

Preventing Alcohol-Exposed Pregnancy Among an American Indian/Alaska Native Population: Effect of a Screening, Brief Intervention, and Referral to Treatment Intervention

Annika C. Montag, Stephanie K. Brodine, John E. Alcaraz, John D. Clapp, Matthew A. Allison, Daniel J. Calac, Andrew D. Hull, Jessica R. Gorman, Kenneth L. Jones, and Christina D. Chambers

Background: Fetal alcohol spectrum disorders are the result of alcohol-exposed pregnancies (AEP) and believed to be the leading known cause of developmental disabilities in the United States. Our objective was to determine whether a culturally targeted Screening, Brief Intervention, and Referral to Treatment (SBIRT) intervention may reduce risky drinking and vulnerability to AEP among American Indian/Alaska Native (AIAN) women in Southern California.

Methods: Southern California AIAN women of childbearing age who completed a survey including questions regarding alcohol consumption and contraceptive use were randomized into intervention or treatment as usual groups where the former group completed an online SBIRT intervention, and were followed up at 1, 3, and 6 months postintervention.

Results: Of 263 women recruited and 247 with follow-up data, one-third were at high risk of having an AEP at baseline. Both treatment groups decreased self-reported risky drinking behavior (drinks per week, p < 0.001; frequency of heavy episodic [binge] drinking episodes per 2 weeks, p = 0.017 and risk of AEP p < 0.001 at 6 months postintervention) in the follow-up period. There was no difference between treatment groups. Baseline factors associated with decreased risk of an AEP at follow-up included the perception that other women in their peer group consumed a greater number of drinks per week, having reported a greater number of binge episodes in the past 2 weeks, and depression/impaired functionality.

Conclusions: Participation in assessment alone may have been sufficient to encourage behavioral change even without the web-based SBIRT intervention. Randomization to the SBIRT did not result in a significantly different change in risky drinking behaviors. The importance of perception of other women's drinking and one's own depression/functionality may have implications for future interventions.

Key Words: Fetal Alcohol Spectrum Disorders, Native American Women, Alcohol, Prevention Research, Screening, Brief Intervention, and Referral to Treatment.

FETAL ALCOHOL SPECTRUM disorders (FASD), a range of conditions resulting from prenatal alcohol exposure, are the leading known cause of preventable

From the Department of Pediatrics (ACM, KLJ, CDC), University of California, San Diego, San Diego, California; Department of Family and Preventive Medicine (ACM, MAA), University of California, San Diego, San Diego, California; Division of Epidemiology and Biostatistics (SKB, JEA), San Diego State University, San Diego, California; Department of Social Work (JDC), The Ohio State University, Columbus, Ohio; Southern California Tribal Health Clinic (DJC), San Diego, California; Department of Reproductive Medicine (ADH), University of California, San Diego, San Diego, California; and Moores Cancer Center (JRG), University of California, San Diego, California.

Received for publication May 7, 2014; accepted October 17, 2014.
Reprint requests: Annika C. Montag, PhD, Division of Dysmorphology and Teratology, Department of Pediatrics, University of California, San Diego, 7910 Frost Street, San Diego, CA 92123; Tel.: 858-246-1755; Fax: 858-246-1793; E-mails: annikamontag@gmail.com, amontag@ucsd.edu Copyright © 2015 by the Research Society on Alcoholism.

DOI: 10.1111/acer.12607

developmental disabilities and learning disabilities. In the most severe form of FASD, fetal alcohol syndrome (FAS), fetal development is so affected as to result in neurobehavioral dysfunction, growth restriction, microcephaly, and characteristic facial features (Jones et al., 1973). FASD result in persistent deficits in cognitive and motor functions including learning and memory, complex thought, attention, and motor control, as well as psychosocial behavior (Secretary of Health and Human Services, 2000; Streissguth et al., 1978). Less severe forms of FASD are more difficult to identify but thought to be more prevalent. Specifically, current estimates are that FASD affects 2 to 5% of young elementary school children in the United States and that FAS may affect 0.2 to 0.7% (May et al., 2009). Significant variation in FASD prevalence among populations is associated with differences in magnitude and prevailing patterns of alcohol consumption as well as variability in how prevalence is measured. In addition, there may be modification of risk by nutritional status, maternal age, and genetics (May et al., 2011).

