


RESEARCH ARTICLE

Baseline results from *NenUnkUmbi/EdaHiYedo*: A randomized clinical trial to improve sexual and reproductive health among American Indian adolescents

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Abstract

We report on baseline findings from *NenUnkUmbi/EdaHiYedo*, a community based participatory research randomized controlled trial with American Indian adolescents to reduce sexual and reproductive health disparities. American Indian adolescents aged 13–19 years participated in a baseline survey that was administered in five schools. We used zero-inflated negative binomial regression to evaluate how the count of protected sexual acts was associated with independent variables of interest. We stratified models by self-reported gender of adolescents and tested for a two-way interaction effect between gender and the independent variable of interest. Two hundred twenty-three girls and 222 boys ($n = 445$) were sampled. The average number of lifetime partners was 1.0 (standard deviation = 1.7). Each additional lifetime partner was associated with a 50% increase in the number of protected sexual acts incident rate ratio (IRR = 1.5, 95% confidence interval [CI] 1.1–1.9) and more than a twofold increase in the likelihood of not having protected sexual acts (adjusted odd ratio [aOR] = 2.6, 95% CI 1.3–5.1). Each additional number of substances used in adolescents' lifetime was associated with an increased likelihood of not having protected sexual acts (aOR = 1.2, 95% CI 1.0–1.5). In boys, each one standard deviation increase in depression severity was associated with a 50% reduction in the number of times a condom was used adjusted IRR (aIRR = 0.5, 95% CI 0.4–0.6, $p < .001$). Each 1-unit increase in positive prospectations of pregnancy was associated with a pronounced decrease likelihood of not having protected sexual acts (aOR = 0.01, 95% CI 0.0–0.1). Findings support the importance of tribally driven tailoring of sexual and reproductive health interventions and services for American Indian adolescents.

KEYWORDS

American Indian adolescents, community based participatory research, randomized control trial, sexual and reproductive health

1 | INTRODUCTION

1.1 | Sexual and reproductive health disparities among American Indian adolescents

American Indian adolescents experience more sexual and reproductive health inequities as compared to nonindigenous adolescents in the United States, including higher rates of teen birth, low birth weight, sexually transmitted infections,

hepatitis C virus, and human immunodeficiency virus (de Ravello et al., 2015; Kaufman et al., 2007; King Bowes et al., 2018; Martin et al., 2018). Such sexual and reproductive health disparities place American Indian adolescents at greater risk for miscarriages, still births, ectopic pregnancies, and infertility than nonindigenous adolescents and jeopardize the health of future generations of American Indian people.

Previous research has established several predictors of sexual and reproductive health disparities among American Indian adolescents brought about by centuries of settler colonialism, historical trauma, and cultural degrading. For example, substance use is associated with early sexual initiation and risky sexual behavior in American Indian adolescents (Kaufman et al., 2007; Markham et al., 2015). Chronic stress, negative life events, and prevalence of trauma have been linked to the comorbidity of substance use disorders and mental illness, such as depression and anxiety (Hellerstedt et al., 2006; Markham et al., 2015; Whitbeck et al., 2004). Poverty, isolation, and physical and sexual victimization have been identified as factors that influence unintended pregnancies and sexually transmitted infections among American Indian adolescents (Rutman et al., 2012; Sarche & Spicer, 2008; Whitesell et al., 2014). Self-reported confidence in ability to use protective skills during sexual encounters and to avoid unsafe situations has been linked to lower risk sexual behavior for American Indian adolescents (Hellerstedt et al., 2006; Markham et al., 2015). Furthermore, ambivalence towards sex has been reported as a predictor of high risk sexual behavior for American Indian adolescents (Hellerstedt et al., 2006; Markham et al., 2015). Finally, in rural reservation communities American Indian adolescents sexual and reproductive health outcomes are exacerbated by physical and structural barriers to care, including long travel distances, few clinical locations, limited access to comprehensive sexual health education, and discrimination in medical settings (Cahn et al., 2019; Kaufman et al., 2007; Whitbeck et al., 2004).

1.2 | Tribally centered community based participatory research interventions for American Indian adolescents

The complex factors that influence sexual and reproductive health disparities among American Indian adolescents warrant novel multilevel, interventions that are centered in cultural beliefs and practices as well as the context in which American Indian adolescents live. However, mistrust of research and researchers from outside tribal communities persists among American Indian people due to the legacy of neglect and betrayal by the United States government and by nonindigenous research groups (Christopher et al., 2008; Cochran et al., 2008; Smith, 2012). This mistrust has impeded cooperation between tribal communities and outside researchers to design, implement, and evaluate effective clinical trial interventions to address sexual and reproductive health disparities among American Indian adolescents (Christopher et al., 2008; Cochran et al., 2008; Smith, 2012).

Community based participatory research has become an established methodological framework for multisectoral, multilevel stakeholder partnering with American Indian communities to overcome the legacy of research mistrust (Gavin et al., 2014; Wallerstein & Duran, 2006; Wallerstein et al., 2017). At present, there is growing scientific evidence for how CBPR is used to develop, adapt, and implement interventions, such as randomized control trials (RCTs), with tribal communities in the United States because the use of community based participatory research supports collaborative intervention design, implementation, and evaluation between tribal and academic partners (Crump et al., 2020; Rink, Knight, et al., 2020).

