health disparities. The AI/AN teen birth rate was 27.3 per 1000 for AI/AN youth (15-19 years) in 2014, exceeding the national rate in the United States of 24.2 per 1000.[3] The prevalence of repeat teen births (21.6%) also exceeds that of Hispanic (20.9%), Black (20.4%), and White (14.8%) females.[4] Further, in 2011 AI/AN females (15-24 years) exhibited the highest rates of *Chlamydia* infection among US women.[5]

Pregnancy and risk for sexually transmitted infection (STI) are associated with early sexual initiation.[6] AI/AN high school students are more likely than White students to report sexual debut before age 13 (9.6% vs 3.3%, $P = .05$)[7-10] and have a rate of condom use lower than the US national rate.[11,12] This is important given that across racial/ethnic groups, early initiation of sex (before age 14) is associated with greater frequency of sex, multiple lifetime sexual partners, alcohol or drug use before sex, and a lower rate of condom use.[6]

Nonetheless, a complex array of protective biological, psychological, social, and environmental factors have been described that are associated with delayed sexual debut among AI/AN youth.[12,13] These factors include being female, achieving a higher level of academic performance, valuing school achievement, having greater sexual health knowledge, having less intent to engage in oral or vaginal sex in the next year, and having greater self-efficacy to abstain from and to refuse sex.[8,9,10,13-15] Traditional cultural values, Native identity, and a sense of belonging to a Native community delay early sexual debut when youth believe their risky sexual behaviors conflict with their traditional values.[10] Strong parental relationships that feature monitoring and parent-child communication about sexual health topics are also protective.[8]

Conversely, environmental risk factors also have been associated with early sexual debut in AI/AN youth. These include substance abuse,[9,15,16] experiences of sexual violence,[7,9,17] household structure, financial hardship, and lower parental levels of education.[9,13] A traditional AI/AN social environment featuring strong family support may provide a welcoming and caring environment for newborns. Such a social context may enable AI/AN teen parents to experience little interruption in their

lives but may also diffuse perceptions of negative effects or consequences of teen pregnancy.[10] The value placed on the child and the support of the family can make childbirth appear desirable to youth while making condom use more challenging, highlighting a “condom conundrum” in which condom use may be in direct conflict with family-building plans.[10] More broadly, contraceptives may be associated with population loss or be counter to tribal ideals of life and birth.[10] Environmental factors including geographic isolation and limited access to health services and sexual and reproductive health education also contribute to the high prevalence of teen pregnancy and STIs that exist among AI/AN youth.[12]

Our understanding of critical antecedent factors for early sexual debut in AI/AN youth has not translated into many sexual health programs. There are few evidence-based HIV infection, STI, and pregnancy prevention programs for early-adolescent AI/AN youth younger than 14 years of age. A need exists for programs that affect modifiable protective factors related to early sexual experience for this population. A utilitarian response may be to adapt existing evidence-based sexual health programs for use in AI/AN communities.[18] Programs adapted for AI/AN youth need to be culturally sensitive and relevant to the youth and tribal community stakeholders to optimize acceptance without sacrificing program fidelity and core educational components.[19]

Ideally, sexual health programs should enable tribal communities to overcome the challenges to achieving program fidelity, reach, and effectiveness.[20] Given this, the Internet has been proposed to deliver sexual health education that is on a familiar channel, accessible, and culturally appropriate.[20] AI/AN youth use technology to access health information, and their general technology use rates exceed national averages.[21,22] To date, the benefits of telemedicine, distance programs, and digital storytelling have been demonstrated in health contexts among AI/AN populations,[23] and the feasibility of Internet-based education programs to reach urban and rural AI/AN communities has been established for online programs on health topics including nutrition, hearing, biology, smoking cessation, and sexual health.[24]

The purpose of this study was to evaluate the effect of *Native It’s Your Game (Native IYG)*, an online culturally sensitive 13-lesson HIV, STI, pregnancy prevention curriculum adapted for youth in tribal middle schools.[25,26] The study hypothesis was that youth (12-14 years) who complete *Native IYG* would demonstrate significantly improved short-term

psychosocial determinants of sexual initiation (knowledge, self-efficacy, attitudes, beliefs, friend perceptions, parent-child communication, and intentions) compared with youth not completing *Native IYG*. Sexual behavior was not assessed because of the focus on short-term (3-month) follow-up.

METHODS

Study Design and Participants

This study represents a collaboration between the Alaska Native Tribal Health Consortium (ANTHC), the Inter Tribal Council of Arizona, Inc. (ITCA), the Northwest Portland Area Indian Health Board (NPAIHB), and the University of Texas Health Science Center at Houston (UTHealth) School of Public Health. The study was approved by the Alaska Area Institutional Review Board (IRB), the Portland Area IRB, the UTHealth IRB, and 16 tribal organizations (ie, tribal councils, tribal health boards, villages, and community agencies) in Alaska, Arizona, and the Pacific Northwest. *Native IYG* was evaluated in a pre-post randomized controlled study incorporating 25 tribal sites in Alaska, Arizona, and the Pacific Northwest with planned online survey measurement at baseline and 3-month follow-up (described below). In each region, recruitment, baseline data collection, implementation of *Native IYG*, and post-intervention follow-up data collection were coordinated by one of three organizations (**Figure 1**) that collectively serve 295 regional AI/AN tribes. Tribal names are not reported so that research collaborative agreements to protect the confidentiality of participating tribes and communities are observed.[11]

Convenience sampling was used to recruit AI/AN communities that were interested in participating in an early adolescent sexual health trial. Regional staff recruited study sites by sending flyers to local and regional schools, tribal community centers, and after school and summer camp programs, and by advertising on organizational Web sites, social media outlets, and/or newsletters. Alaska staff also distributed interest letters and recruitment packets to families on school mailing lists, at local community events, and via other existing tribal programs.