There is no known safe level of alcohol consumption during pregnancy. A recent study evaluating prenatal alcohol exposure and a number of outcomes including growth parameters, facial dysmorphology characteristic of prenatal alcohol exposure, and minor structural malformations found a linear relationship and no evidence of a threshold (Sawada Feldman et al., 2012). A review of well-controlled studies including 6 published studies examining the effect of low to moderate alcohol consumption on the cognitive, social, and emotional development of children found that 4 of the 6 showed an association between prenatal alcohol exposure and negative outcome (hyperactivity, behavioral problems, emotional problems, peer relationship problems, and attention deficit disorder) in children from 3 to 16 years (Holmgren, 2009). Despite current controversy (Kesmodel et al., 2012), there is at best inconclusive evidence of a threshold and the preponderance of data supports that there is no safe dose of prenatal alcohol exposure. One reason for the controversy is the difficulty involved in teasing out neurobehavioral effects of a particular exposure given the myriad potential confounders (nutrition, genetics, etc.; Coriale et al., 2014; May and Gossage, 2011). In 2005, the Surgeon General of the United States issued an advisory for all women who are pregnant or might become pregnant to not consume alcohol (Services, 2005).

However, the pattern of prenatal alcohol consumption associated with the greatest risk of FASD is heavy episodic drinking or binge drinking (Paintner et al., 2012). Binge drinking results in higher blood alcohol concentrations which are associated with greater injury to the fetus. Drinking a greater number of drinks per week or month also increases the risk of harm (Maier and West, 2001).

Timing of alcohol consumption during pregnancy influences the type of injury to the fetus; the particular injury is related to the developmental phase of the fetus at the time of exposure. A particularly sensitive time for the development of the brain and some of the characteristic dysmorphology associated with FAS occurs early in the first trimester (Roussotte et al., 2012). This is relevant as more than half of all pregnancies in the United States are unplanned (Finer and Zolna, 2011), and many women are unaware they are pregnant 4 to 6 weeks postconception (Floyd et al., 1999). To prevent alcohol-exposed pregnancies (AEP), it is therefore important to include all women of childbearing age who may consume alcohol in prevention/intervention.

While most women reduce or stop drinking alcohol upon becoming aware that they are pregnant, some groups of women appear to be at greater risk of continued drinking: women who are unmarried, unemployed, depressed, risky drinkers, exposed to violence, or simply confused by health warning messages and the amount of alcohol their drinks contain (Havens et al., 2009; Kaskutas, 2000; Skagerstróm et al., 2011). Drinking during pregnancy is heavily influenced by social norms and therefore varies widely among populations. For example, the percent of women who report drinking alcohol during pregnancy is 0% in Saudi Arabia, 6% in

Sweden (Nilsen et al., 2008), 7.4% in the United States (Marchetta, 2012), and 34% in New Zealand (Mallard et al., 2013). Similarly, among the limited populations studied, drinking during pregnancy among the heterogeneous American Indian/Alaska Native (AIAN) populations of the United States differs significantly. May and colleagues (2004) published data from a prenatal clinic among Northern Plains Indians indicating 16.2% of pregnant women consumed alcohol. Other AIAN studies have reported 36% of urban and 14% of reservation residing pregnant women consuming alcohol (Warren et al., 1990) and 53.4% at 1 prenatal clinic in the Northern Plains (Bad Heart Bull et al., 1999). Risky prepregnancy drinking is a strong predictor of drinking during pregnancy (Ethen et al., 2009). Further exacerbating risk are associations of binge drinking with increased risk of unintended pregnancies (Naimi et al., 2003). Within the population addressed in this study, approximately a third of women between the ages of 18 and 45 years are estimated to be at risk of having an AEP (Montag et al., unpublished

Effectiveness of FASD prevention strategies implemented among various AIAN populations was recently reviewed (Montag et al., 2012). Available evidence suggests that an effective intervention should strive to include local community members in all aspects of the program, create a relevant and understandable intervention recognizing specific risk and protective factors within the community, and address logistic barriers to participation.