Given the existing data that underscores the substantial sexual and reproductive health disparities among American Indian adolescents, there is an acute need for the rigorous testing of interventions using randomized controlled trial designs that are developed in collaborative tribal-academic partnerships using a community based participatory research framework. Intervention science research with tribal communities indicates a need for the integration of Indigenous Research Methods with western science to examine the cultural, ecological perspective, and political contexts within randomized controlled trial designs (Allen et al., 2018; Moilanen et al., 2014). Furthermore, methodological innovations must be explored that can address statistical power, concepts of validity, and generalizability with small populations, such as Indigenous communities in the United States (Rasmus et al., 2019). And, finally, an examination of what constitutes fidelity, acceptability, and sustainability with respect to randomized controlled trials implemented with tribal communities is needed (Romero et al., 2015; Rushing et al., 2017; Whitesell et al., 2020).

1.3 | Purpose

In this manuscript we present the baseline results of *NenUnkUmbi/EdaHiYedo* a 6-year tribally centered community based participatory research randomized controlled trial with the Fort Peck Tribes (Assiniboine and Sioux). The translation of *NenUnkUmbi/EdaHiYedo* stands for the term, "We are here now," to represent the coming of age ceremonies for Assiniboin and Sioux American Indian adolescents. The overall aim of *NenUnkUmbi/EdaHiYedo* is to test the efficacy of a multi-level,

multi-component intervention to prevent sexually transmitted infections, human immunodeficiency virus, hepatitis C virus, and teen pregnancy among American Indian adolescents. The findings reported in this manuscript establish *NenUnkUmbi/EdaHiYedo's* baseline data for our outcomes variables which include sexual behavior, substance use, psychosocial factors, prospections of pregnancy consequences, and sexual and reproductive health self-efficacy. We pay particular attention in this manuscript to the development of our data collection instrument, implementation of our data collection, and our collaborative data analysis process with tribal partners. In addition we address how we determine the meaning of our baseline findings within the context of establishing efficacy for our intervention.

2 | METHODOLOGY

2.1 | Setting

Our study takes place on the Fort Peck Reservation (herein referred to as Fort Peck) located in northeastern Montana. The reservation is located in a northern plains prairie environment, spans 2.1 million acres, and includes 3200 square miles. Approximately 8000 enrolled members of the tribes live on the reservation. *NenUnkUmbi/EdaHiYedo* is implemented in five schools that serve American Indian adolescents living on the reservation. The study's five participating schools are located in separate, culturally distinctive communities that are separated by 10–30 miles each across the reservation. The five schools vary in student body population, ranging from 40 students to 250 students.

2.2 | Tribal-Academic partnership

NenUnkUmbi/EdaHiYedo was designed within the context of a 17 year tribal-academic partnership and based on the Fort Peck Tribal Council's desire to implement a holistic sexual and reproductive health intervention for American Indian adolescents at Fort Peck that intervene at multiple levels within tribal adolescents human ecology. The details of the research leading up to *NenUnkUmbi/EdaHiYedo's* design and implementation are published elsewhere (Rink et al., 2022). *NenUnkUmbi/EdaHiYedo's* research team consists of three tribal members and two tribal elders that implement the study at the reservation through Fort Peck Community College and the Fort Peck Tribes Language and Culture Department. Other research team members include the nonnative Principal Investigator at Montana State University, a Native Coinvestigator at Northern Arizona University, and the study's lead analyst, a nonnative Coinvestigator at Florida International University. A nonnative graduate research assistant at Montana State University conducts data management for the study. A 5-member community advisory board of tribal members provides project implementation oversight, methodological guidance, cultural and local interpretation of the data collected in the study, and suggestions about how and with whom to share the research results. The community advisory board members were selected by the Fort Peck Tribal Council based on their knowledge of the multiple interconnected issues influencing sexual and reproductive health at Fort Peck, their respect within the communities across the reservation, and their understanding of Assiniboine and Sioux culture. In addition, the research team members at Fort Peck and *NenUnkUmbi/EdaHiYedo's* principal investigator met with and discussed the overall vision and purpose of the study as well as their roles as community advisory board members. In accordance with National Institute of Health policies for clinical trials, *NenUnkUmbi/EdaHiYedo* also includes a data safety monitoring board to review adherence to the study's research protocols.

2.3 | *NenUnkUmbi/EdaHiYedo's* community based participatory research randomized controlled trial design

The research team's previous community based participatory research studies with the Fort Peck Tribes have demonstrated that sexual and reproductive health disparities among American Indian adolescents are markers of underlying issues operating and interacting at the individual, family, school, community, and systems levels within American Indian communities (Anastario, FireMoon, Ricker, et al., 2020; Anastario, FireMoon, Rink, 2020; Rink, Knight, et al., 2020). The interconnectedness of these different levels in the human ecology of American Indian adolescents were foundational to *NenUnkUmbi/EdaHiYedo's* design. *NenUnkUmbi/EdaHiYedo* is a multilevel, multicomponent sexual and reproductive health intervention, constructed on Bronfenbrenner's Ecological Systems Theory (Bronfenbrenner, 1995, 1999) and intervenes at the individual, family, cultural, and system levels within an adolescents life. *NenUnkUmbi/EdaHiYedo* includes an individual level school-based sexual and reproductive health skill building and education component, a parent education level, a cultural mentoring program at the community level, and at the system's level the coordination of sexual and reproductive health services for American Indian adolescents living on the reservation. *NenUnkUmbi/EdaHiYedo* uses a cluster randomized

stepped wedge design, in which the five reservation-based schools are the clusters randomized into the intervention one at a time, with all schools eventually being randomized to the intervention (Mdege et al., 2011; Woertman et al., 2013). Data reported here comprise the baseline observations for American Indian adolescents from the five schools participating in *NenUnkUmbi/EdaHiYedo*. These data lay the foundation for determining the efficacy of our multilevel intervention to reduce sexual and reproductive health disparities among American Indian adolescents.