There were 25 sites that agreed to participate. Sites comprised urban (n=13) and rural settings (n=12) and included tribal schools, tribal community health centers, tribal Boys and Girls Clubs, and after school and summer youth programs. Sites were randomized to the treatment (*Native IYG*) intervention (n=14) or to the comparison intervention (n=11)

which included a suite of online programs (described below). Randomization was conducted for sites in each region (**Figure 1**).

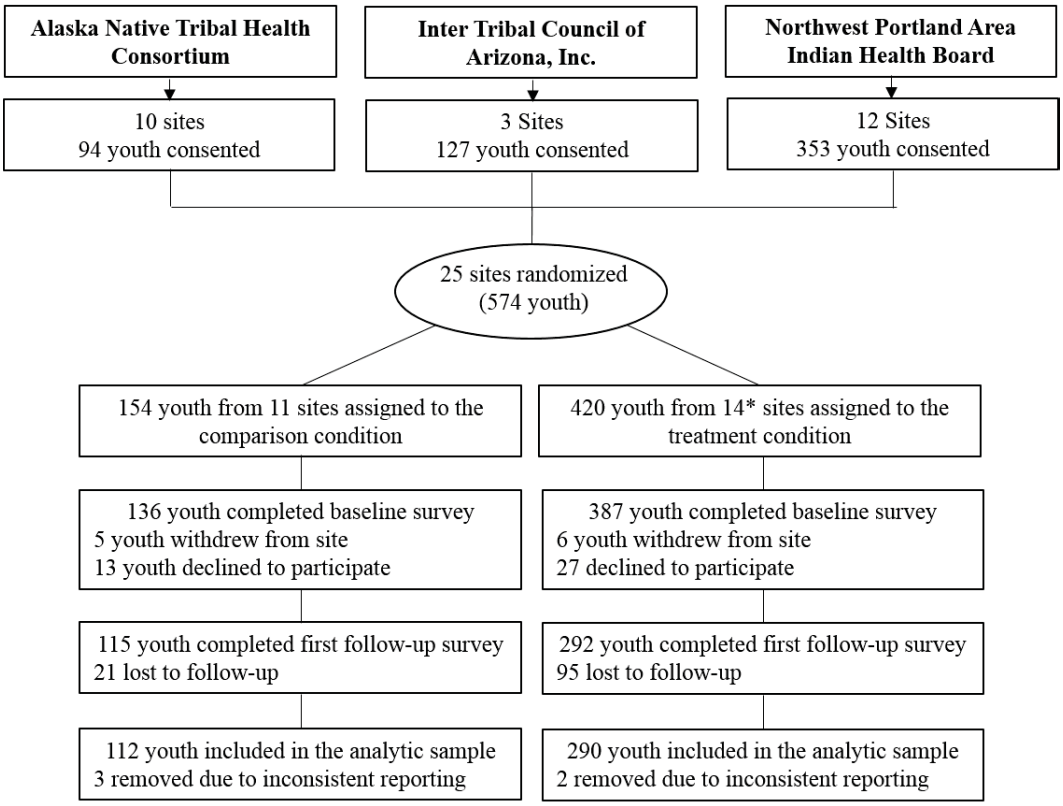

Figure 1. Diagram of participant flow.

* One site assigned to the treatment group collected no first follow-up surveys; thus, the treatment group in the final analytic sample comprises 290 youth from 13 sites.

Participant inclusion criteria were that youth be 12 to 14 years of age, be fluent in English, and have no gross mental or developmental disorders that might impede independent progression through *Native IYG* or comparison programs. This was determined by site coordinators according to the ability of youth to complete online surveys. No youth were excluded for this criterion. Recruitment actively targeted AI/AN youth. However, non-AI/AN youth were not excluded from the study. Youth who returned a parental permission form and youth assent form received a $5 incentive. In accordance with IRB and tribal guidelines, ANTHC, NPAIHB, and ITCA staff also recruited youth by hosting parent meetings. Active parental consent and youth assent were obtained from 574 eligible youth (**Figure 1**). Of these, 523 (91%) completed baseline surveys between December 2012 and October 2014. Youth who did not complete the baseline survey were either absent on the survey dates or declined to participate. A follow-up survey was completed by 407 treatment and comparison youth (78% retention). Youth received a $5 incentive for completing the baseline survey and another for completing the follow-up survey. One site was unable to complete the first follow-up survey and was dropped from the study. The final analytic sample included participants from those sites providing baseline and follow-up data – 13 treatment sites and 11 comparison sites (24 sites total) (**Figure 1**). Five youth were excluded from the analysis because of inconsistent reporting of determinants across time, leaving a final analytic sample of 402.

Interventions

The treatment intervention (*Native IYG*) and comparison intervention (a suite of online health programs not focused on sexual health) were accessed on desktop and laptop computers in school computer labs, or in community settings. Before intervention implementation, local technical support staff at each participating tribal school, tribal health center, and tribal Boys and Girls Clubs completed a computer-based education inventory survey[27] and connectivity and bandwidth testing.[28] Overall, program connectivity was satisfactory despite variable bandwidth ranging from 0.24-93.5 Mbps (mean=25.6±31.1).

