Prevention of Sexually Transmitted Diseases and Pregnancy Prevention Among Native American Youths: A Randomized Controlled Trial, 2016–2018

Lauren Tingey, PhD, MPH, MSW, Rachel Chambers, PhD, MPH, Hima Patel, MSPH, Shea Littlepage, MPH, Shauntel Lee, Angelita Lee, Davette Susan, Laura Melgar, Anna Slimp, and Summer Rosenstock, PhD, MHS

Objectives. To evaluate the efficacy of the Respecting the Circle of Life program (RCL) among Native American youths 11 to 19 years of age residing in a rural reservation community in the southwestern United States.

Methods. Between 2016 and 2018, we conducted a randomized controlled trial of the RCL program with 534 Native youths. Participants completed assessments at baseline and 9 and 12 months after the intervention. We conducted intention-to-treat analyses based on study group randomization.

Results. At 9 months, intervention participants had significantly better condom use self-efficacy ($P < .001$), higher intentions to use condoms ($P = .024$) and abstain from sex ($P = .008$), and better contraceptive use self-efficacy ($P < .001$) than control participants, as well as better condom use ($P = .032$) and contraceptive use ($P = .002$) negotiation skills. At 12 months, intervention participants had significantly better sexual and reproductive health knowledge ($P = .021$), condom use self-efficacy ($P < .001$), contraceptive use self-efficacy ($P < .001$), and contraceptive use negotiation skills ($P = .004$) than control participants. Intervention participants reported significantly more communication with their parents about sexual and reproductive health than control participants at both 9 and 12 months ($P = .042$ and $P = .001$, respectively).

Conclusions. The RCL program has a significant impact on key factors associated with pregnancy prevention among Native youths and should be used as an adolescent pregnancy prevention strategy.

Trial Registration. Clinical Trials.gov identifier: NCT02904629. (*Am J Public Health*. Published online ahead of print September 16, 2021:e1–e11. https://doi.org/10.2105/AJPH.2021.306447)

AJPH Published online ahead of print September 16, 2021

Despite recent decreases, US rates of adolescent pregnancy are higher than those of other developed nations.[1] The consequences of adolescent pregnancy are vast. Adolescent mothers are less likely to earn a high school diploma than nonadolescent mothers (50% vs 90%), and only 2% of all US adolescent mothers earn a college degree.[2,3] Babies born to adolescent mothers are more likely to be premature or have a low birth weight, to live in poverty, to drop out of high school, to be incarcerated as adolescents, and to themselves become adolescent parents.[4] There is also an immense societal cost of adolescent births: in 2015 alone, declines in adolescent births saved an estimated $4.4 billion.[5]

Within the United States, Native American (Native) adolescents have the highest adolescent birth rate of all racial/ethnic groups (33 births per 1000

girls).[6] This rate is nearly double the US adolescent birth rate (19 births per 1000 girls) and more than double the rate among non–Hispanic White girls (13 births per 1000 girls).[6] Nearly one third (32%) of all Native girls begin having children as adolescents, and the prevalence of repeated adolescent births is highest in this group.[6,7] National data show that Native youths are more likely to initiate sex before the age of 13 years than all other groups with the exception of African American youths.[7]

Despite these disparities, Native communities and ways of life are laden with strength-based practices that promote overall health and well-being.[8,9] In most Native communities, there is strong familial, cultural, and community attachment and an inherent support system for youths during adolescence.[10,11] Key factors protecting against sexual risk specific to Native communities include positive cultural identities, self-esteem, having future aspirations, and an absence of internalizing and externalizing behaviors.[12–14] Research shows that programs building on these strengths are both desirable and impactful in Native communities.[15]

In addition to being strength based, programs targeting the sexual behaviors of Native youths need to work across well-established key precursor domains of behavior change, including knowledge, self-efficacy, intention, partner negotiation skills, and communication.[16–24] Measuring the effects of sexual and reproductive health programming on these domains is especially important for evaluations conducted with youths who may not yet be sexually active, as the behaviors of interest may not be observed across follow-ups.[25]

For most US adolescents, school-based programming is a primary means of receiving medically accurate sexual and reproductive health information. However, in Arizona, where the current study took place, school-based sexual health education is optional; the state does not require this type of instruction in school and, if it is available, parents may opt their children out.[26] Moreover, only 31% of Arizona school districts provide sexual health education at all, and of those the majority use abstinence-only curricula that do not offer instruction on methods of pregnancy and sexually transmitted infection (STI) prevention.[27] Thus, developing evidence-based comprehensive sexual health promotion programs that take a strength-based approach, work across established precursors for behavior change, and operate in nonschool settings is essential for adolescent pregnancy and STI prevention in Native communities.

The US Department of Health and Human Services established the national Teen Pregnancy Prevention Program with the goals of replicating existing evidence-based adolescent pregnancy prevention programs (tier 1) and rigorously evaluating new, promising approaches (tier 2).[28,29] This federal program is widely touted as a bipartisan, evidence-based policy-making initiative.[30]

In the present study, we assessed the Johns Hopkins Center for American Indian Health's Respecting the Circle of Life: Mind, Body and Spirit (RCL) program. In 2015, the center was awarded a Teen Pregnancy Prevention Program tier 2 grant to implement and rigorously evaluate this innovative and promising program in partnership with a tribal community. (To respect community confidentiality, we do not name the tribe here but, rather, describe the setting: a rural reservation in Arizona.) The tribe and the center have been working together to develop and evaluate RCL since 2011 (as described subsequently). Here we describe 9- and 12-month outcomes from the 5-year (2015–2020) evaluation to determine the impact of RCL.

