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# The Respecting the Circle of Life trial for American Indian adolescents: rationale, design, methods, and baseline characteristics

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This paper describes the rationale, design, methods, and baseline results of a randomized controlled trial to evaluate the impact of an adapted evidence-based intervention (EBI), "Respecting the Circle of Life" (RCL) to reduce behavioral risks for HIV/AIDS among American Indian (AI) adolescents. A participatory approach shaped intervention adaptation and study design. A total of 267 participants (aged 13–19) were randomized by peer groups of the same sex to receive the RCL intervention or a control condition. Self-report assessments were administered at four intervals. The sample was predominately female (57%), had low HIV knowledge prevention scores, early sexual initiation (mean 14.6 years), and 56% reported intention to use a condom at next sex. Baseline characteristics were evenly distributed between groups with the exception of age and extrinsic reward scores. This is the first rigorous evaluation of an adapted EBI for HIV/AIDS prevention among AI adolescents, an at-risk and understudied population.

Keywords: American Indian; adolescents; HIV/AIDS; evidence-based intervention; randomized controlled trial; paraprofessional interventionists

# Introduction

HIV/AIDS is an emerging disease for American Indian/ Alaska Native (AI/AN) populations. AI/ANs are diagnosed with HIV at a rate 30% higher than Whites and from 2007 to 2010 were the only racial/ethnic group in which HIV incidence increased (Hamilton, Martin, & Ventura, 2010). A constellation of HIV/AIDS risk and contextual factors affect AI/AN populations, namely high rates of unprotected sex and substance use (Beauvais, 1992; Blum, Harmon, Harris, Bergeisen, & Resnick, 1992; Office of Applied Studies & International, 2004). Stigmatization and concerns about privacy in rural reservation-based settings lead to poor testing, a lack of early identification of HIV, and shorter survival following diagnosis when compared to other US groups (CDC & U.S. Department of Health and Human Services, 2007).

Evidence-based interventions (EBIs) for HIV/AIDS prevention have reduced behavioral risk among different adolescent racial/ethnic groups as documented by the Centers for Disease Control and Prevention's Compendium (Albarracin et al., 2005; Centers for Disease Control and Prevention, 2014). Adaptations of EBIs can take advantage of the research rigor that established the original EBI, add culturally grounded community input, and may be best at addressing behavioral health disparities among underrepresented groups in the EBI literature (Barrera, Castro, & Steiker, 2011). While some HIV/AIDS prevention interventions have been designed for and evaluated among AI adolescent populations, none are cited in or have been adapted from an EBI in the CDC Compendium (Albarracin et al., 2005; Baldwin et al., 1996; Centers for Disease Control and Prevention, 2014; Kaufman, Litchfield, Schupman, & Mitchell, 2012; Kaufman et al., 2010; Kaufman et al., 2014; Nelson & Tom, 2011; Scott & Langhorne, 2012; Smith, Rushing, & the Native STAND Curriculum Development Group, 2011). Further, while there are several EBIs currently undergoing adaptation for AI/AN populations, results of trials evaluating their efficacy are not yet published.

This study is a randomized controlled trial of an adapted EBI conducted with a sample of reservationbased AI adolescents. This paper describes adaptation of the EBI, the study design evaluating its efficacy, and baseline characteristics of participants.

# Methods

# Adaption of EBI

#### Selection

The EBI "Focus on Youth" (FOY) was selected for adaptation due to its targeted age group (adolescents), skills-focused curricula, theoretical underpinnings promoting protective factors (Borowsky, Resnick, Ireland, & Blum, 1999), capacity for delivery by trained community members, nonschool-based intervention setting, and track

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record of successful cross-cultural replication (Gong et al., 2009; Kaljee et al., 2005; Lerdboon et al., 2008; Lwin, Stanaland, & Chan, 2010). The Protection Motivation Theory (PMT; B. F. Stanton, Aronson, Borgatti, Galbraith, & Feigelman, 1993) is the framework for FOY and posits that the perceived threat of HIV infection initiates two cognitive pathways: threat appraisal (risk) and coping appraisal (protective) which combine to create the intention to respond by engaging in either the risky or protective behavior (B. F. Stanton et al., 1993). Eight weekly sessions are delivered by pairs of adult interventionists from the community to peer groups of the same sex/age in community centers (B. F. Stanton et al., 1996). Six FOY sessions are considered minimum intervention dosage.

#### Adaptation

The study team utilized a formative participatory research approach; we conducted 14 focus groups, 9 with youth and 5 with parents (34 males and 56 females), and 3 community advisory board meetings. Focus group discussions lasted 60–90 minutes and had an average of seven participants. Discussions explored intervention delivery and content changes essential for community acceptance and impact including behaviors that elicit intrinsic/extrinsic rewards, perceptions of HIV severity and vulnerability, relative costs in choosing protective behaviors, and relevant examples and language (Lerdboon et al., 2008).