2.4 | Participants

Study participants ($n = 445$) include male and female American Indian adolescents ages 13–19 in grades 9th–12th who attend school from the reservation. Inclusion criteria for participation in *NenUnkUmbi/EdaHiYedo* and our baseline data collection was: (1) adolescents ages 13–19 years old; (2) adolescents who were a registered member of a federally recognized American Indian tribe; and (3) adolescents who lived on the reservation with a parent/legal guardian.

2.5 | Recruitment and consent

Members of *NenUnkUmbi/EdaHiYedo*'s research team, including the Fort Peck tribal members of the research team and the principal investigator, collaborated with the teachers and administrators of the five schools participating in the study to recruit adolescents and at least one parent/legal guardian to participate in the study. This process included several meetings with teacher and administrators to discuss the study, the content of the survey, and plan the recruitment. Study participants were recruited via mail, during parent–teacher conferences, and by word of mouth. In addition, the tribal and academic research team members and community advisory board members made presentations with parent organizations, schools boards, as well as with health and social service organizations on the reservation about the study. Consent for adolescents participation in the study was obtained from a parental/legal guardian. Adolescents provided written and verbal assent for their participation in the study.

2.6 | Data collection

The baseline data collection took place in Spring 2019, one year before the COVID-19 pandemic. The baseline data collection was administered by the tribal members working on *NenUnkUmbi/EdaHiYedo*'s research team. The data was collected on password protected iPads using the REDCap electronics data capture tools (Harris et al., 2009). Students completed a 12-section survey during a 45-min classroom period. Each student's survey responses were collected on the iPads using a unique study identification number for that particular student. Students were placed in the classroom at least 6 feet apart. The survey instructions, an overview of the survey content, and the purpose of *NenUnkUmbi/EdaHiYedo* was provided to the students before the start of the data collection. Surveys took 30–45 min to complete. Students received incentives for completing the survey in the form of a \$10.00 gift card for iTunes. Students who were not present at the time of the survey administration were followed up with the next school day to complete the survey.

2.7 | Survey instrument development

The development of the survey used for our baseline data collection involved a collaborative dialog between the members of the study's community advisory board and the research team members. First, advisory board and research members reviewed and discussed the findings from our previous community based participatory research studies with tribal adolescents and compared these previous community based participatory research studies of ours with existing research on sexual and reproductive health with American Indian adolescents. Second, from this work we identified our primary, secondary, and tertiary outcome variables to address in our intervention. Third, *NenUnkUmbi/EdaHiYedo*'s university based investigators drew on several existing measures that had been implemented and validated in research studies with American Indian adolescents to develop the survey instrument (DiClemente et al., 2007; Kaufman, 2012; Kaufman et al., 2010, 2014; Moilanen et al., 2014; Rushing & Gardner, 2016; Schuster et al., 2008; Schweigman et al., 2011; Smith & DiClemente, 2000; Smith & Rushing, 2011; Tingey et al., 2015; Villarruel et al., 2008; Whitesell et al., 2012; Whitesell et al., 2014). Fourth, once the survey instrument was developed using the primary, secondary, and tertiary outcome variables agreed upon between the community advisory board members and the research team, the survey instrument was reviewed and discussed one additional time for any final edits and a final approval from the advisory board members.

2.8 | Measures

The measures used for *NenUnkUmbi/EdaHiYedo*'s baseline data collection are presented below.

2.8.1 | Sexual behavior

Our primary outcome measure is the number of times a condom was used during vaginal or anal sexual intercourse in the month preceding the questionnaire. Adolescents were asked the question “During the past month, how many TIMES have you had sex?” followed by “Of the times you had sex over the past month, how many TIMES was a condom used?” The frequency of condom use variable ranged from 0 to 20. We truncated the variable at the 99th percentile of its distribution (8 protected sex acts). Over four fifths of the sample provided a zero response (84.0% girls and 84.3% boys). The final variable had a mean of 0.4 and a standard deviation of 1.2.

2.8.2 | Substance use

Participants reported both their lifetime and recent (past 30 days) number of instances of illicit substance use, including alcohol, marijuana, meth, cocaine, ecstasy, and inhalants. We developed two measures from these items: overall number of substances used during the lifetime (range 0–5), and overall number of substances used within the past 30 days (range 0–4).

2.8.3 | Depression

We used an adapted version of the Center for Epidemiologic Studies-Depression 10 scale that was previously tested among American Indian college students to develop a measure of depression severity (Beals et al., 1991). Respondents reported on 7 items indicating frequency of depressive feelings within the last week using a Likert scale (1 = None of the time/0 days; 2 = Rarely or a little of the time/1–2 days; 3 = Some of the time/3–4 days; 4 = Most or all of the time/5–7 days). Seven items derived from the Center for Epidemiologic Studies-Depression 10 were summed and standardized, with higher scores corresponding to greater depression severity. The Cronbach's α coefficient for the Center for Epidemiologic Studies-Depression 10 is 0.80.

2.8.4 | Life events

We administered a version of the Negative Life Events Scale that was adopted from Pathways of Choice survey (Novins & Mitchell, 1998). The 24-item set asked respondents to report if they had experienced specific stressful life events (Yes/No). We summed all items to develop a measure that represents overall number of life events occurring in the past year, ranging from 0 to 24.

2.8.5 | Prospections of pregnancy consequences

We adapted questions regarding beliefs about pregnancy consequences among adolescents from Pathways of Choice to measure participants' level of agreement with 13 statements regarding a prospective pregnancy and a Cronbach's α coefficient of .70 (C. Mitchell et al., 2000; Rink et al., 2017). Responses were scored using a 3-point Likert scale to evaluate level of agreement (1 = Disagree; 2 = Neither agree nor disagree; 3 = Agree). An exploratory factor analysis supported a two factor solution: one factor representing “negative prospections” (which included items such as “It would take away my freedom,” “It would interfere with my plans,” and “It would make it difficult to stay in school”) and the other factor representing “Positive prospections,” (which included items such as “It would give my life direction,” “I would consider it a great gift,” and “It would encourage me to keep my job or look for a better job”).