METHODS

Youths were enrolled in this randomized controlled trial across 3 cohorts (2016, 2017, and 2018); each cohort was followed for 12 months. Youths selected a parent or trusted adult participant (e.g., grandparent, aunt or uncle) to enroll with them in the study. All participants were blinded to their randomization status.[31]

Intervention

The Johns Hopkins Center for American Indian Health adapted RCL in 2011 from an evidence-based STI and HIV risk reduction intervention called FOY + ImPACT.[22] We conducted 11 focus groups with Native youths and 7 with Native parents and led a community-engaged curriculum adaptation process. This effort included input and collaboration from tribal stakeholders through a community advisory board composed of diverse members of tribal governance groups, the Indian Health Service, and community-based organizations.[32,33]

We learned that the best method for RCL implementation was an 8-day summer basketball camp in addition to a lesson delivered at home to the youths together with their parents or trusted adults. Native paraprofessionals from the community were selected as facilitators and trained in RCL content.

AJPH Published online ahead of print September 16, 2021

The first 8 RCL lessons are delivered to peer groups organized according to gender (male or female) and age group (e.g., 11–12, 13–15, and 16–19 years), with 8 to 12 youths per peer group. Lessons are taught daily at the camp by 2 facilitators per group. The ninth lesson is delivered 3 months or less after the completion of the camp by a youth peer-group leader.

The RCL curriculum involves comprehensive sexual and reproductive health education and covers anatomy, puberty, how pregnancy occurs, how HIV and other STIs are spread, effective methods for prevention of pregnancy and STIs or HIV (including condoms and all forms of contraception), and how to identify and reduce related risk behaviors. RCL incorporates development of soft skills such as problem solving, communicating with sexual partners and parents or trusted adults, and goal setting. The program includes modeling of learned skills, a "family tree" to contextualize abstract concepts, culturally appropriate interactive activities, and extensive practice of condom and contraceptive use skills.

RCL is expected to produce both short- and long-term outcomes because it reflects Native cultural knowledge, traditional practices, and family and individual values and beliefs and is specific to the local context. RCL emphasizes individual-, family-, and community-level responsibility for preventing STIs, HIV, and unintended pregnancies. Curriculum content and activities take a positive youth development approach and teach skills young people need to make healthy choices, including role-playing, sexual partner negotiation skills, and decision making. RCL is delivered to youths in peer groups and a private session with their parent or trusted adult to effect behavior change across key influencers.

Control Group

The control group received 9 educational lessons on nutrition, fitness, outdoor recreation, and nature; topics were selected by community stakeholders to provide benefit to all participants. The format of the control program was the same as that of RCL (e.g., 8 peer-group lessons at camp and a ninth session at home with the parent or trusted adult) to rule out intervention effects attributable to program delivery. Each program was delivered in a separate camp facility to avoid contamination.

Participants

Participants were recruited at local events, with flyers, and via radio announcements. Youths were eligible if they were (1) 11 to 19 years of age, (2) of Native American ethnicity (self-identified), (3) enrolled members or residents of the participating tribal community, (4) willing to be randomized, and (5) able to participate in the program and the evaluation. Participants who were minors had parental permission and provided assent; young adult participants (those 18 years or older) provided informed consent. Youths self-sorted into peer groups after individual randomization.

Data Collection

We collected self-report data at baseline and 9 and 12 months after program completion via culturally adapted versions of the Youth Health Risk Behavior Inventory, the Parent Adolescent Communication Scale, and the Parental Monitoring Scale.[22,31] Baseline surveys were administered before randomization during 2 precamp registration days. Follow-up surveys were administered at a private location (e.g., participant's home, local study office). We used the audio computer-assisted self-interviewing technique[31] to administer surveys on a laptop or tablet or via hard copy. All assessments were administered by independent evaluators to limit response bias.

All outcome data were collected and analyzed for the full sample to avoid endogenous subgroups. Primary outcomes included (1) history of vaginal sex (yes or no question: "Have you ever had vaginal sex?"), assessed at baseline and all follow-up time points; (2) sexual and reproductive health knowledge (number of correct responses on a 30-question knowledge assessment); (3) condom use self-efficacy (mean on a 6-item Likert scale ranging from 1 [no, I could not] to 5 [yes, I could]; Cronbach $\alpha = 0.8680$); and (4) intention to use a condom if having sex in the next 6 months (on a dichotomized Likert scale; maybe, don't know, probably not, and no were coded as 0 and yes was coded as 1).

Secondary outcomes included (1) intention to have sex in next 12 months (on a dichotomized Likert scale; no, definitely not and no, probably not were coded as 0 and yes, definitely and yes, probably were coded as 1); (2) contraceptive use self-efficacy (mean on a 6-item Likert scale ranging from 1 [no, I could not] to 5 [yes, I could]; Cronbach $\alpha = 0.9085$); (3) perceived partner negotiation skills regarding condom use (yes or no: "I could refuse to have sex if my partner will not use a condom"); (4) perceived partner negotiation skills regarding contraceptive use (yes or no: "I could refuse to have sex if

AJPH Published online ahead of print September 16, 2021

my partner will not use birth control"); (5) parent–adolescent communication (sum of 32 dichotomized items focusing on youths' openness or problems in communication with their parent or trusted adult around sensitive topics, originally coded as a Likert scale ranging from 1–5 [higher = better]; Cronbach $\alpha = 0.9323$); (6) frequency of talking with parent about sexual and reproductive health, specifically how to use condoms or contraception and how to access various methods (mean on a 7-item Likert scale ranging from 1–4 [higher = more]; Cronbach $\alpha = 0.9159$); and (7) talking with parents specifically about drugs and alcohol in the past 3 months (yes or no).

Analyses

Intention-to-treat analyses were performed based on study group randomization regardless of level of participation. We conducted equivalence testing of sociodemographic and outcome variables for the full analytic sample at baseline and at the 9- and 12-month follow-ups (Table 1). We defined baseline equivalence as no statistically significant difference ($P < .05$) between groups in baseline values for a given outcome in the analytic sample at each time point. Intervention impact was assessed at the 9- and 12-month follow-ups via logistic regression for binary outcomes and linear regression for continuous outcomes. All models controlled for gender and age at baseline. For the outcomes of parent–adolescent communication and talking with parent about sexual and reproductive health, we controlled for baseline levels owing to statistically significant ($P < .05$) differences in baseline equivalence at the 9- or 12-month follow-up.