Screening, Brief Intervention, and Referral to Treatment (SBIRT) is a prevention and early intervention approach that uses wide screening, education and feedback specific to the participant, and professional treatment for those identified by the screening as positive for alcohol abuse problems (Babor et al., 2007). The latter component, the incorporation of specialized treatment as warranted, sets the approach apart from those offering only brief interventions which have demonstrated largely positive but mixed results (Whitlock et al., 2004). Some reasons for lack of proven benefit may be that assessment alone may have a mitigating effect on risky drinking (although this has been controlled for in some studies) or that extreme risky drinking may decrease over time due to "regression toward the mean." Valuable lessons learned from Brief Intervention studies include that protocols with multiple contacts are more likely to alter behavior than single contact protocols (Longabaugh et al., 2001) and that effectiveness may be related to the severity of the underlying condition (Bernstein and Bernstein, 2008). SBIRT has been used to motivate a reduction in alcohol consumption in a number of populations including emergency room and other healthcare setting patients (Madras et al., 2009), college freshmen (Bezilla, 2010), and WIC participants (Delrahim-Howlett et al., 2011).

Within the Native American Research Centers for Health (NARCH) framework, this intervention sought to develop and test an SBIRT adaptation for reducing risky drinking in AIAN women of childbearing potential in Southern

128 MONTAG ET AL.

California. NARCH is an initiative funded through a partnership between the National Institutes of Health (NIH) and the Indian Health Service. As a NARCH project, the overarching goals go beyond the specific aims of any single study to address tribally identified health priorities, reduce distrust of research by the community, and develop future competitive AIAN researchers.

MATERIALS AND METHODS

Sample Source

The population sample consisted of AIAN women from 18 to 45 years of age, of childbearing potential, recruited from 1 of 3 AIAN health clinics located in Southern California between April 2011 and September 2012. The sample used for each analysis will vary and is described in association with the particular analysis.

Ethics

This protocol was approved by University of California, San Diego, San Diego State University, and Southern California Tribal Health Clinic Institutional Review Boards. A Certificate of Confidentiality was obtained from the NIH to further protect the confidentiality of participants' data. All research staff complete human research subject protections training.

Recruitment and Study Protocol

Potential participants were approached in waiting areas of health clinics and screened for eligibility (see Fig. 1 for study flowchart). Interested and eligible participants were brought to a private room where, following the consenting procedure, they were assigned a unique identification number, completed a paper-based self-administered baseline survey, and were randomized into the intervention or control group. Randomization was accomplished by the research assistant, in blinded fashion, pulling a label preprinted with either "intervention" or "control" from a single-study randomizing container containing equal numbers of each label. Participants randomized into the intervention group completed a web-based survey which provided personalized feedback including analysis of risk, advice, and helpful hints that could be printed out in a confidential manner. Participants randomized into the control group received

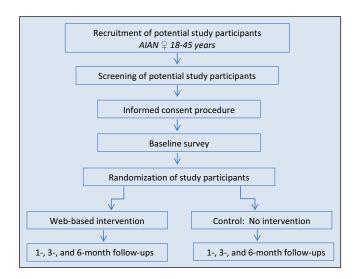


Fig. 1. Study flowchart.

"treatment as usual" which consisted of access to displayed educational brochures about health in the various waiting areas but did not include specific FASD information. All participants had the opportunity to request referral for treatment to a professional substance abuse counselor. At 1, 3, and 6 months following baseline assessment, participants were contacted by telephone to complete follow-up surveys. At each follow-up, participants were again offered referrals to treatment. Participants were provided incentives in the form of a \$10 gift card and the choice of a fan or T-shirt emblazoned with the project logo at enrollment and a \$15 gift card following completion of the final follow-up questionnaire. Additional retention incentives were added during the study to improve follow-up completion rates. Participants received 1 raffle ticket representing a chance to win a \$100 prize for each completed follow-up interview.

Data Collection

Data were collected on 3 separate occasions during the study: at recruitment, all participants completed the baseline questionnaire which is referred to as "assessment," during the web-based intervention participants randomized into the intervention arm of the study responded to the web-based questionnaire, and during each follow-up all participants able to be contacted for follow-up answered questions in the follow-up questionnaire. A few questions appeared in both the baseline and web-based questionnaires.