Treatment intervention. Native IYG is a 13-lesson, multimedia HIV, STI, and pregnancy prevention curriculum for AI/AN youth (12-14 years). The curriculum was adapted from a curriculum for urban middle schools entitled *It's Your Game-Tech (IYG-Tech)*,[29] an Internet-based version of an evidence-based curriculum entitled *It's Your Game … Keep It Real!*[30,31] The adaptation phases included a pre-adaptation needs assessment and

usability test of the *IYG-Tech* curriculum; programming of the resultant adaptation, *Native IYG*; and usability testing of *Native IYG*.

Surface and deep cultural adaptations, described elsewhere, were made to ensure that *Native-IYG* was culturally acceptable.[29,32,33] Surface adaptations included modifications of the text, graphics, audio, or animation to deliver a given message. This included changing the program name to *Native IYG* and the program logo to symbolically reflect the tribal collaborative, changing the images and names of characters in animations and interactive activities to reflect Native imagery and surnames, and adding video and music produced by Native artists. Deep cultural program adaptation included incorporating a video of Native elders and a tribal health educator to provide a tribal "voice" reflecting cultural, social, historical, environmental, and psychological influences. Blessings and core cultural motifs were included. The Native Wellness Model integrates physical, emotional, social, mental, and spiritual dimensions of health, and it was referenced by the elders who introduced the curriculum and sensitive lessons. Videos also featured AI/AN tribal youth providing peer perspectives and insights. These were developed regionally and represented heterogeneous perspectives on content, including maintaining healthy friendships, setting personal rules, and protecting personal rules. The *Native IYG* program moved to reflect a more holistic concept of health and well-being, embracing the concept of the AI/AN "relational worldview" defining human behavior as an integrated, balanced, cyclical interaction. Health domains of substance abuse and dating violence were fortified in the adapted curriculum.

Native IYG was assessed for cultural appropriateness before efficacy testing.[25,26] AI/AN middle school youth rated the *Native IYG* lessons favorably in meeting the needs of AI/AN youth (54%-86% agreement across lessons) and in comparison with other learning channels (57%-100%), and they rated the lessons as helpful in making better health choices (73%-100%). Tribal stakeholders provided approval of cultural appropriateness and its suitability for implementation in tribal settings.

Native IYG is housed on a secure server in the UTHealth School of Public Health. The 13-lesson curriculum is designed to be accessible to middle school students during their typical school health education or physical education lessons, or during after school or summer camp programs. Each lesson is approximately 35 minutes long and features interactive activities, quizzes, animations, peer and expert role model videos, and fact

sheets that target determinants of sexual risk taking. Selected lesson activities are tailored on gender, self-reported sexual experience, and intentions. Content is delivered sequentially through a series of domains comprising the following: characteristics of healthy friendships, setting and protecting personal limits, puberty and reproduction, characteristics of healthy dating relationships, consequences of sex (HIV, STI, and pregnancy), refusal skills training, the importance of testing if a person is sexually active, and skills training in condom and contraceptive use. Pilot testing indicated the acceptability, usability, and motivational appeal of *Native IYG* among AI/AN youth.[25]

Comparison intervention. The control condition comprised five health-related computer-based programs that addressed tobacco smoking (ASPIRE),[34] hearing (Dangerous Decibels),[35] alcohol (N-Squad) and drugs (Reconstructors),[36-38] and diet and physical activity (The Quest to Lava Mountain).[39] The control programs were delivered in a standard number of sessions (n=13) and duration (approximately 35 minutes) that approximated a learning time on task comparable with that of *Native IYG*.[24]

Site coordinator training. At each study site, at least one contact (teacher, counselor, nurse, college student, or wellness coordinator) was trained to serve as the site coordinator. Training on study protocols was conducted in person by regional research staff and through centrally coordinated webinars to review the manual of procedures, including study objectives, recruitment, data collection protocols, and frequently asked questions from parents and youth. Coordinators completed the Collaborative Institutional Training Initiative (CITI) Program's online certification in human subjects research and a live webinar (tailored for treatment or control) coordinated by UTHealth on intervention content and protocols for logging in youth, documentation, and maintaining confidentiality.

Data collection. Students' self-reported data were collected with an Internet-based Qualtrics® survey. At each study site, trained site coordinators logged participants into the survey on computers located in a quiet location (eg, an empty classroom). The baseline survey included an automated skip pattern preventing sexually inexperienced youth from exposure to sexually explicit items and took about 30 minutes to complete. Youth received a unique study ID number upon entering the study, and no names were associated with the surveys. Measures were drawn from *It's*

Your Game … Keep It Real! surveys and the *Native IYG* survey previously described.[15,30,33]

Demographic and behavioral baseline measures. Demographic measures included gender, age, race/ethnicity, and household structure. Other measures included financial hardship or difficulty (a 3-item scale with a response set of "often" to "never"; eg, "In the past 12 months, how often did your household not have enough money for food/heat/electricity?"); academic performance ("In general, how well do you do in school?" with a response set of *A's* to *F's*); educational intentions ("How much education do you intend to get?" with a response set of "Don't plan to finish high school" to "Graduate with an advanced degree [doctor, lawyer, dentist]"); parental monitoring (a 4-item scale; eg, "How much does this person know about who your friends really are?" with a response set of "They don't know" to "They know a lot" and Cronbach's alpha of 0.88); and cultural identification (a 5-item scale; eg, "Being American Indian or Alaska Native is a major part of my identity" with a response set of "strongly disagree" to "strongly agree" and Cronbach's alpha of 0.79).