Missing data for history of vaginal sex were logically imputed on the basis of available data. If a participant reported having had vaginal sex at a previous time point, that response was carried forward. Likewise, missing data were logically imputed if a participant reported not ever having vaginal sex at a later time point and there were no contradictory data at a previous time point. Four missing values (2 intervention and 2 control values) were imputed at baseline, 28 (9 intervention and 19 control values) at 9 months, and 27 (13 intervention and 14 control values) at 12 months. Because missing values were imputed, the sample sizes at 9 and 12 months for this variable exceeded those presented in Table 1 for these time points. No other outcomes required logical imputation, and retention was sufficiently high that multiple imputation was not warranted.

Regression-adjusted means and percentages are reported along with between-group adjusted mean differences or odds ratios and 95% confidence intervals (CIs). We report *P* values using 2-tailed testing with a .05 threshold for significance. We did not adjust for multiple comparisons because each outcome was reflective of a unique, distinct domain of a necessary precursor to sexual behavior change.[16–24]

In sensitivity analyses, results were examined without control for age or gender, with control for cohort, with exclusion of cohort 3, and with exclusion of siblings of the enrolled participant in each family (when more than 1 youth from the same family enrolled in the same cohort). Results of the models presented in Tables 2 and 3 are comparable with results with these alternative specifications.

At 12 months, given the sample sizes (223 in the intervention group and 223 in the control group) and the observed values in the control group, we had 80% power to detect (at the 5% significance level) a 10.7-percentage-point between-study group difference in the percentages of participants who reported ever having had sex, a 2-point difference in mean sexual and reproductive health knowledge scores, a 0.29-point difference in mean condom use self-efficacy scores, and a 13.5-percentage-point difference in condom use intention.

Unfortunately, there was a major disruption in the evaluation between years 3 and 4 caused by threatened termination before grant end. To deliver programming to cohort 3, we hosted the third camp in June 2018 (as opposed to July, when the cohort 1 and cohort 2 camps were hosted). In this community, there are scheduling conflicts in June with respect to study enrollment, including summer school, other camps, and off-reservation activities. Hosting the final camp in June resulted in a smaller and younger sample than planned for in cohort 3, as well as a smaller and younger sample overall.[34]

In addition, a smaller proportion of youths were sexually active than assumed for our power analyses. Our assumption that approximately 20% of control youths would be sexually active was based on a prior evaluation of RCL in the same community (in which the average age was 15.4 years).[34,35] In this study, the average age (13.27 years) and the low prevalence of sexual activity (13.3% in the intervention group and 12.5% in the control group at 12 months) diminished our power to detect significant differences in one of the primary outcomes (percentage of participants who had ever had vaginal

AJPH Published online ahead of print September 16, 2021

TABLE 1— Demographic Characteristics and Baseline Unadjusted Primary and Secondary Outcomes: Respecting the Circle of Life Program, Arizona, 2016–2018

	Baseline Analytic Sample, % (No.) or Mean (SD)		9-Month Analytic Sample, % (No.) or Mean (SD)		12-Month Analytic Sample, % (No.) or Mean (SD)	
	Intervention (n = 266)	Control (n = 268)	Intervention (n = 219)	Control (n = 231)	Intervention (n = 223)	Control (n = 223)
Demographic characteristics						
Age category, y						
11–12	38.3 (102)	37.3 (100)	38.8 (85)	36.8 (85)	39.0 (87)	36.8 (82)
13–14	38.0 (101)	41.0 (110)	37.0 (81)	42.0 (97)	37.2 (83)	42.6 (95)
15–19	23.7 (63)	21.6 (58)	24.2 (53)	21.2 (49)	23.8 (53)	20.6 (46)
Gender						
Male	47.7 (127)	47.0 (126)	48.4 (106)	47.2 (109)	47.1 (105)	47.1 (105)
Female	52.3 (139)	52.6 (141)	51.6 (113)	52.8 (122)	52.9 (118)	52.9 (118)
Transgender	0.0 (0)	0.4 (1)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)
Race/ethnicity						
American Indian or Alaska Native	100.0 (266)	100.0 (268)	100.0 (219)	100.0 (231)	100.0 (223)	100.0 (223)
Asian	0 (0.0)	0 (0.0)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)
Native Hawaiian or Pacific Islander	0 (0.0)	0 (0.0)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)
Black or African American	0 (0.0)	0 (0.0)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)
White	0 (0.0)	0 (0.0)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)
>1 race	0 (0.0)	0 (0.0)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)
Unknown or not reported	0 (0.0)	0 (0.0)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)
Baseline unadjusted primary and secondary outcomes						
Primary outcomes						
Ever had sexual intercourse[a,b]	8.3 (22)	5.6 (15)	8.2 (18)	6.1 (14)	8.5 (19)	5.4 (12)
Sexual/reproductive health knowledge[c]	15.71 (6.89)	15.19 (7.42)	15.65 (6.80)	15.39 (7.45)	15.78 (6.63)	15.36 (7.28)
Condom use self-efficacy[d]	3.08 (1.17)	3.08 (1.07)	3.12 (1.16)	3.08 (1.08)	3.09 (1.16)	3.04 (1.08)
Intend to use condom in next 6 months[e]	31.0 (78)	29.8 (76)	31.6 (66)	30.7 (67)	30.7 (65)	27.0 (57)
Secondary outcomes						
Intend to have sex in next year[f]	87.4 (221)	90.7 (225)	86.0 (178)	91.6 (195)	85.9 (182)	91.8 (189)
Contraceptive use self-efficacy[g]	3.07 (1.14)	3.18 (1.11)	3.12 (1.10)	3.18 (1.12)	3.09 (1.11)	3.16 (1.12)
Perceived partner negotiation skills regarding condom use[h]	39.9 (97)	43.9 (107)	38.1 (77)	42.5 (88)	38.1 (78)	42.8 (86)
Perceived partner negotiation skills regarding contraceptive use[c]	27.8 (74)	33.0 (88)	27.4 (60)	32.2 (74)	26.9 (60)	31.5 (70)
Parent–adolescent communication	2.46 (4.55)	1.97 (3.43)	2.40 (4.41)	2.02 (3.44)	2.52* (4.51)	1.77* (2.99)