2.8.6 | Birth control selection

Respondents were asked to evaluate important characteristics when selecting a birth control method using 6 items selected from the Contraceptive Attributes Questionnaire (Beckman et al., 1992). The Cronbach's α coefficient for the Contraceptive

Attributes Questionnaire is 0.60. Responses were scored using a 5-point Likert scale indicating how important the characteristic was in selection (1 = Not important; 2 = Slightly important; 3 = Moderately important; 4 = Very important; 5 = Extremely important). An exploratory factor analysis supported a two-factor solution, and we chose to only examine the factor representing “convenience” for the purposes of this analysis.

2.8.7 | Condom use self-efficacy

We derived 3 items from the original 28-item Condom Use Self-Efficacy Scale that correspond to the “intoxicant” subscale (Brafford & Beck, 1991; Brien et al., 1994). This version of the Condom Use Self-Efficacy Scale has been used in other research with American Indian adolescents and included culturally adapted language (C. Mitchell et al., 2000). The Cronbach's α coefficient for these three items was 0.91. Respondents were asked to indicate their level of agreement with self-efficacy statements using a 3-point Likert scale (1 = Disagree; 2 = Neither agree nor disagree; 3 = Agree). Items were scored such that a higher score correlated to higher condom use self-efficacy while intoxicated. We developed one latent factor to represent condom use self-efficacy while intoxicated.

2.8.8 | Sexual refusal self-efficacy

Participants responded to a 7-item sexual refusal skill self-efficacy scale previously tested in Native STAND sexual health intervention for American Indian adolescents (Craig Rushing, 2016; C. M. Mitchell et al., 2017; Smith & Rushing, 2011). The Cronbach's α coefficient is .80. Items were scored on a 5-point Likert scale measuring ability to refuse sex in various circumstances (1 = I definitely can say no; 2 = I can say no; 3 = I don't know; 4 = I can't say no; 5 = I definitely can't say no). An exploratory factor analysis supported a one-factor solution, which was used for the purpose of this analysis.

2.8.9 | Demographics

Control variables included sex, age, and site of data collection. Sex was measured as a nominal variable (1 = male, 2 = female, 3 = neither male nor female). Age was measured by the participants being asked to fill in on the survey how old they were in years. The site of data collection was inputted by the research team during before the data collection taking place.

2.9 | Statistical analysis

Our data analysis was conducted in two phases. Phase One included a quantitative analysis based on standard western science practices for statistical analysis. Phase Two included an iterative conversation amongst *NenUnkUmbi/EdaHiYedo's* advisory board and research team members to interpret and present the results of the quantitative analysis in a way that is reflective of the social-cultural context of the reservation and centers the results in a tribal perspective. Phase Two was grounded in *NenUnkUmbi/EdaHiYedo's* community based participatory research framework and addressed the ongoing importance of decolonizing research methods in partnership with tribal communities (Dickerson et al., 2020; Walters et al., 2020).

For the first phase of the data analysis STATA 14.1 was used (StatCorp, 2015). During this first phase we examined the relationship of the dependent variable to substance use, depression, life events, prospections regarding pregnancy, and self-efficacy measures controlling for potential confounders. We then conducted a test of overdispersion of the dependent variable (a count variable) by evaluating the z statistic, and chose to use negative binomial regression as opposed to Poisson regression (Cameron & Trivedi, 1986). Further, the elevated prevalence of 0's in the dependent variable (84.2%) suggests zero-inflated models. We used zero-inflated negative binomial regression to evaluate a negative binomial equation predicting the count of events for adolescents not in the zero group, and a logit equation predicting membership in the zero group, with two sets of parameters estimated. In all zero-inflated negative binomial regression models, we controlled for the potentially confounding effects of gender, age, and number of lifetime partners, we offset the models by the number of sexual acts in the month proceeding the survey, and we adjusted for clustering of the error by site. We used the adjusted incident rate ratio (aIRR) to interpret effects of the independent variables on the count of protected sexual acts, and the adjusted odds ratio (aOR) to interpret the effects of the independent variables on membership in the zero group. We also stratified each model by self-reported gender of adolescents and tested for a two-way interaction effect between gender and the independent variable of interest.

For the second phase of the data analysis, advisory board and research team members discussed the results of the quantitative analysis during a regularly scheduled quarterly joint meeting. This discussion focused on talking about the findings for the variables analyzed in the first phase of data analysis and situating these findings within the context of the

reservation. Emphasis was placed on interpreting the quantitative data analysis with an understanding of the social-cultural environment that adolescents on the reservation live in. Particular attention was given to how to present the findings that is reflective of a tribal perspective. Through this discourse, consensus was reached among the advisory board and research team members regarding how to interpret and present the data in this manuscript.

3 | RESULTS

3.1 | Demographics

Of all adolescents sampled, 445 (223 girls and 222 boys) responded to questions regarding the variables of interest. On average, boys were 0.4 years older than girls sampled (15.8 vs. 15.4, $|t| = 2.2$, $p < .05$). The average number of lifetime partners in the sample was 1.0 (standard deviation [SD] = 1.7). Most participants were from School 1 (212) and School 3 (150), followed by School 4 (41), School 2 (28), and School 5 (25).

3.2 | Sexual risk

Of all potential confounders examined, each additional lifetime partner was associated with a 50% increase in the number of protected sexual acts (IRR = 1.5, 95% confidence interval [CI] 1.1–1.9, $p < .01$) as well as more than a twofold increase in the likelihood of not having any protected sexual acts (aOR = 2.6, 95% CI 1.3–5.1, $p < .01$) (Table 1).