Due to basketball's widespread popularity, an eightday summer basketball camp was suggested for curriculum delivery as it would (1) capitalize on availability (i.e., not compete with school-based activities), (2) be viewed as a positive recreational outlet, (3) attract both genders, (4) be inclusive of adolescents who had dropped out of school, and (5) maintain attendance. Concerns with adapting FOY from eight weeks to eight days (i.e., curriculum fatigue and less time to internalize behavior change messages) were outweighed by the potential benefits and endorsed by the architect of FOY, Dr Bonita Stanton.

Formative research dictated content adaptations and addition of activities to address local teens' lack of knowledge about sexual risk behaviors, reproduction, and sexual anatomy. A need for self-efficacy and communication skills among adolescents also prompted a deeper focus on communication-building activities and additional facilitator training related to forced sex. Local references were used in stories and scenarios where relevant. Activities where confidentiality or embarrassment was a concern were removed or adapted. Finally, due to feasibility concerns, ongoing group projects (postprogram completion) were removed.

The adapted intervention was renamed by local partners "Respecting the Circle of Life: Mind, Body and Action" (RCL) to reflect Native beliefs in the connection between mental, physical, and spiritual health.

# Respecting the Circle of Life trial design

The trial was a peer-group randomized controlled comparison of the RCL intervention vs. control and evaluated from baseline through 12-month follow-up (Figure 1). Two cohorts were recruited during two summer camps

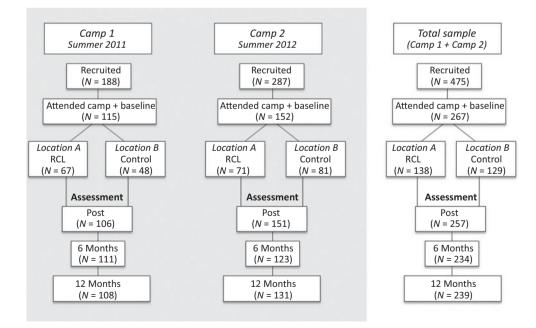


Figure 1. Flow of participants through each stage of a randomized trial to evaluate the RCL intervention.

(each eight, four-hour weekdays), held approximately one year apart (2011 and 2012). The study site was a rural reservation in Arizona with a tribal population of ~17,000. A total of 475 AI teens aged 13–19 were eligible; N = 267 completed the baseline assessment and attended camp. Participants formed self-selected samesex peer groups/teams within the same age range (13 to 15 or 16 to 19) and were randomized. To reduce contamination, camp was held at separate gymnasiums for intervention and control groups. Each day consisted of 90 minutes of basketball, a 30-minute lunch, and a 90-minute lesson (RCL or a noncompeting educational control lesson).

Data were gathered through hard copy via the selfreport, Youth Health Risk Behavior Inventory, which was adapted and pilot tested prior to use. Specifically, we added questions assessing alcohol and drug use before/during sex and removed questions irrelevant to a rural setting measuring urban crime and weapon carrying. Confirmatory factor analysis (CFA) and examination of Cronbach's  $\alpha$  scores were conducted on all scale items to attain the most reliable variables for this sample (B. Stanton et al., 1995; B. F. Stanton et al., 1996). CFA was used to generate loadings for individual items onto each factor, and Cronbach's assessments were used to compare the reliability of different factor versions. Factors with low eigenvalues were removed when they did not significantly contribute to explaining the variance within a set of variables. Distribution of sociodemographic characteristics, psychosocial and behavioral risks, and PMT constructs were compared to determine quality of randomization by conducting chi-squared tests of association and t-tests for differences in means.

The study was approved by relevant tribal, Indian Health Service, and university research review boards. This paper was approved by the governing Tribal Council and Health Advisory Board. There was no Data Safety and Monitoring Board.

# **Baseline results**

A total of 30 peer groups/teams were randomized, 16 to the RCL intervention and 14 to the control condition (ranged from 6 to 12 participants per group, average 8.9 participants). The total sample was 267 (138 RCL intervention, 129 control). The 2011 camp had 115 participants (43%) and the 2012 camp had 152 (57%).

# Sociodemographics and participation

RCL intervention participants were significantly older (15.4 vs. 14.8 years, p < 0.01; Table 1). Other key demographic variables were evenly distributed between intervention and control groups at baseline. Over half (56.2%) of participants were female and the majority (88.4%) were enrolled in school. A high proportion reported a history of school suspension (29.2%) and alcohol and marijuana use (19.9% and 22.1%, respectively). Over 80% of participants attended six or more camp days ( $\geq$  75% of all lessons).

# Behavioral risks

There were no significant between-group differences at the p < 0.05 level for HIV-related behavioral risks at baseline (Table 2). Condom effectiveness knowledge for preventing HIV/STIs was low (~54%), and 56% said

Table 1. Sociodemographic characteristics and camp participation rates of youth at baseline, by treatment group.