Continued

AJPH Published online ahead of print September 16, 2021

TABLE 1— Continued

	Baseline Analytic Sample, % (No.) or Mean (SD)		9-Month Analytic Sample, % (No.) or Mean (SD)		12-Month Analytic Sample, % (No.) or Mean (SD)	
	Intervention (n = 266)	Control (n = 268)	Intervention (n = 219)	Control (n = 231)	Intervention (n = 223)	Control (n = 223)
Talking with parent about sexual/ reproductive health[i]	1.59 (0.76)	1.48 (0.65)	1.60* (0.75)	1.47* (0.64)	1.60* (0.77)	1.44* (0.63)
Talking with parent about drugs/alcohol[j]	23.5 (62)	28.5 (75)	24.3 (53)	29.2 (66)	23.9 (53)	28.0 (61)

[a]Refers to vaginal sex only.

[b]Intervention group is missing 1 value at baseline.
[c]Control group is missing 1 value at all time points.
[d]Intervention group is missing 11 values at baseline and 10 values at the 9- and 12-month follow-ups. Control group is missing 9 values at baseline and the 9-month follow-up and 8 values at the 12-month follow-up.
[e]Intervention group is missing 14 values at baseline, 10 values at the 9-month follow-up, and 11 values at the 12-month follow-up. Control is missing 13 values at baseline and the 9-month follow-up and 12 values at the 12-month follow-up.
[f]Intervention group is missing 13 values at baseline, 12 values at the 9-month follow-up, and 11 values at the 12-month follow-up. Control group is missing 20 values at baseline, 18 values at the 9-month follow-up, and 17 values at the 12-month follow-up.
[g]Intervention group is missing 16 values at baseline and 14 values at the 9- and 12-month follow-ups. Control group is missing 17 values at baseline and the 9-month follow-up and 16 values at the 12-month follow-up.
[h]Intervention group is missing 23 values at baseline, 17 values at the 9-month follow-up, and 18 values at the 12-month follow-up. Control group is missing 24 values at baseline and the 9-month follow-up and 22 values at the 12-month follow-up.
[i]Intervention group is missing 12 values at baseline, 9 values at the 9-month follow-up, and 10 values at the 12-month follow-up. Control group is missing 12 values at baseline, 11 values at the 9-month follow-up, and 10 values at the 12-month follow-up.
[j]Intervention group is missing 2 values at baseline and 1 value at the 9- and 12-month follow-ups. Control group is missing 5 values at all time points.
*$P < .05$.

AJPH Published online ahead of print September 16, 2021

sex). We had sufficient statistical power to detect significant differences in the remaining primary and secondary outcomes.

RESULTS

Of the 703 participants who provided informed consent, 80.5% (n = 566) completed the baseline portion of the study and 76.0% (n = 534) were randomized. The age and gender of those who provided consent but did not complete baseline and randomization were similar to those who did (age: 13.22 vs 13.27 years; percentage male: 53.5% vs 47.7%).

A total of 534 youths completed baseline and were randomized between May 13, 2016, and June 7, 2018 (intervention: 266; control: 268), 154 in cohort 1 (2016), 245 in cohort 2 (2017), and 135 in cohort 3 (2018). At the 9-month follow-up, differential attrition was 3.9% and overall attrition was 15.7%. At the 12-month follow-up, differential attrition was 0.6%, with 16.5% overall attrition (Figure 1). At baseline, the mean age was 13.27 years, 52.4% of the participants were female, and all of the participants' self-reported race/ethnicity was Native American; 6.9% of participants reported having ever had sexual intercourse.

Youths attended an average of 6.57 of the 8 peer-group sessions (intervention mean = 6.43, SD = 2.10; control mean = 6.71, SD = 1.90), and most completed the parent–youth session (intervention: 82.3%; control: 86.9%). The time between the final peer-group session and the ninth session ranged from 1 to 125 days, with an average of 41.99 days (intervention mean = 42.5, control mean = 41.3).

Primary Outcomes

There were no significant differences in history of vaginal sex between the intervention and control groups at the 9- or 12-month follow-up (9-month adjusted odds ratio [AOR] = 1.51; 95% CI = 0.83, 2.76; 12-month AOR = 1.08; 95% CI = 0.63, 1.86; Table 2). Youths in the intervention group had significantly better sexual and reproductive health knowledge at the 12-month follow-up (adjusted mean difference [AMD] = 1.22; 95% CI = 0.18, 2.25) than youths in the control group. RCL youths had significantly better condom use self-efficacy than control youths at both 9 months (AMD = 0.56; 95% CI = 0.41, 0.72) and 12 months (AMD = 0.40; 95%

TABLE 2— Effects of the Respecting the Circle of Life Program on Primary Outcomes: Arizona, 2016–2018