3.3 | Substance use

On average, adolescents described using 1.3 substances in their lifetime (SD = 1.2) and 0.7 substances in the past month (SD = 1.0). Neither of the substance use measures were associated with a change in the positive count of protected sexual acts. Each additional number of substances used in adolescents' lifetime was associated with an increased likelihood of not having any protected sexual acts (aOR = 1.2, 95% CI 1.0–1.5, $p < .05$). For substance use in the 30 days preceding the survey, gender-differentiated effects were observed (Table 2). Each additional number of substances used in the 30 days preceding the survey was associated with more than a fourfold increase in the likelihood of not having any protected sexual acts for boys (aOR = 4.8, 95% CI 1.8–12.4, $p < .01$), which was pronounced in comparison to the insignificant effect for girls (aOR = 1.2, 95% CI 0.4–3.6, $p > .05$) (Table 2).

3.4 | Depression

On average, adolescents had a depression severity score of 14.0 (SD = 6.5) and reported 8.4 life events in the year preceding the survey (SD = 4.7). In boys, each one standard deviation increase in depression severity was associated with a 50% reduction in the number of times a condom was used (aIRR = 0.5, 95% CI 0.4–0.6, $p < .001$). This difference did not have a statistically stronger relationship in boys than girls. Each additional life event was associated with a 4% increase in the number of protected sexual acts (aIRR = 1.04, 95% CI 1.0–1.07, $p < .05$), as well as a 1.1 increase in the likelihood of not having any protected sexual acts (aOR = 1.1, 95% CI 1.0–1.1, $p < .05$) (Table 3).

3.5 | Prospections of pregnancy

Negative prospections of pregnancy were not associated with condom use, but each 1-unit increase in the positive prospections factor score was associated with a pronounced decrease likelihood of not having any protected sexual acts (aOR = 0.01, 95% CI 0.0–0.1, $p < .01$) (Table 4).

3.6 | Birth control

A one-unit increase in the birth control selection attitudes factor score was associated with a decreased likelihood of not having any protected sexual acts (aOR = 0.6, 95% CI 0.4–0.7, $p < .001$). A one-unit increase in the refusal skill self-efficacy

TABLE 1 Sample characteristics and the number of protected anal or vaginal sexual intercourse acts, past month, total sample and by gender: results of zero-inflated negative binomial regression ($n = 445$).

Characteristic of respondent	Total ($n = 445$)	Males ($n = 222$)	Females ($n = 223$)	Effects	95% CIs
Negative binomial equation^a					
Gender ^b	50.0%	–	–	1.3	(0.6–2.8)
Age, (mean, SD)	15.6 (1.5)	15.8 (1.5)	15.4 (1.5)	1.1	(0.9–1.4)
No. lifetime partners, (mean, SD)	1.0 (1.7)	1.0 (1.7)	1.1 (1.7)	1.5**	(1.1–1.9)
Site					
School 1, n (%)	212 (46.5%)	106 (47.8%)	104 (46.9%)	–	
School 2, n (%)	28 (6.1%)	12 (5.4%)	13 (5.9%)	0.9	(0.2–3.2)
School 3, n (%)	150 (32.9%)	81 (36.5%)	66 (29.73%)	1.0	(0.5–2.3)
School 4, n (%)	41 (9.0%)	14 (6.3%)	25 (11.3%)	0.6	(0.1–2.9)
School 5, n (%)	25 (5.5%)	9 (4.1%)	14 (6.3%)	1.7	(0.4–6.3)
Logit equation^c					
Gender ^b				0.6	(0.1–4.6)
Age				1.3	(0.6–2.7)
No. lifetime partners				2.6**	(1.3–5.1)
Site					
School 1				–	
School 2				0.0	(0.0–0.0)
School 3				6.5	(0.9–49.2)
School 4				0.2	(0.0–379.8)
School 5				0.0	(0.0–0.0)
Alpha				2.1***	
–2 log likelihood				247.3	
Adj. McFadden's R^2				0.15	

Abbreviations: CI, Confidence Intervals; SD, Standard Deviation.

^aIncident Rate Ratios are the effects presented;

^bEstimates are for males, referents are females;

^cOdds Ratios are the effects presented.

** $p < .01$; *** $p < .001$.

score was associated with a 20% increase in the number of protected sexual acts in boys (aIRR = 1.2, 95% CI 1.1–1.2, $p < .001$), which was opposite the effect for girls (Table 5).

4 | DISCUSSION

NenUnkUmbi/EdaHiYedo's baseline results identify key behaviors that position our community based participatory research randomized controlled trial to evaluate sexual and reproductive health disparities among American Indian adolescents using a multilevel multicomponent intervention. Two types of condom users are evident in our baseline sample.