	RCL intervention $(n = 138)$	Control $(n = 129)$	Total ( $N = 267$ )
Sociodemographic characteristics			
Age, mean (SD)*	15.4 (1.7)	14.8 (1.5)	15.1 (1.7)
Gender, $n$ (%)			
Male	59 (42.8)	58 (45.0)	117 (43.8)
Female	79 (57.2)	71 (55.0)	150 (56.2)
Currently in school, <i>n</i> (%)	123 (89.1)	113 (87.6)	236 (88.4)
Ever been suspended from school, $n$ (%)	40 (29.0)	38 (29.5)	78 (29.2)
Currently have boyfriend/girlfriend, $n$ (%)	50 (37.3)	42 (33.3)	92 (35.4)
Drug use in past 6 months, $n$ (%)			
Alcohol	30 (21.7)	22 (17.2)	52 (19.9)
Cigarettes	15 (10.9)	12 (9.3)	27 (10.1)
Marijuana	35 (25.4)	24 (18.8)	59 (22.1)
Camp participation			
Number of days attended camp, mean (SD)	6.7 (2.0)	6.7 (2.0)	6.7 (2.0)
Attended six or more days of camp, $n$ (%)	115 (83.3)	106 (82.2)	221 (82.8)

p < 0.01 for test of between-group differences.

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Table 2. HIV-related behavioral risk profile at baseline, by treatment group.	Table 2.	HIV-related	behavioral	risk	profile at	baseline.	b١	v treatment group.
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	RCL intervention $(n = 138)$	Control $(n = 129)$	Total ( $N = 267$ )
Knowledge, efficacy, and intention outcomes			
HIV-related knowledge, mean (SD) (range 0-1)			
Prevention (Cronbach's $a = 0.62$ )	0.7 (0.3)	0.7 (0.2)	0.7 (0.3)
Transmission (Cronbach's $a = 0.72$ )	0.8 (0.2)	0.8 (0.2)	0.8 (0.2)
Total knowledge (Cronbach's $a = 0.73$ )	0.8 (0.2)	0.8 (0.2)	0.8 (0.2)
Believe condoms prevent HIV/STIs, $n$ (%)	77 (55.8)	67 (51.9)	144 (53.9)
Believe abstinence prevents HIV/STIs, $n$ (%)	49 (35.5)	54 (41.9)	103 (38.6)
Condom use self-efficacy	2.5 (1.0)	2.6 (1.0)	2.6 (1.0)
Mean (SD) (range 1–5) (Cronbach's $a = 0.83$ )		. ,	
Partner negotiation skills related to condom use	2.5 (1.0)	2.5 (1.0)	2.5 (1.0)
Mean (SD) (range 1–4) (Cronbach's $a = 0.94$ )		. ,	
Partner negotiation skills related to sex and drug use	4.5 (0.8)	4.5 (0.8)	4.5 (0.8)
Mean (SD) (range 1–5) (Cronbach's $a = 0.79$ )			
Intend to use condom at next sex, $n$ (%)	76 (55.1)	73 (56.6)	149 (55.8)
Sexual activity outcomes, among entire sample			
Ever had vaginal sex, $n$ (%)	37 (26.8)	24 (18.9)	61 (23.0)
Age at sexual initiation, mean (SD)	15 (1.7)	14 (1.4)	15 (1.6)
Had vaginal sex in past 6 months, $n$ (%)	32 (23.2)	19 (14.7)	51 (19.1)
Ever had anal sex, $n$ (%)	5 (3.8)	7 (5.7)	12 (4.7)
Diagnosed with STI in past 6 months, $n$ (%)	1 (0.8)	3 (2.4)	4 (1.6)
Contraceptive use in past 6 months, $n$ (%)			
Condom	26 (18.9)	18 (14.0)	44 (16.5)
Pill	3 (2.2)	3 (2.3)	6 (2.3)
Depo	4 (2.9)	3 (2.3)	7 (2.6)
	RCL intervention $(n = 37)$	Control $(n = 24)$	Total $(N = 61)$
Sexual activity outcomes, among youth that have ever had s	ex		
Had more than one sexual partner in past 6 months, $n$ (%)	10 (28.6)	5 (21.7)	15 (25.9)
Talked about using condoms at last sex, $n$ (%)	29 (78.4)	16 (69.6)	45 (75.0)
Condom use at last sex, $n$ (%)	26 (74.3)	17 (77.3)	43 (75.4)
Ever use withdrawal during sex, $n$ (%)	23 (65.7)	10 (47.7)	33 (58.9)
Frequency of sex with substance use, $n$ (%)			
Ever drink prior to sex	6 (17.7)	8 (36.6)	14 (25.0)
Ever use drugs prior to sex	4 (11.8)	7 (33.3)	11 (20.0)

they intended to use a condom at next sexual intercourse. Almost one quarter (23.0%) reported a history of vaginal sex, 19% in the past 6 months, with mean age of initiation of 14.6 years. Of those sexually active, three quarters said they had both talked about and used a condom at last sex. The majority ( $\sim$ 59%) of those sexually active had used withdrawal during sex; one quarter (25.0%) reported alcohol and 20.0% illicit drug use prior to sex.