	No., Intervention/ Control	Intervention,[a] % (No.) or Mean (SE)	Control,[a] % (No.) or Mean (SE)	OR or AMD (95% CI)
Ever had vaginal sex[b]				
Baseline	265/268	4.7 (22)	2.9 (15)	1.66 (0.80, 3.47)
9 months	236/238	10.1 (37)	6.9 (28)	1.51 (0.83, 2.76)
12 months	224/220	13.3 (42)	12.5 (39)	1.08 (0.63, 1.86)
Sexual/reproductive health knowledge				
Baseline	266/267	15.71 (0.41)	15.19 (0.41)	0.52 (−0.62, 1.66)
9 months	218/230	21.37 (0.40)	21.48 (0.39)	−0.11 (−1.21, 0.98)
12 months	220/223	22.31 (0.37)	21.09 (0.37)	1.22 (0.18, 2.25)
Condom use self-efficacy				
Baseline	255/259	3.08 (0.06)	3.08 (0.06)	−0.00 (−0.17, 0.17)
9 months	211/224	4.06 (0.06)	3.50 (0.06)	0.56 (0.41, 0.72)
12 Months	217/216	4.04 (0.06)	3.63 (0.06)	0.40 (0.25, 0.56)
Intend to use condom in next 6 months				
Baseline	252/255	28.9 (78)	27.3 (76)	1.08 (0.72, 1.63)
9 months	208/222	57.8 (120)	46.8 (104)	1.55 (1.06, 2.28)
12 months	216/217	59.9 (129)	52.5 (114)	1.35 (0.92, 1.98)

Note. AMD = adjusted mean difference; CI = confidence interval; OR = odds ratio.

[a]All models controlled for gender and age at baseline. Means and proportions represent regression-adjusted estimates.
[b]Data were logically imputed. If a participant reported having had vaginal sex at a previous time point, that response was carried forward. Likewise, missing data were logically imputed if a participant reported not ever having vaginal sex at a later time point and there were no contradictory data at a previous point. Four values were imputed at baseline, 28 at 9 months, and 27 at 12 months.

CI = 0.25, 0.56). In addition, intention to use a condom in the next 6 months was significantly higher among intervention youths than control youths at 9 months (AOR = 1.55; 95% CI = 1.06, 2.28).

Secondary Outcomes

Intention to have sex in the next year was significantly lower among RCL youths than among control at 9 months (AOR = 0.56; 95% CI = 0.37, 0.86; Table 3). Intervention youths had significantly better contraceptive use self-efficacy than control youths at both 9 months (AMD = 0.39; 95% CI = 0.23, 0.56) and 12 months (AMD = 0.35; 95% CI = 0.18, 0.52). Perceived partner negotiation skills regarding condom use were significantly better among RCL youths than control youths at 9 months (AOR = 1.55; 95% CI = 1.04, 2.31). Perceived partner negotiation skills regarding contraceptive use were significantly better among intervention youths than control youths at 9 months (AOR = 1.87; 95% CI = 1.27, 2.75) as well as 12 months (AOR = 1.76; 95% CI = 1.20, 2.58).

Overall, between-group differences in parent–adolescent communication did not reach significance at 9 months (AMD = −0.03; 95% CI = −1.01, 0.96) or 12 months (AMD = 0.91; 95% CI = −0.11, 1.94). Intervention youths reported significantly more frequent conversations with their parent or trusted adult about sexual and reproductive health than control youths at both 9 months (AMD = 0.16; 95% CI = 0.01, 0.31) and 12 months (AMD = 0.26; 95% CI = 0.11, 0.41). The analyses did not reveal between-group differences in frequency of talking with parents or trusted adults about drugs and alcohol.

DISCUSSION

Our results show that the RCL program had significant, long-term effects on 3 of our 4 primary outcomes: sexual and reproductive health knowledge, condom use self-efficacy, and condom use intention. Two primary outcomes were sustained 12 months after program

AJPH Published online ahead of print September 16, 2021

TABLE 3— Effects of the Circle of Life Program on Secondary Outcomes: Arizona, 2016–2018

	No., Intervention/ Control	Intervention,[a] % (No.) or Mean (SE)	Control,[a] % (No.) or Mean (SE)	OR or AMD (95% CI)
Intend to have sex in next year				
Baseline	253/248	92.0 (221)	94.3 (225)	0.70 (0.38, 1.29)
9 months	209/214	63.0 (131)	75.1 (160)	0.56 (0.37, 0.86)
12 months	213/211	53.1 (113)	51.1 (108)	1.08 (0.74, 1.59)
Contraceptive use self-efficacy				
Baseline	250/251	3.08 (0.07)	3.18 (0.07)	−0.10 (−0.28, 0.08)
9 months	211/225	3.83 (0.06)	3.44 (0.06)	0.39 (0.23, 0.56)
12 months	216/216	3.87 (0.06)	3.53 (0.06)	0.35 (0.18, 0.52)
Perceived partner negotiation skills regarding condom use				
Baseline	243/244	39.5 (97)	42.9 (107)	0.87 (0.59, 1.27)
9 Months	211224	64.6 (134)	54.1 (121)	1.55 (1.04, 2.31)
12 months	216/216	64.8 (138)	56.3 (121)	1.43 (0.96, 2.13)
Perceived partner negotiation skills regarding contraceptive use				
Baseline	266/267	27.0 (74)	32.2 (88)	0.78 (0.53, 1.14)
9 months	217/229	57.7 (124)	42.2 (98)	1.87 (1.27, 2.75)
12 months	221/223	56.4 (124)	42.3 (95)	1.76 (1.20, 2.58)
Parent–adolescent communication[b]				
Baseline	266/268	2.46 (0.25)	1.97 (0.25)	0.49 (−0.20, 1.18)
9 months	219/231	3.42 (0.36)	3.45 (0.35)	−0.03 (−1.01, 0.96)
12 months	223/223	3.62 (0.37)	2.71 (0.37)	0.91 (−0.11, 1.94)
Talking with parent about sexual/reproductive health[b]				
Baseline	254/256	1.59 (0.04)	1.48 (0.04)	0.11 (0.00, 0.23)
9 months	207/223	1.87 (0.06)	1.71 (0.05)	0.16 (0.01, 0.31)
12 months	216/218	1.90 (0.05)	1.63 (0.05)	0.26 (0.11, 0.41)
Talking with parent about drugs/alcohol				
Baseline	264/263	23.3 (62)	28.4 (75)	0.77 (0.52, 1.14)
9 months	214/228	30.3 (65)	25.3 (58)	1.28 (0.85, 1.95)
12 months	222/222	32.7 (73)	28.1 (63)	1.24 (0.83, 1.86)

Note. AMD = adjusted mean difference; CI = confidence interval; OR = odds ratio.