Our first type of condom user, American Indian adolescents with more lifetime partners over the course of time, may perceive their sexual relationships to be casual or not committed. A perception of a more casual or noncommittal relationship may contribute to American Indian adolescents with more lifetime partners perceiving that they are at risk for acquiring sexually transmitted infections, human immunodeficiency virus, and having an unintended pregnancy. Perceived risk of acquiring an sexually transmitted infection, including the human immunodeficiency virus, or having an unintended pregnancy increased their likelihood of using condoms during sex. Our second type of condom user, American Indian

TABLE 2 Number of protected anal or vaginal sexual intercourse acts, past month in relation to lifetime and past 30 day substance use, total sample and by gender: results of zero-inflated negative binomial regression ($n = 445$).^a

	Total	Males ($n = 222$)	Females ($n = 223$)	Sig. Diff in Effects by Gender
Lifetime recall period				
Negative binomial equation ^b				
Number of substances used	1.1 (0.9–1.4)	1.1 (0.9–1.3)	1.3 (1.0–1.7)	NS
Logit equation ^c				
Number of substances used	1.2* (1.0–1.5)	7.1 (0.4–110.6)	0.7* (0.6–1.0)	NS
Alpha	2.1*	2.4*	1.8*	
–2 log likelihood	247.2	119.8	124.1	
Adj. McFadden's R^2	0.19	0.17	0.2	
Past 30 days recall period				
Negative binomial equation ^b				
Number of substances used	1.2 (0.9–1.5)	1.1 (0.9–1.4)	1.2 (0.9–1.8)	NS
Logit equation ^c				
Number of substances used	1.6 (0.7–4.0)	4.8** (1.8–12.4)	1.2 (0.4–3.6)	*
Alpha	2.2*	2.4*	1.9***	
–2 log likelihood	249.8	123.2	124.6	
Adj. McFadden's R^2	0.19	0.16	0.19	

Abbreviations: CI, Confidence Intervals; NS, Not Significant.

^aCoefficients have been adjusted for the potentially confounding effects of age and number of lifetime partners and offset by number of sexual acts, and standard errors have been adjusted for clustering by study site;

^bIncident Rate Ratios and 95% CIs are presented;

^cOdds Ratios and 95% CIs are presented.

* $p < .05$; ** $p < .01$; *** $p < .001$.

adolescents with multiple lifetime partners with no current use of condoms, may perceive their sexual relationships as longer term and, as such, not at risk for sexually transmitted infections, human immunodeficiency virus, or unintended pregnancy. This aforementioned finding supports our previous research with late adolescent American Indian males which found that condom use decreased over time in longer term relationships even though our sample of late adolescent American Indian males reported that they did not perceive they were currently in committed long-term relationships (Rink et al., 2017). Both types of condom users in our study suggest that relationship characteristics may influence condom use behavior and provides insights into how perceptions of sexual relationships may influence condom use behaviors among American Indian adolescents.

Other findings related to condom use in our baseline results are noteworthy. The overall number of substances recently used in American Indian boys was strongly associated with no condom use. This association was not statistically significant for American Indian girls. We also found condom use self-efficacy was associated with increased protected sex for American Indian boys but not American Indian girls. These findings are supported by Chambers and colleagues who found that American Indian males and females make different decisions regarding their sexual behavior which impacts their condom use (Chambers et al., 2016). These findings also highlight the importance of examining more nuanced linkages between condom use, substance use, self-efficacy and gender among American Indian adolescents (Chambers et al., 2016; Kaufman et al., 2007; Rosenstock et al., 2020; Tingey et al., 2020).

Our baseline results also demonstrated that depression and life-time adverse events were associated with a significant reduction in condom use among American Indian boys and girls. The current literature related to American Indian adolescents and mental health demonstrates a relationship between depression, anxiety, and sexual risk behaviors (Kaufman et al., 2007; Kaufman et al., 2017). Our earlier research with the Fort Peck Tribes also found a strong association between mental health, the legacy of sexual violence and trauma with sexual risk behaviors in American Indian adolescents and young adults. The clustering of depression, anxiety, and experiences of trauma that influence sexual risk behaviors among American

TABLE 3 Number of protected anal or vaginal sexual intercourse acts, past month in relation to depression and life events, total sample and by gender: results of zero-inflated negative binomial regression ($n = 445$).^a

	Total	Males ($n = 222$)	Females ($n = 223$)	Sig. Diff in Effects by Gender
Depression model ^a				
Negative binomial equation ^b				
Depression severity, past week ^c	0.6 (0.4–1.0)	0.5*** (0.4–0.6)	0.7 (0.5–1.1)	NS
Logit equation ^d				
Depression severity, past week	0.8 (0.03–24.1)	0.0*** (0.0–0.0)	1.0 (0.4–2.9)	**
Alpha	2.3**	3.0***	1.8***	
–2 log likelihood	237.7	116.3	117.0	
Adj. McFadden's R^2	0.19	0.18	0.20	
Life events model ^a				
Negative binomial equation ^b				
Life events, past year ^e	1.0* (1.0–1.1)	1.0 (1.0–1.1)	1.0 (1.0–1.1)	NS
Logit equation ^d				
Life events, past year	1.1* (1.0–1.1)	1.1 (0.9–1.4)	1.1 (0.8–1.4)	NS
Alpha	2.3*	2.7**	1.8***	
–2 log likelihood	231.6	108.7	122.3	
Adj. McFadden's R^2	0.18	0.14	0.19	

Abbreviations: CI, Confidence Intervals; NS, Not Significant.

^aCoefficients have been adjusted for the potentially confounding effects of age and number of lifetime partners and offset by number of sexual acts, and standard errors have been adjusted for clustering by study site;

^bIncident Rate Ratios and 95% CIs are presented;

^cDepression scores are derived from a 7-item symptom severity summary score ranging from 7 to 28, which was then standardized before being entered into the model;

^dOdds Ratios and 95% CIs are presented;

^eLife events are derived from a 24-item inventory summary score ranging from 0 to 24 life events.

* $p < .05$; ** $p < .01$; *** $p < .001$.

Indian adolescents warrant further investigation by gender to provide more nuanced understandings of how mental health may impact American Indian boys and girls sexual risk behaviors differently.