Behaviors assessed at baseline included avoidance of risky situations (a 7-item scale with a response set of "6 or more times" to "never" and Cronbach's alpha of 0.83;eg, "In the past 3 months, how often have you been alone with someone you are very attracted to?"); alcohol use ("Have you ever had more than a few sips of beer, wine, sweetened alcohol drinks, or liquor?"), drug use ("Have you ever used the following drugs [list of 23 drugs] not prescribed for you by a doctor, even once?); dating violence victimization (6-itsms; eg, "How often has a boyfriend or girlfriend hit, kicked, or pushed you in a mean way in the past year?" with a response set of "often" to "never"); and perpetration (eg, "How often have you hit, kicked, or pushed a boyfriend or girlfriend in a mean way in the past year?" with a response set of "often" to "never"), and sexual experience (oral, vaginal) (eg, "Have you ever had vaginal sex?").

Short-term outcome measures. Determinants of sexual behavior (ie, psychosocial factors) were hypothesized to be affected by *Native IYG* (**Table 1**). These individual-level factors included the following: (1) knowledge of STIs and condoms; (2) self-efficacy for refusing sex and negotiating and using condoms; (3) attitudes and beliefs about sex, condoms, and pregnancy, including reasons not to have sex; (4) beliefs about friends' attitudes toward abstinence and perceived norms regarding peer sexual behavior; (5) parental communication about sex; (6) intentions

to remain abstinent, to use a condom at next sexual encounter, or to engage in oral or vaginal sex. All scales have been extensively pilot tested.[40-43] Reliability indices were calculated with the analytical sample, limited to those who took the follow-up survey (**Table 1**). All items were coded so that a higher score indicated greater protection. Additional information about each measure (ie, number of items, range of scores, and Cronbach's alpha) is provided in Table 1.

Table 1. Description of Psychosocial (Protective Factor) Measures

Psychosocial Variable[a]	Sample Item (No. Items); Cronbach's Alpha[b]	Response Options[c]	Range/ Categories
Knowledge			
Condom knowledge	Do condoms help a person keep from getting HIV, the virus that causes AIDS? (9); 0.77	*No, yes, not sure*	0-1
HIV/STI knowledge	Some STIs put you at higher risk for getting infected with HIV (4); 0.69.	*True, false, not sure*	0-1
STI signs and symptoms knowledge	Mark whether you think the following are common signs of having an STI.(7); NA	7 options (eg, *throwing up or vomiting, headache, a blister or sore on the penis or vagina, no symptoms)*	0-1
Self-efficacy			
Sexual refusal self-efficacy	Could you stop this person you like if they wanted to have oral sex with you, if you did not want to? (7); 0.90	*I definitely could not* to *I definitely could*	1-4
Condom negotiation self-efficacy	Imagine that you and your partner have been having sex but have not used condoms. You really want to start using condoms. How sure are you that you could tell your partner that you want to start using condoms? (2); 0.80	*Not sure at all* to *definitely sure*	1-3
Condom use self-efficacy	How sure are you that you could use a condom correctly or explain to your partner how to use a condom correctly? (1); NA	*Not sure at all* to *definitely sure*	1-3
Condom availability self-efficacy	If you wanted to get a condom, how sure are you that you could go to the store and get one? (4); 0.80	*Not sure at all* to *definitely sure*	1-3
Attitudes and beliefs			
Conservative beliefs about sex	I believe it's OK for people my age to have sex with a steady boyfriend or girlfriend (4); 0.82	*Strongly agree* to *strongly disagree*	1-4
Reasons not to have sex	Here are some reasons why people your age might choose not to have sex. Choose your own reasons for not having sex (11); 0.79	11 options (eg, *I do not want to get pregnant or get a girl pregnant; I want to wait until I am married; I don't want to disappoint my parents*)	1-11

Condom beliefs	I believe condoms should always be used if a person my age has sex (3); 0.93	*Strongly agree* to *strongly disagree*	1-4
Friend perceptions			
Perceived friends' beliefs about sex	Most of my friends believe people should wait until they are older before they have sex (3); 0.81	*Strongly disagree* to *strongly agree*	1-4
Perception of friends' behavior	How many of your friends have had oral sex? (2); NA	*None to all*	None; at least some; don't know
Parent factors			
Parental-child communication	How many times has your parent ever talked to you about how to about prevent pregnancy or birth? (8); 0.88	*Never* to *most of the time*	1-4
Intentions			
Intention to have oral sex in the next year	Do you intend to have oral sex in the next year? (1); NA	*Yes, definitely* to *no, definitely not*	1-4
Intention to have vaginal sex in the next year	Do you intend have vaginal sex in the next year? (1); NA	*Yes, definitely* to *no, definitely not*	1-4
Intention to remain abstinent until the end of high school	Do you intend to be sexually abstinent (not have sex) from now until the end of high school? (1); NA	*Yes, definitely* to *no, definitely not*	1-4
Intention to use a condom	Do you intend to use a condom if you have sex in the next 3 months? (1); NA	*Yes, definitely* to *no, definitely not*	1-4

NA, not applicable.