[a]All models controlled for gender and age at baseline. Means and proportions represent regression-adjusted estimates.
[b]Controlled for baseline level of outcome variable owing to differences in baseline equivalence at the 9- or 12-month follow-up.

completion: sexual and reproductive health knowledge and condom use self-efficacy. Also, RCL had significant 9-month effects on 5 of our 7 secondary outcomes: intention to have sex, contraceptive use self-efficacy, perceived partner negotiation skills regarding condom use, perceived partner negotiation skills regarding contraceptive use, and talking with a parent or trusted adult about sexual and reproductive health. Three secondary

AJPH Published online ahead of print September 16, 2021

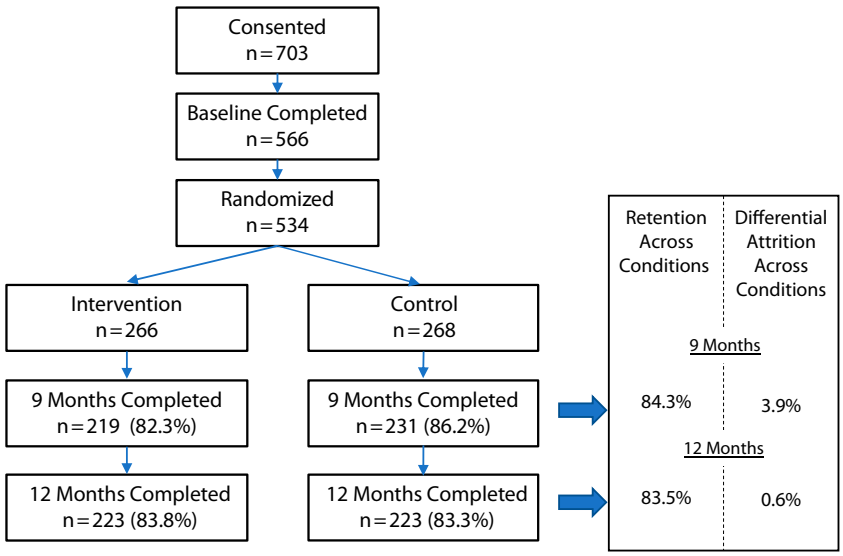

FIGURE 1— Enrollment and Follow-Up Diagram: Respecting the Circle of Life Program, Arizona, 2016–2018

outcomes were sustained at 12 months: contraceptive use self-efficacy, perceived partner negotiation skills regarding contraceptive use, and talking with a parent or trusted adult about sexual and reproductive health. Taken together, these results strengthen the evidence that the RCL program significantly affects several domains associated with prevention of pregnancy and STIs among Native American youths and adolescents.[16–24,35]

In a previous randomized controlled trial of the RCL peer-group lessons only, we found significant 6-month intervention effects on condom use self-efficacy, sexual health knowledge, condom beliefs, and talking with a parent or trusted adult about HIV/AIDS; however, all of these effects with the exception of condom use self-efficacy had attenuated by 12 months.[35] This impact analysis indicates how inclusion of the parent or trusted adult lesson has the potential to broaden intervention effects produced from the peer-group lessons to include intention to have sex, intention to use a condom, contraceptive use self-efficacy, perceived partner negotiation skills regarding both condom and contraceptive use, and talking with a parent or trusted adult about sexual and reproductive health. Furthermore, inclusion of that lesson may be key for sustaining RCL effects on sexual and reproductive health knowledge, contraceptive use self-efficacy, perceived partner negotiation skills regarding contraceptive use self-efficacy, and talking with a parent or trusted adult about sexual and reproductive health longitudinally through 12 months.

Noteworthy are the significant improvements in talking with a parent or trusted adult about sexual and reproductive health at 12 months. Our results suggest that implementation of RCL with Native youths and families can promote healthy conversations around sex during a critical period of development when youths may become sexually active. These findings mimic those of Stanton et al. (the developers of FOY + ImPACT, from which RCL was adapted), who showed that FOY intervention effects could be extended with the addition of ImPACT, and support the literature demonstrating the importance of parents and family in Native youths' decision making.[12,19,22]

As described, this impact evaluation was funded by a Teen Pregnancy Prevention Program tier 2B grant. Tier 2B grantees were expected to conduct their evaluations according to the quality assessment criteria set forth in the US Department of Health and Human Services evidence review. To achieve a high rating, evaluations were expected to (1) involve rigorous research designs, (2) involve no reassignment of participants, (3) demonstrate low attrition or differential attrition, (4) maintain baseline equivalence between groups, and (5) include no confounding factors. Our impact evaluation met all of the evidence review criteria necessary for this study to be designated as of high quality. Further, our analyses showed statistically significant favorable effects on 3 primary outcomes and 5 secondary outcomes.

Thus, there is strong evidence the RCL program is effective according to the evidence review criteria. That our evaluation was conducted at a high level of quality in a rural reservation-based context and able to demonstrate evidence in spite of the disruption caused by threatened grant termination is a testament to the strength of our tribal–academic partnership and the commitment of the participating community to this research.

Limitations

This study involved limitations. As a result of the young mean age of the sample and lower than originally anticipated prevalence of sexual activity, we did not have sufficient statistical power

AJPH Published online ahead of print September 16, 2021

to examine one of our primary outcomes (the percentage of youths who reported ever having had vaginal sex). This study was conducted in partnership with a single tribal community; thus, our results are not representative of the entire US Native youth population. Data were collected via self-report and are subject to social desirability bias. Contamination was possible in this reservation community; to limit this bias, we delivered each program in separate camp facilities.