Overall, our findings related to condom use suggest that teaching American Indian adolescents the skills necessary to understand and negotiate sexual relationship dynamics, emotions, and behaviors that may influence condom use may be an effective strategy to decrease sexual risk taking in relationships. This strategy supports tribal cultural values regarding respecting one's body and personal identity as well as honoring relationships with others (Rouner et al., 2015; Rushing et al., 2017). Deeper insights into gender are particularly important given the difference in traditional cultural teachings related to gender in American Indian communities versus the contemporary gender norms for American Indian adolescents in reservation communities (Hanson et al., 2014; Kaufman et al., 2017; Tingey et al., 2020).

Finally, we would like to highlight our results that suggest positive perceptions of pregnancy are associated with decreases in protected sex among our sample of American Indian adolescents. These findings warrant specific attention given the traditional cultural belief in some American Indian communities that children are a gift from the Creator regardless of what stage of life the parents are in when a pregnancy occurs (Deloria, 2003; Miller, 2012; Red Horse, 1997). In traditional American Indian communities, the raising of children was shared with grandparents, aunts and uncles taking a primary role in child rearing with shared parenting remaining prominent in contemporary American Indian families (Bigfoot & Funderburk, 2011; Red Horse, 1997). Taking into consideration traditional beliefs about pregnancy and cultural practices that support shared parenting, emerging research identifies the importance of involving parents and extended family members in culturally grounded sexual and reproductive health multilevel interventions for American Indian adolescents. Interventions that foster culturally appropriate discussions between adolescents, adults, and elders within families to strengthen the understanding of how to combine traditional American Indian cultural beliefs about pregnancy and the contemporary realities of social, educational, and economic challenges of having children at a young age even with family support are warranted (Rink, Anastario, et al., 2020; Tingey et al., 2017). Such interventions necessitate multilevel designs

TABLE 4 Number of protected anal or vaginal sexual intercourse acts, past month in relation to pregnancy prospections, total sample and by gender: results of zero-inflated negative binomial regression ($n = 445$).^a

	Total	Males ($n = 222$)	Females ($n = 223$)	Sig. diff in effects by gender
Negative prospections model ^a				
Negative binomial equation ^b				
Prospections score ^c	1.0 (0.9–1.2)	1.1 (0.8–1.5)	0.9 (0.5–1.7)	NS
Logit equation ^d				
Prospections score ^c	0.8 (0.4–1.4)	0.7 (0.1–6.8)	0.9 (0.3–2.6)	NS
Alpha	2.2*	2.6*	1.9**	
–2 log likelihood	250.4	124.6	125.0	
Adj. McFadden's R^2	0.18	0.15	0.19	
Positive prospections model ^a				
Negative binomial equation ^b				
Prospections score ^c	1.1 (0.9–1.3)	0.8 (0.6–1.1)	1.3 (0.7–2.3)	NS
Logit equation ^d				
Prospections score ^c	0.01** (0.0–0.1)	0.3* (0.1–0.7)	0.1 (0.0–3.1)	NS
Alpha	2.7**	1.1	1.9**	
–2 log likelihood	246.5	106.7	120.8	
Adj. McFadden's R^2	0.20	0.19	0.22	

Abbreviations: CI, Confidence Intervals; NS, Not Significant

^aCoefficients have been adjusted for the potentially confounding effects of age and number of lifetime partners and offset by number of sexual acts, and standard errors have been adjusted for clustering by study site;

^bIncident Rate Ratios and 95% CIs are presented;

^cProspection scores are derived from an exploratory factor analysis with a two-factor solution;

^dOdds Ratios and 95% CIs are presented.

* $p < .05$; ** $p < .01$.

that give voice to the integration of traditional knowledge, beliefs, and practices that honor the importance of family and tribal culture within the day to day contemporary context of American Indian adolescents living on a reservation.

Our study had limitations. Our results are based on adolescent self-report and may not accurately represent true perceptions or behaviors. Our study is specific to adolescents living on a northern plains reservation and may not be generalizable to American Indian adolescents living on reservations in other parts of the United States or in urban areas. Members of *NenUnkUmbi/EdaHiYedo's* research team who live on the reservation and were known to the adolescents participating in the survey administered the baseline data collection which creates concerns with social desirability in a western science context. However, the importance of collaborating with tribal members who the community is familiar with for data collection to enhance community participation and trust in the research is well established within the community based participatory research literature (Christopher et al., 2008; Israel et al., 2008; Lucero & Roubideaux, 2020; Wallerstein & Duran, 2006). In addition, the measures used to assess perceptions of pregnancy, condom use self-efficacy, and sexual refusal self-efficacy although validated for American Indian adolescents are adaptations of existing sexual and reproductive health measures from nonnative adolescents populations were not specifically designed for American Indian adolescents. Therefore, culturally grounded perspectives of pregnancy, condom use, and sexual refusal skills may be lacking in the measures used in this study. As gender was measured using three categories (male, female, neither male, or female) based on recommendations from our community advisory board we are not able to assess gender along a continuum. Sexual intercourse was defined as vaginal or anal intercourse only in relationship to condom use. We were therefore not able to assess oral sex or other kinds of sexual activity in our sample, nor other kinds of protection such as dental dams. Finally, different polysubstance use combinations could not be examined in relation to sexual risk behavior in this sample due to the small proportion of participants reporting ecstasy or cocaine use. Future analyses focused within polysubstance using adolescents may illustrate differential sexual risk profiles in relation to the substances used.