[a] Unless otherwise noted, measures come from the *It's Your Game … Keep It Real!* survey (Tortolero et al, 2010[3230]; Markham et al, 2012[3331] and the *Native IYG* survey previously described in Markham et al, 2015[15]).

[b] All items were coded so that a higher score indicated greater protection

[c] Reliability indices were calculated with the analytical sample, limited to those who took the follow-up survey.

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Process measures. All lessons were accessed on desktop or laptop computers located in classrooms or community centers (ie, tribal Boys and Girls Clubs, community camps). Two treatment sites and two comparison sites experienced bandwidth problems during the trial and accessed downloadable versions of the respective treatment or comparison programs. Intervention exposure (number and type of lessons completed) among the treatment and comparison intervention youth was assessed with paper-based attendance logs that were completed by site coordinators for each lesson.

Data analysis. Multilevel regression models were used to test for differences from baseline between treatment interventions for 16 psychosocial variables. Age, gender, AI/AN ethnicity, and time between measures were entered into all models as covariates to adjust for any group differences that may have been present before intervention implementation. Multilevel models were used to adjust the regression coefficients and their standard errors for intraclass correlation present in the data resulting from students being nested within sites. Intraclass correlation ranged from 0.00 to 0.33 across the various determinants. A Wald test was used to test for significance of group differences, with type I error rate set at 0.05.

RESULTS

Sample Baseline Characteristics

Demographics. At baseline, the sample (n=402) was 55.5% female (mean age, 13.0±0.97 years and 86.1% self-reported AI/AN (**Table 2a**). Most reported receiving A/B grades (69%), intended to complete high school (68.8%), and lived in a household with two or more adults (65.5%). For those identifying as AI/AN, there was strong cultural identification (m=7.79±1.86). Close to 41% reported that they had not experienced financial hardship or difficulty in the past year. Most parents had completed high school or an advanced degree (56.39%), with only 7.5% not completing high school. Some youth were unsure of their parents' education (36.2%). More than 50% of the sample reported moderate to high levels of parental monitoring (awareness of their child's activities, location, and participation). Youth in the treatment intervention were significantly younger than those in the comparison condition (m=12.90±0.98 vs 13.30±0.86). Participants in the treatment and comparison interventions did not significantly differ on other baseline demographic variables.

Table 2a. Baseline Demographics of the Analytic Sample (N=402)

	Total		Intervention (n=290)		Comparison (n=112)		
Variable	**N[a]**	**% or Mean (SD)**	**n**	**% or Mean (SD)**	**n**	**% or Mean (SD)**	***P***
Gender (% female)	223	55.5	165	56.9	58	51.8	.3553
Age (y)	399	13.01 (0.97)	288	12.90 (0.98)	111	13.30 (0.86)	.0002
Race							
American Indian/Alaska Native	346	86.1	244	84.1	102	91.1	.0719
Academic performance							
Usually *A*'s and *B*'s	275	69.10	204	70.83	71	64.55	.2247
Educational intentions							
More than high school	275	68.75	209	72.07	66	60.00	.6704
Cultural identification	323	7.79 (1.86)	229	7.844 (1.82)	94	7.68 (1.96)	.4863
Household structure Two or more adults	258	65.48	188	65.96	70	64.22	.7445
Financial hardship or difficulty in the past year No financial hardship	162	40.81	112	39.02	50	45.45	.2433
Parent education High school or more	225	56.39	165	41.35	60	15.04	.1110
Parental monitoring	371	2.72 (0.96)	270	2.72 (0.96)	101	2.73 (0.97)	.9256

SD, standard deviation.
[a] Numbers vary because of missing data. SD, standard deviation.

Risk behaviors. Most youth at baseline were not sexually experienced, with 95.1% reporting never having had sex (oral or vaginal) (**Table 2b**). Rates for oral sex, vaginal sex, and oral and vaginal sex were 4.1%, 3.8%, and 3.1%, respectively. Most youth reported infrequently being (1-2 times) or never being in risky situations that could lead to sex (>70%). Most youth reported never having used alcohol (73.8%) and never having used drugs (70.3%). Fewer than half the youth (43.5%) reported having no boyfriend or girlfriend in the past year. Of those who did have a boyfriend or girlfriend, 20.7% reported being a victim of dating violence and 13.26% reported being a perpetrator of dating violence. Participants in the treatment and comparison interventions did not significantly differ on these behaviors.

Table 2b. Baseline Risky Behaviors of the Analytic Sample (N=402)

	Total		Intervention (n =290)		Comparison (n = 112)		
Variable	**N[a]**	**% or Mean (SD)**	**n**	**% or Mean (SD)**	**n**	**% or Mean (SD)**	***P***
Sexual experience							
Never had oral[b] or vaginal sex[c]	371	95.13	267	94.68	104	96.30	.5072
Ever used alcohol	100	26.25	71	25.00	29	29.90	
Avoidance of risky situations that could lead to sex	372	3.57 (0.57)	272	3.56 (0.59)	100	3.61 (0.55)	.4883
Drug use							
Never used drugs	263	70.32	192	69.57	71	72.45	.5914
Ever used drugs	111	29.68	84	30.43	27	27.55	
Dating violence victimization							
No boyfriend/girlfriend in past year	164	42.49	120	42.55	44	42.31	.2377
Was not a dating violence victim[d]	142	36.79	109	38.65	33	31.73	
Was a dating violence victim[b]	80	20.73	53	18.79	27	25.96	
Dating violence perpetration							
No boyfriend/girlfriend in past year	164	43.50	120	43.64	44	43.14	.4665
Was not a dating violence perpetrator[d]	163	43.24	122	44.36	41	40.20	
Was a dating violence perpetrator[d]	50	13.26	33	12.00	17	16.67	

[a] Numbers vary because of missing data.