Conclusions

The RCL program, designed specifically for Native communities, shows evidence of improving numerous precursor domains necessary for prevention of pregnancy and STIs among Native youths. Future research should examine whether RCL can have an impact on behaviors related to sexual initiation, pregnancy, and STIs and establish the extent to which the domains it does affect are sufficient for long-term behavior change. There is also a need for examinations of differential RCL effects among subgroups, a responder–nonresponder analysis, and cost-effectiveness assessments. RCL addresses the needs and assets of Native communities, takes advantage of young people's availability during summer, and accounts for diverse caregivers in Native families. Thus, the program may be particularly suitable for replication in other rural reservation communities. In conclusion, our impact evaluation makes an important contribution to the field of adolescent pregnancy prevention.

ABOUT THE AUTHORS

The authors are with the Bloomberg School of Public Health, Center for American Indian Health, Johns Hopkins University, Baltimore, MD.

CORRESPONDENCE

Correspondence should be sent to Lauren Tingey, PhD, MPH, MSW, Johns Hopkins University, Bloomberg School of Public Health, Center for American Indian Health, 415 N Washington St, Baltimore, MD 21231 (e-mail: ltingey1@jhu.edu).

PUBLICATION INFORMATION

Full Citation: Tingey L, Chambers R, Patel H, et al. Prevention of sexually transmitted diseases and pregnancy prevention among Native American youths: a randomized controlled trial, 2016–2018. *Am J Public Health*. Published online ahead of print September 16, 2021:e1–e11.

Acceptance Date: June 7, 2021.

DOI: https://doi.org/10.2105/AJPH.2021.306447

CONTRIBUTORS

L. Tingey led the study design and implementation and the original drafting of the article. R. Chambers managed study implementation and training and assisted with the original drafting of the article. H. Patel managed data collection systems, assisted with training and the original drafting of the article, and reviewed the article. S. Littlepage assisted with data cleaning, contributed to coding and quality assurance, and reviewed the article. S. Lee and D. Susan assisted with data collection and quality assurance and reviewed the article. A. Lee managed study implementation and team supervision and reviewed the article. L. Melgar and A. Slimp delivered programming, assisted with fidelity monitoring, and reviewed the article. S. Rosenstock conducted all of the data analyses and assisted with the original drafting of the article.

ACKNOWLEDGMENTS

This study was funded by the Office of Population Affairs (tier 2B grant TP2AH000041).

We acknowledge with deep respect the participating tribal community for its dedication to this research.

CONFLICTS OF INTEREST

None of the authors report potential or actual conflicts of interest from funding- or affiliation-related activities.

HUMAN PARTICIPANT PROTECTION

This study was approved by the institutional review board of the Johns Hopkins University School of Public Health. The study was reviewed and approved by the participating tribal community's Health Advisory Board and Tribal Council. All participants provided informed consent.

REFERENCES

1. World Bank. Adolescent fertility rate (births per 1,000 women ages 15–19). Available at: https://data.worldbank.org/indicator/SP.ADO.TFRT?contextual=region&locations=MY. Accessed August 26, 2020.
2. Perper K, Peterson K, Manlove J. Diploma attainment among teen mothers. Available at: https://www.childtrends.org/publications/diploma-attainment-among-teen-mothers. Accessed August 26, 2020.
3. Schuyler Center for Analysis and Advocacy. Teenage births: outcomes for young parents and their children. 2008. Available at: http://www.scaany.org. Accessed August 26, 2020.
4. Hoffman SD, Maynard RA. *Kids Having Kids: Economic Costs and Social Consequences of Teen Pregnancy*. Washington, DC: Urban Institute; 2008.
5. Power to Decide. National data. Available at: https://powertodecide.org/what-we-do/information/national-state-data/national. Accessed August 26, 2020.
6. Martin HA, Hamilton BE, Osterman MJK. Births in the United States, 2017. Available at: https://www.cdc.gov/nchs/products/index.htm. Accessed August 26, 2020.
7. Centers for Disease Control and Prevention. High School Youth Risk Behavior Survey data, 1991–2013. Available at: http://nccd.cdc.gov/youthonline. Accessed August 26, 2020.
8. Cajete G. *Indigenous Community: Rekindling the Teachings of the Seventh Fire*. St. Paul, MN: Living Justice Press; 2015.
9. Sarche M, Spicer P. Poverty and health disparities for American Indian and Alaska Native children: current knowledge and future prospects. *Ann N Y Acad Sci.* 2008;1136:126–136. https://doi.org/10.1196/annals.1425.017
10. Ulrich-Schad JD. Rural natives' perceptions of strengths and challenges in their communities. Available at: https://scholars.unh.edu/carsey/190. Accessed August 26, 2020.
11. Adams G, Fryberg SA, Garcia DM, Delgado-Torres EU. The psychology of engagement with indigenous identities: a cultural perspective. *Cultur Divers Ethnic Minor Psychol.* 2006;12(3):493–508. https://doi.org/10.1037/1099-9809.12.3.493
12. Henson M, Sabo S, Trujillo A, Teufel-Shone N. Identifying protective factors to promote health in American Indian and Alaska Native adolescents: a literature review. *J Prim Prev.* 2017;38(1–2):5–26. https://doi.org/10.1007/s10935-016-0455-2
13. Tingey L, Cwik MF, Rosenstock S, et al. Risk and protective factors for heavy binge alcohol use among American Indian adolescents utilizing emergency health services. *Am J Drug Alcohol Abuse.* 2016;42(6):715–725. https://doi.org/10.1080/00952990.2016.1181762
14. McMahon TR, Hanson JD, Griese ER, Kenyon DB. Teen Pregnancy Prevention Program recommendations from urban and reservation Northern Plains American Indian community members. *Am J Sex Educ.* 2015;10(3):218–241. https://doi.org/10.1080/15546128.2015.1049314
15. Cheon JW. Best practices in community-based prevention for youth substance reduction: towards strengths-based positive development policy. *J Community Psychol.* 2008;36(6):761–779. https://doi.org/10.1002/jcop.20256
16. Kaufman CE, Shelby L, Mosure DJ, et al. Within the hidden epidemic: sexually transmitted diseases and HIV/AIDS among American Indians and Alaska Natives. *Sex Transm Dis.* 2007;34(10):