TABLE 5 Number of protected anal or vaginal sexual intercourse acts, past month in relation to self efficacy, Total sample and by gender: results of zero-inflated negative binomial regression ($n = 445$).^a

	Total	Males ($n = 222$)	Females ($n = 223$)	Sig. Diff in Effects by Gender
Birth control selection ^a				
Negative binomial equation ^b				
Preference for convenience ^c	1.0 (0.9–1.0)	1.1** (1.0–1.1)	0.9 (0.7–1.2)	NS
Logit equation ^d				
Preference for convenience ^c	0.6*** (0.4–0.7)	1.2 (0.7–2.0)	0.3* (0.1–1.0)	NS
Alpha	2.2*	1.1	1.9***	
–2 log likelihood	236.8	98.5	119.5	
Adj. McFadden's R^2	0.19	0.19	0.20	
Condom use self-efficacy ^a				
Negative binomial equation ^b				
While intoxicated ^e	1.0 (0.9–1.1)	0.8 (0.7–0.9)***	1.0 (0.9–1.2)	NS
Logit equation ^d				
While intoxicated ^e	0.7 (0.3–1.4)	0.2*** (0.1–0.3)	0.8 (0.2–3.3)	NS
Alpha	2.2**	2.8*	1.9***	
–2 log likelihood	250.4	125.3	125.0	
Adj. McFadden's R^2	0.19	0.15	0.19	
Refusal skill self-efficacy ^a				
Negative binomial equation ^b				
Score	0.9 (0.7–1.1)	1.2*** (1.1–1.2)	0.7 (0.4–1.0)	*
Logit equation ^d				
Score	0.8 (0.2–2.7)	1.8 (0.6–5.5)	0.5*** (0.5–0.6)	NS
Alpha	2.3**	1.2	2.0***	
–2 log likelihood	220.7	100.3	106.7	
Adj. McFadden's R^2	0.18	0.18	0.19	

Abbreviations: CI, Confidence Intervals; NS, Not Significant.

^aCoefficients have been adjusted for the potentially confounding effects of age and number of lifetime partners and offset by number of sexual acts, and standard errors have been adjusted for clustering by study site;

^bIncident Rate Ratios and 95% CIs are presented;

^cBirth control attitudes scores are derived from an exploratory factor analysis of the Contraceptive Attributes Questionnaire, with higher scores representing more preference for more convenience in birth control;

^dOdds Ratios and 95% CIs are presented;

^eScores are derived from the latent factor representing the intoxicants subscale of the Condom Use Self Efficacy Scale;

^fScores are derived from an exploratory factor analysis of the 7-item refusal skill self-efficacy scale.

* $p < .05$; ** $p < .01$; *** $p < .001$.

5 | CONCLUSION

Previous interventions with American Indian adolescents on sexual and reproductive health have lacked an ecological design and implementation because it has neither addressed nor leveraged the interconnectedness of the individual, family, community, and larger systems in preventing sexually transmitted infections, human immunodeficiency virus, hepatitis C virus, and teen pregnancy (Goodkind et al., 2010; McMahon et al., 2015; Okamoto et al., 2014). *NenUnkUmbi/EdaHiYedo* is one of the few community based participatory research randomized controlled trials that tests the efficacy of a multilevel, multicomponent intervention to reduce sexual and reproductive health disparities among American Indian adolescents. Our baseline findings identify the importance of understanding condom use among American Indian adolescents within the

context of their perception of intimate relationships. Substance use, depression, anxiety, and exposure to trauma and their impact of sexual and reproductive health decision making and behavior warrant further investigation by gender. Understanding gender roles among American Indian adolescents and the overlay of traditional cultural beliefs and practices related to gender and sexual and reproductive health with contemporary gender norms in tribal communities may assist in tailoring sexual and reproductive health interventions for American Indian adolescents. Our baseline findings can assist in gender specific-tribally driven tailoring of sexual and reproductive health prevention interventions and services for American Indian adolescents. Furthermore, our baseline data collection and the first year of the intervention took place before the COVID-19 pandemic. The baseline data presented in this manuscript lay the foundation for future analysis that can assess the unanticipated 3-way interaction effects in RCTs with tribal communities as well as evaluate the impact of the COVID-19 pandemic on American Indian adolescents sexual and reproductive health.

NenUnkUmbi/EdaHiYedo's community based participatory research framework and long standing partnership models a way in which to decolonize research in collaboration with tribal communities. We accomplish the restructuring of research with tribal communities by privileging the perspectives *NenUnkUmbi/EdaHiYedo's* tribal community advisory board and research team members in the design, interpretation, and presentation of our study. Our ability to design, recruit, and implement *NenUnkUmbi/EdaHiYedo* in 5 different schools in 5 different communities on the reservation is possible due to several factors: (1) the respectful reputations of *NenUnkUmbi/EdaHiYedo's* community advisory board members and tribal research team members among families across the reservation and their deep contextual knowledge of the cultural and social norms on the reservation; (2) the Fort Peck Tribal Council's commitment to and support of the study; (3) the principal investigator's long term established partnership with the Fort Peck Tribal Council, Fort Peck Community College, and the Fort Peck Tribes Language and Culture Department as well as her understanding of the schools and communities participating in the study. Together *NenUnkUmbi/EdaHiYedo's* research team and community advisory board engaged in discussions about how to honor traditional cultural beliefs and practices with contemporary life on the reservation in the implementation of *NenUnkUmbi/EdaHiYedo*. Specifically we were attentive to how we understand and present the results of our study within a multidimensional social-cultural context on the reservation. It is through *NenUnkUmbi/EdaHiYedo's* transparent tribal-academic partnership that includes a consistent, iterative, and open dialog amongst *NenUnkUmbi/EdaHiYedo's* advisory board and research team that we contribute to generating new ways of understanding the efficacy of randomized controlled trials with tribal communities.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

ETHICS STATEMENT

Human subjects approval for this study was given by the Institutional Review Board at Montana State University and the Fort Peck Tribes Institutional Review Board. In addition, *NenUnkUmbi/EdaHiYedo's* community advisory board and the Fort Peck Tribes Institutional Review Board approved this manuscript for publication.

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