[b] Oral sex is defined as putting one's mouth on his or her partner's penis or vagina, or letting the partner put his or her mouth on one's penis or vagina.
[c] Vaginal sex is defined as a boy putting his penis inside a girl's vagina.
[d] Among students who reported having a boyfriend or girlfriend in the past year.

Intervention Effects on Psychosocial Determinants of Sexual Behavior

Significant between-group differences were demonstrated for 5 of the 16 psychosocial variables examined (**Table 3**). At first follow-up, AI/AN youth exposed to *Native IYG* reported greater knowledge about condoms (beta=0.323, *P*<0.001) and HIV/STIs (beta=0.232, *P*<0.001), greater self-efficacy to acquire condoms (beta=0.332, *P*<0.001) and use condoms (beta=0.464, *P*<0.001), and more reasons not to have sex (beta=1.016, *P*<0.01) than youth in the comparison condition. Other psychosocial variables were not significantly affected by *Native IYG*.

Table 3. Intervention Effects on Psychosocial Outcomes by First Follow-up Among the Analytic Sample[a]

Outcome[b]	Sample Size[c]	Beta (Difference in Adjusted Mean)	95% CI		SE[d]
Knowledge					
Condom knowledge	308	0.323	0.216	0.430**	0.055
HIV/STI knowledge	324	0.232	0.112	0.352**	0.061
STI signs and symptoms knowledge	317	0.052	-0.001	0.106	0.027
Self-efficacy					
Sexual refusal self-efficacy	366	-0.061	-0.230	0.109	0.086
Condom negotiation self-efficacy	345	0.159	-0.002	0.321	0.082
Condom use self-efficacy	343	0.464	0.264	0.663**	0.102
Condom availability self-efficacy	321	0.332	0.171	0.493**	0.082
Attitudes and beliefs					
Conservative beliefs about sex	372	-0.023	-0.167	0.121	0.073
Reasons not to have sex	330	1.016	0.409	1.623*	0.310
Condom beliefs	340	0.109	-0.093	0.311	0.103
Friend perceptions					
Perceived friends' beliefs about sex	367	0.005	-0.151	0.160	0.079
Parent factors					
Parent-child communication	360	0.098	-0.067	0.264	0.084
Intentions					
Intention to remain abstinent until the end of high school	358	0.069	-0.200	-0.200	0.137
Intention to use a condom next time of sex	341	-0.001	-0.279	-0.279	0.142
Intention to have oral sex in the next year	366	-0.071	-0.267	0.124	0.100
Intention to have vaginal sex in the next year	362	-0.054	-0.228	-0.228	0.089
	Sample Size	**OR**	**95% CI**		**SE**
Perception of friends' behavior (referent = none)	341				
At least some		1.31	0.37	4.66	0.645
I don't know		0.578	0.255	1.30	0.417

CI, confidence interval; OR, odds ratio; SE, standard error; STI, sexually transmitted infection.

[a] Models are adjusted for baseline measure, age, gender, Native American (yes, no), and time between measures.

[b] All psychosocial variables coded as protective factors except for oral sex intentions and vaginal sex intentions.

[c] Sample sizes vary because of missing data.

[d] Intraclass correlation ranged from 0.0 to 0.34.

*P < .01, **P < .001.

Process Findings: Retention, Exposure, and Channel.
Sample retention. Of the baseline sample (n=523), 402 youth were retained at follow-up (77% retention). Those who did not complete the follow-up survey were not significantly different from those who did in terms of gender, race/ethnicity, cultural identification, or experimental status (*P*>.05). However, noncompleters indicated significantly (*P*<.01) higher rates of sexual experience at baseline than completers: oral sex (10.9% vs 4.0%), vaginal sex (11.8% vs 3.8%), and any sex (15.1% vs 4.8%). Noncompleters were also slightly but significantly older (m=13.4 years for noncompleters, m=13.0 years for completers, *P*<.001). Retention rates for youth in the treatment and comparison groups were 75% and 84%, respectively.

Intervention exposure. Exposure to the *Native IYG* and comparison suite curricula varied.

NATIVE IYG INTERVENTION. Complete exposure data were obtained for 266 of the 290 youth (92%) in the *Native IYG* condition because of the failure of one treatment study site to complete attendance logs. Of these 266 youth, 83% had full exposure (completing the full 13-lesson *Native IYG* curriculum) and 15% had a high level of exposure (completing 9-12 lessons). A small number of youth received no lessons (0.4%).

COMPARISON INTERVENTION. Complete exposure data were obtained for 74 of the 112 youth (66%) in the comparison suite intervention condition because of the failure of one comparison study site to complete attendance logs. Of these 74 youth, 64% had full exposure (completing the full 13-lesson comparison suite curriculum) and 14% had a high level of exposure (completing 9-12 lessons). A small number of youth received no lessons (5%).