Table 3. PMT construct scores at baseline, by treatment group.

	RCL intervention $(n = 138)$	Control $(n = 129)$	Total (N = 267)
PMT outcomes (all range from 1 to 5)			
Coping appraisal constructs			
Self-efficacy, mean (SD) (Cronbach's $a = 0.66$ )	4.3 (0.7)	4.2 (0.7)	4.3 (0.7)
Response efficacy, mean (SD) (Cronbach's $a = 0.69$ )	3.7 (0.7)	3.8 (0.8)	3.8 (0.7)
Response cost, mean (SD) (Cronbach's $a = 0.58$ )	2.8 (0.5)	2.9 (0.6)	2.9 (0.6)
Threat appraisal constructs			
Intrinsic rewards, mean (SD) (Cronbach's $a = 0.88$ )	1.6 (0.7)	1.7 (0.8)	1.6 (0.7)
Extrinsic rewards, mean (SD)* (Cronbach's $a = 0.72$ )	3.3 (0.8)	3.1 (0.7)	3.2 (0.8)
Severity, mean (SD) (Cronbach's $a = 0.42$ )	3.7 (0.6)	3.6 (0.7)	3.6 (0.7)
Vulnerability, mean (SD) (Cronbach's $a = 0.78$ )	1.6 (0.8)	1.7 (0.8)	1.7 (0.8)

p < 0.05 for test of between-group differences.

#### Protection motivation theoretical constructs

Study groups were equal with regard to all seven theoretical constructs, with the exception of the intervention group scoring higher on extrinsic rewards (3.3 vs. 3.1, p < 0.05; Table 3).

# Discussion

Results demonstrate that participants have a risk profile appropriate for study aims. Compared to other US-based samples that received FOY, our sample had higher rates of truancy (e.g., 29% vs. 16%), history of alcohol use (20% vs. 14%), and drug use (22% vs. 7%) at baseline (Li, Stanton, Feigelman, & Galbraith, 2002; B. Stanton et al., 1997; B. F. Stanton et al., 1996). Small proportions of youth believed abstinence and condom use prevent HIV/STIs (39% and 54%, respectively). Relative to other FOY trials at baseline, this sample reported greater condom use self-efficacy, lower rates of sexual activity (23% vs. 36-37%), and higher condom use intention (56% vs. 36%) (Gong et al., 2009; Kaljee et al., 2005; Lerdboon et al., 2008; Li et al., 2002; Lwin et al., 2010; B. Stanton et al., 1997; B. F. Stanton et al., 1996; Wu et al., 2003).

The customization of PMT constructs within this and other FOY samples make it difficult to draw direct comparisons. Generally, youth in our sample scored better on self-efficacy, response efficacy, intrinsic rewards, and vulnerability constructs and moderately on response cost, extrinsic rewards, and severity constructs (Gong et al., 2009; Kaljee et al., 2005; Lerdboon et al., 2008; Li et al., 2002; Lwin et al., 2010; B. Stanton et al., 1997; B. F. Stanton et al., 1996; Wu et al., 2003). Most of our scaled outcome measures had average to good Cronbach's  $\alpha$  scores with minimum values of 0.70, suggesting they will be effective markers of change over time in future analyses (Kline, 2000).

Statistically significant differences between RCL intervention and control groups at baseline including age and average extrinsic reward score, as well as peer group/team and camp cohort, will be adjusted for in the longitudinal analysis.

# Conclusions

This trial is unique in its utilization of basketball camps as an implementation and retention strategy of a community-based sample in a hard-to-reach population. Reliance on AI paraprofessionals as interventionists was innovative; they comprised a ready workforce who illuminated culturally meaningful aspects of RCL content and addressed a lack of skilled health educators in an under-resourced community (Barlow & Walkup, 2008; Barlow et al., 2013; Miller & Pylypa, 1995; Mullany et al., 2012; Roman et al., 2007).

If RCL is demonstrated efficacious, tribes may have a novel approach that is practical, culturally and contextually appropriate, and evidence-based to prevent HIV/ AIDS risk among adolescents. This is urgent for AI populations who are suffering from already high rates of STIs and related behavioral risk factors, the fastest increasing rates of HIV, and access barriers to treatment which contribute to higher case fatality due to AIDS.

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No potential conflict of interest was reported by the authors.

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