Baseline Questionnaire. The self-administered questionnaire included questions regarding current relationship situation, employment, religiosity, income, gravidity, parity, birth control use, current use of prescription and nonprescription medications, smoking, illegal drug use, depression and functionality, awareness of FASD, knowledge regarding the risks of alcohol consumption to women and to pregnancy, and alcohol consumption including number of drinks consumed per week and per occasion, and number of binge episodes in the past 2 weeks (binge defined as consuming ≥3 drinks per occasion).

Web-Based Questionnaire. Participants randomized into the intervention arm of the study self-reported information by computer regarding alcohol consumption over the past 2 weeks, current use of prescription or nonprescription medications, pregnancy status, the age they began drinking alcohol, and contraceptive use. Illustrations of various alcoholic beverage containers were used to prompt recall. They were asked to complete a series of true or false knowledge questions about risks associated with alcohol consumption.

Follow-Up Questionnaire. In the follow-up telephone questionnaire, research assistants asked questions regarding current relationship status, pregnancy status, birth control use, and alcohol consumption, including binge drinking, over the past 2 weeks.

Intervention

eCHECKUP TO GO, a web-based brief assessment and intervention tool based on the e-CHUG web tool developed for college students by Drs. Van Sickle and Moyer at San Diego State University, was tailored to the population participating in this study (Gorman et al., 2013; Venner et al., 2007). Participants answered questions in a confidential manner at their own pace and received individualized web-based feedback at the end of the session regarding their risk for an AEP, the impact of alcohol exposure to the fetus, the physical and financial cost of their alcohol consumption, and how their drinking compared with that of other Native women. A resource page at the end of the web session provided information on resources for additional information or assistance and could be

printed out. The intervention took approximately 20 minutes to complete.

Study Measures

The "Vulnerability to Alcohol-Exposed Pregnancy" variable was defined in 2 categories: not at high risk and at high risk. Being "at high risk" for an AEP was defined as (i) currently drinking 3 or more standard drinks per occasion and/or 8 or more standard drinks per week and (ii) using a less than a highly effective contraceptive method. We defined "binge" or "risky" drinking as 3 or

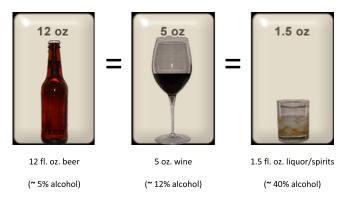


Fig. 2. Definition of a "standard drink."

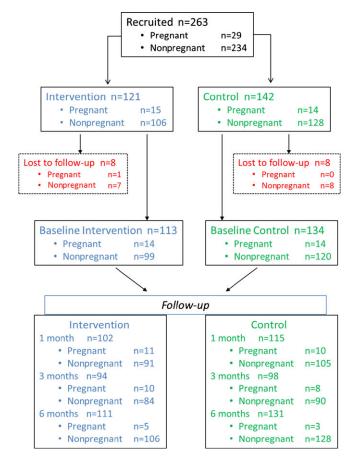
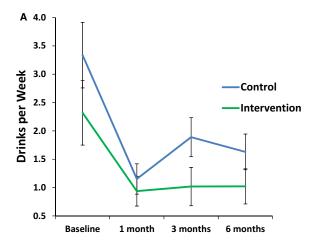
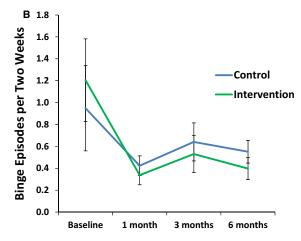


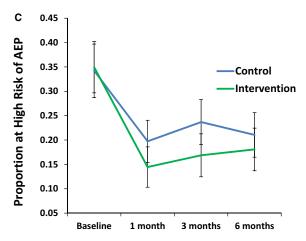
Fig. 3. Recruitment flowchart.



Treatment by time interaction p = 0.687; Time effect p = 0.000



Treatment by time interaction p = 0.551; Time effect p = 0.017



Treatment by time interaction p = 0.716; Time effect p = 0.000

Fig. 3. (**A–C**) Change over time in primary outcome variables (estimated marginal means and SE). (**A**) Average number drinks per week, total population without missing values (n=157, 80 Control/77 Intervention). Treatment by time interaction p=0.687; Time effect p=0.000. (**B**) Number binge episodes in the past 2 weeks, total population without missing values (n=161, 83 control/78 intervention). Treatment by time interaction p=0.551; Time effect p=0.017. (**C**) Proportion of population at high risk of alcohol-exposed pregnancies (AEP), total population without missing values (n=159, 83 control/76 intervention). Treatment by time interaction p=0.716; Time effect p=0.000.