AJPH Published online ahead of print September 16, 2021

767–777. https://doi.org/10.1097/01.olq.0000260915.64098.cb

17. Markham CM, Craig Rushing S, Jessen C, et al. Factors associated with early sexual experience among American Indian and Alaska Native Youth. *J Adolesc Health.* 2015;57(3):334–341. https://doi.org/10.1016/j.jadohealth.2015.06.003
18. Markham CM, Fleschler Peskin M, Addy RC, Baumler ER, Tortolero SR. Patterns of vaginal, oral, and anal sexual intercourse in an urban seventh-grade population. *J Sch Health.* 2009;79(4):193–200. https://doi.org/10.1111/j.1746-1561.2008.00389.x
19. Chewning B, Douglas J, Kokotailo PK, LaCourt J, Clair DS, Wilson D. Protective factors associated with American Indian adolescents' safer sexual patterns. *Matern Child Health J.* 2001;5(4):273–280. https://doi.org/10.1023/a:1013037007288
20. Buhi ER, Goodson P. Predictors of adolescent sexual behavior and intention: a theory-guided systematic review. *J Adolesc Health.* 2007;40(1):4–21. https://doi.org/10.1016/j.jadohealth.2006.09.027
21. Poobalan AS, Pitchforth E, Imamura M, et al. Characteristics of effective interventions in improving young people's sexual health: a review of reviews. *Sex Educ.* 2009;9(3):319–336. https://doi.org/10.1080/14681810903059185
22. Stanton B, Cole M, Galbraith J, et al. Randomized trial of a parent intervention: parents can make a difference in long-term adolescent risk behaviors, perceptions, and knowledge. *Arch Pediatr Adolesc Med.* 2004;158(10):947–955. https://doi.org/10.1001/archpedi.158.10.947
23. DiClemente RJ, Crittenden CP, Rose E, et al. Psychosocial predictors of HIV-associated sexual behaviors and the efficacy of prevention interventions in adolescents at-risk for HIV infection: what works and what doesn't work? *Psychosom Med.* 2008;70(5):598–605. https://doi.org/10.1097/PSY.0b013e3181775edb
24. Arizona Secretary of State. Sex education. Available at: https://casetext.com/regulation/arizona-administrative-code/title-7-education/chapter-2-state-board-of-education/article-3-curriculum-requirements-and-special-programs/section-r7-2-303-sex-education. Accessed August 26, 2020.
25. Talashek ML, Norr KF, Dancy BL. Building teen power for sexual health. *J Transcult Nurs.* 2003;14(3):207–216. https://doi.org/10.1177/1043659603014003007
26. Day JK, Tanaka A, Cherian A, et al. "Comprehensive" sexuality education in Arizona schools: searching for a clearer understanding of policies and practices regarding sexuality education. Available at: https://mcclellandinstitute.arizona.edu/sites/mcclellandinstitute.arizona.edu/files/Sexuality%20Education%20in%20Arizona%20Final%20ResearchLink.pdf. Accessed August 26, 2020.
27. Koh H. The Teen Pregnancy Prevention Program: an evidence-based public health program model. *J Adolesc Health.* 2014;54(suppl 3):S1–S2. https://doi.org/10.1016/j.jadohealth.2013.12.031
28. US Department of Health and Human Services. About TPP. Available at: https://www.hhs.gov/ash/oah/grant-programs/teen-pregnancy-prevention-program-tpp/about/index.html. Accessed August 26, 2020.
29. Hart N, Yohannes M. Evidence works: cases where evidence meaningfully informed policy. Available at: https://bipartisanpolicy.org/wp-content/uploads/2019/06/Evidence-Works-Cases-Where-Evidence-Meaningfully-Informed-Policy.pdf. Accessed August 26, 2020.
30. Chambers R, Tingey L, Mullany B, Parker S, Lee A, Barlow A. Exploring sexual risk taking among American Indian adolescents through protection motivation theory. *AIDS Care.* 2016;28(9):1089–1096. https://doi.org/10.1080/09540121.2016.1164289
31. Tingey L, Chambers R, Goklish N, et al. Rigorous evaluation of a pregnancy prevention program for American Indian youth and adolescents: study protocol for a randomized controlled trial. *Trials.* 2017;18(1):89. https://doi.org/10.1186/s13063-017-1842-6
32. Tingey L, Mullany B, Strom R, Hastings R, Barlow A, Rompalo A. The Respecting the Circle of Life Trial for American Indian adolescents: rationale, design, methods and baseline characteristics. *AIDS Care.* 2015;27(7):885–891. https://doi.org/10.1080/09540121.2015.1015481
33. Tufts University. ACASI: audio computer-assisted self-interview software. Available at: https://acasi.tufts.edu/acasi.htm. Accessed August 26, 2020.
34. Tingey L, Mullany B, Chambers R, et al. Respecting the circle of life: one year outcomes from a randomized controlled comparison of an HIV risk reduction intervention for American Indian adolescents. *AIDS Care.* 2015;27(9):1087–1097. https://doi.org/10.1080/09540121.2015.1028879
35. Tingey L, Chambers R, Rosenstock S, Lee A, Goklish N, Larzelere F. The impact of a sexual and reproductive health intervention for American Indian adolescents on predictors of condom use intention. *J Adolesc Health.* 2017;60(3):284–291. https://doi.org/10.1016/j.jadohealth.2016.08.025

AJPH Published online ahead of print September 16, 2021