Access to other sexual health programs. Youth were not restricted from accessing other sexual health programs occurring in schools and the community. Youth (48%) reported participating in programs in which “you talked about not having sex or the importance of using condoms and other birth control if you have sex.” Youth in the treatment intervention group reported greater access to other sexual health education programs than did those in the comparison group (52.5% vs 35.1%).

Time to first follow-up. The time taken between the baseline survey and the first follow-up after completion of either intervention condition ranged

from 0 to 462 days (m=113.95±96.97). The time taken between the baseline survey and the first follow-up immediately after the *Native IYG* curriculum averaged 122.90±88.59 days. The time taken between the baseline survey and the first follow-up immediately after the comparison suite curriculum averaged 90.77±112.10 days (P<0.01).

Delivery channel/connectivity. Treatment intervention sites commenced the study by accessing *Native IYG* as an online streaming program (n=12) or as an uploadable program from a USB drive (n=2). During the study, several sites that initially accessed *Native IYG* as an online streaming program converted to uploading *Native IYG* (n=4) because of the inability of local bandwidth to accommodate larger *Native IYG* video files while providing simultaneous streaming for multiple youth. Comparison condition sites commenced the study by accessing the suite of online health promotion programs through online streaming (n=8) or a combination of online streaming and an uploadable program from DVD (n=2). Information about program access from one site was missing (n=1). During the study, most sites continued to access these programs via Web connection (n=8).

DISCUSSION

In the present study, we evaluated the short-term psychosocial effects of *Native Its Your Game (Native IYG)*, an Internet-based HIV, STI, and pregnancy prevention curriculum for youth in AI/AN communities. We found that *Native IYG* significantly affected protective factors for sexual health. *Native IYG* increased youth knowledge related to condoms and to HIV/STI, improved youth self-efficacy for condom use and for condom availability, and increased the reasons youth had for delaying sex. These short-term results are consistent with previously reported short-term (3-month) effects of sexual health curricula in studies of AI/AN and non-AI/AN middle school youth. Kaufman et al reported significant change in the knowledge of Northern Plains Native boys and older youth (13-16 years) after use of the Circle of Life curriculum,[44] and RCT studies of precedent programs to *Native IYG*, the original *IYG*[30,31] and *IYG-Tech*[29] curricula, have demonstrated effects on an array of determinants of sexual initiation (including knowledge, self-efficacy, and reasons to delay sex) among eighth grade youth. Collectively, these study findings are supportive of previous reports describing the promise of technology-based sexual health education for AI/AN youth.[20,26,45] Sexual behaviors, although assessed at baseline to describe the sample, were not assessed at 3-month follow-up because significant behavioral change was not expected within this limited timeframe.

Although supportive, the findings in the present study were mixed. *Native IYG* did not significantly affect refusal and condom negotiation self-efficacy, peer-based descriptive and subjective (injunctive) norms, and parent-child communication. Previously reported usability testing of *Native IYG* with samples of AI/AN youth have demonstrated its acceptability.[24,26] However, other explanations for the mixed results may at least partly reside with challenges in the present study regarding youth recruitment, youth retention, imbalance in intervention conditions, and program exposure.

Recruitment

We experienced challenges recruiting and retaining youth who were at risk for early sexual initiation. At baseline, the demographic, behavioral, and environmental factors of participating youth were mainly protective of delayed sexual debut. Most youth were sexually inexperienced and not intending to initiate sex and were avoiding risky situations, both associated with lower odds of lifetime sexual intercourse.[15] Self-reported experience with sex, alcohol, and drugs was less than reported in previous studies,[7,9,16,44,46,47] and self-reported avoidance of risky situations that could lead to sex, which is associated with lower odds of lifetime sexual intercourse, was skewed protectively.[15]

The prevalence of any dating violence victimization among those youth who have a boyfriend or girlfriend was 20.7%, and the prevalence of perpetration was 13.26%. Although these rates are disconcerting, they are lower than reported levels because of an increased prevalence of dating violence among middle school youth.[48-50] A survey of all seventh graders from diverse geographic locations found that 37% reported being victims of psychological dating violence and 15% reported being victims of physical dating violence in the last 6 months.[50] These rates were also lower than those in a study of ethnic minority middle school youth demonstrating that, in a sample of multiethnic sixth graders from four US states, almost one-third of Hispanics and one-third of African Americans reported physical dating violence perpetration, compared with only 14% of Whites.[51] Peskin et al reported that by sixth grade, approximately 50% of students will have engaged in a dating relationship.[52] Of these, almost one-third will have perpetrated physical dating violence and almost two-thirds will have perpetrated emotional dating violence.[53] In our previous bivariate analysis, experience of dating violence victimization/perpetration in the past year was associated with a higher odds of sexual experience

(*P*<.20). However, this association was not maintained in multivariate analysis.[24]

The majority of the sample was female, had two or more adults in the home, usually achieved A or B grades, and had intentions to pursue education past high school – all factors protective of sexual initiation.[8,10,13-15] Further, they demonstrated a strong cultural identity, which implicitly places risky sexual behaviors in conflict with their traditional values.[10] Most parents in the study had completed high school or an advanced degree, and a majority of youth reported strong parental relationships that featured monitoring and parent-child communication about sexual health topics at the outset.[8] In keeping with this profile, we also found that almost half of the youth reported participation in a program in which they talked about not having sex or the importance of using condoms and other birth control if they did have sex. This is not surprising because we did not withhold youth from participating in programs to which they would be typically exposed. This was in accord with agreements with our tribal partners. Collectively, our self-selected study sample presented with a relatively low risk for initiation at baseline. This may have been compounded by challenges to retention by first follow-up.

Retention

Our sample retention at first follow-up was 78%, less than that reported in previous urban school-based studies[30,31] but consistent with a previously reported group randomized trial of middle school AI youth.[46] However, we experienced differential attrition. Youth lost to follow-up were older and more sexually experienced than those retained. This is consistent with the higher attrition rate of older youth from the *Native IYG* intervention group at first follow-up. Intervention studies with Native[4445] and non-Native youth[30,31,40] indicate that implementing sexual health promotion interventions in sixth or seventh grade is feasible, may be more effective than delivering interventions at an older age,[45] and may have a sustained effect on delayed sexual initiation in ninth grade.[30,31] This suggests that *Native IYG* may be most suitable for younger sixth and seventh grade learners.

Imbalanced Design

In the present study, we were able to explore the feasibility of conducting collaborative research in tribal communities and to evaluate a promising approach to the dissemination of sexual health programs for geographically disparate underserved AI/AN youth. To our knowledge, this

is the first multisite randomized controlled trial of a technology-based sexual health program incorporating Web-based surveys for youth in AI/AN communities. Our study sample was inclusive of 25 underserved AI/AN communities across five states in three large, geographically separate regions of Alaska, Arizona, and the Pacific Northwest states of Idaho, Oregon, and Washington. Randomization at the site level within each region provided a robust study design. However, two factors contributed to an imbalance: (1) highly varied numbers of youth in each site and (2) our agreement that no eligible youth within a site would be denied an intervention. The resulting imbalance of youth between the treatment (n=290) and comparison (n=112) interventions limited the statistical power of the study.

Exposure

Despite the delivery of standard protocols by our site coordinators, there was significant between-group difference in the level of exposure of youth to the programs. Full exposure to the comparison intervention was considerably less than exposure to the *Native IYG* intervention. This could be due to a variety of factors: that the burden on comparison youth who completed usability surveys for each of five programs in the suite was increased, that the comparison suite was not adapted for Native youth and therefore was less engaging (consistent with usability findings), that tribal liaisons may have been more motivated to provide sexual health life skills training than other health programs, and that the comparison intervention programs, each located on different dedicated servers, were subject to more connectivity problems.[24] Reasons for differential exposure may have varied within and across sites. Understanding these reasons may be helpful in informing future controlled trial research.

Using Internet-based programs in tribal communities is not without challenge despite potential advantages of program fidelity, reach, and cost.[25,26] Internet access was variable and difficult to standardize across five states, which threatened program fidelity and exposure. Some sites experienced freezing or delays caused by busy servers, weather-related outages, or other technical difficulties. In the current study, backup thumb drives disseminated to each site enabled *Native IYG* to be used without loss of fidelity.[24]

Limitations

The present study's findings need to be considered in light of the study limitations. First, generalizability is limited to youth in tribal communities,

but findings cannot be attributed solely to AI/AN youth. Our participating youth self-identified predominantly as AI/AN. However, it is not uncommon for some youth of other race/ethnicities to attend predominantly AI/AN schools or after school programs, and this was reflected in our study sample. A less rigorous convenience sampling design also limited generalizability to English-speaking youth (12-14 years) in AI/AN communities who choose to participate in sexual health education programs. Second, self-reported data may be subject to under- or over-reporting[54,55] despite our use of computer-based data collection systems to provide more valid and reliable data for sensitive topics.[54-58] Third, the time taken between the baseline survey and the first follow-up after completion of either intervention condition was highly variable and differed significantly between treatment and comparison intervention sites. This was a necessary result of being responsive to local study site implementation and measurement schedules across 25 variable sites. Fourth, study contamination could have occurred if youth in the comparison intervention were exposed to information on substance use that is associated with sexual risk taking. This threat was minimal because comparison programs on alcohol and drugs focused on biologic and physiologic effects rather than sexual risk behaviors or negotiation in social contexts, and these programs were of limited exposure (ie, two lessons).

Recommendations from this work include the importance of rigorous training, implementation, and quality assurance of protocols and data collection within a multisite trial; use of webinar-based training in conjunction with regional in-person site visits; embedded study site coordinators to facilitate smooth implementation and overcome potential barriers; a priori assessment of bandwidth, especially for multiple simultaneous users; and availability of backup delivery modalities. The importance of partnerships with tribal elders and AI/AN community stakeholders cannot be overstated. Our collaboration with the Alaska Native Tribal Health Consortium, the Inter Tribal Council of Arizona, Inc., and the Northwest Portland Area Indian Health Board brought a precedent of community collaboration and credibility that facilitated all facets of conducting this study in AI/AN communities.[25]

CONCLUSION

Currently, few culturally relevant sexual health interventions endorsed by granting agencies reflect the unique needs and world views of AI/AN youth.[14,18,4445] This study demonstrates the efficacy of a culturally adapted

Internet-based curriculum (*Native IYG*) to affect short-term psychosocial protective factors that have been associated with delayed sexual debut and offers a promising channel to reach geographically dispersed AI/AN youth. Results need to be interpreted in the context of study limitations but suggest that further assessment of the long-term behavioral effects of *Native IYG* may be warranted.

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