130 MONTAG ET AL.

more standard drinks per occasion and/or 8 or more drinks per week as, despite being a nonstandard definition, this level of consumption has been defined as either risky for women or predictive of risk of adverse pregnancy outcomes in other studies (May et al., 2013). We defined standard drinks as shown in Fig. 2.

Participants were asked to indicate which form(s) of contraception they used from a list. Responses were categorized by effectiveness. Contraceptive effectiveness was defined as: High (<1 pregnancy per 100 women per year), Medium High (2 to 9 pregnancies per 100 women per year), Medium Low (15 to 24 pregnancies per 100 women per year), and Low (≥25 pregnancies per 100 women per year) (WHO, 2011).

The 9-item Patient Health Questionnaire (PHQ-9) was used to measure depression and functionality (Kroenke and Spitzer, 2002). Depression variables derived from this measure included treatment recommendation for depression (treatment recommended or not recommended), minor depression (yes/no), major depression (yes/no), and functionality (impaired or not impaired).

As only the intervention group responded to the web-based questions, questions from the paper-based baseline questionnaire were used in the analysis where possible. However, where a question in the intervention group was left blank in the paper questionnaire, the web-based answer was used. Primary outcome variables included the number of drinks consumed per week, the number of binge episodes over the past 2 weeks, and vulnerability to AEP.

Statistical Analyses

Comparisons were conducted using *t*-tests (continuous), chi-square (dichotomous), Fisher's exact test (dichotomous with small cell sizes), and nonparametric analyses (for data not normally distributed and not transformed). Normality in continuous variables was investigated through skewness and kurtosis. Analysis of variance (ANOVA) was used to examine associations among population characteristics. The vulnerability to AEP outcome variable was tested as dichotomous ("at high risk" vs. "not at high risk"). Change over time analyses were conducted in 2 ways: (i) using only the

subjects available at all follow-ups and (ii) multiple imputation methods. Linear regression was used to test reduction of some drinking parameters from baseline. Repeated ANOVA or mixed-model methods were used to estimate individual change over time and compare trajectories. Change was assessed in 2 ways: (i) using a dichotomous scale where participants were improved or not and (ii) using a 3 category system where participants were categorized as improved, remaining not at risk, and remaining at risk or at increased risk. Regression was used to test for predictors of positive change. First, each predictor was tested to determine whether there were significant independent associations with that 1 factor and change. Then, multiple regression analysis was used examine all variables previously found to be significant. All 2-way interactions among significant variables were tested.

Additional analyses explored the effect of the intervention on high-risk drinkers alone, the effect of missing (or completing) a follow-up session on final outcome, differences between participants lost to follow-up and remaining participants, and the effect of controlling for baseline drinking or risk status on final outcome.

Statistical significance was defined as 2-sided, *p*-value of <0.05. Statistical analyses were carried out using SPSS (PASW 18; SPSS Inc., Chicago, IL).

RESULTS

A total of 263 women were recruited into the study; of these, 16 (6.1%) were lost to follow-up. Figure 3 shows the study recruitment diagram. Baseline characteristics of the sample population are shown in Table 1 by randomized group. Randomized groups were similar in all aspects with the exception of a higher percent of women in the control group having previously had a child.

Alcohol consumption and related variables were not different between randomized groups at baseline (Table 2) nor

 Table 1. Baseline Demographics of Total Population with Follow-Up by Randomized Group

Variable	Total (mean \pm SE or %) $n = 247^a$	Intervention (mean \pm SE or %) $n = 113$	Control (mean \pm SE or %) $n = 134$	<i>p</i> -Value ^b
Maternal characteristics				
Age (years)	28.6 ± 0.5	27.7 ± 0.8	29.4 ± 0.7	0.114
Pregnant currently (%)	11.3	12.4	10.4	0.632
Has had at least 1 child (%)	64.2	57.1	70.1	0.045
Children (number previous)	1.5 ± 0.1	1.3 ± 0.2	1.6 ± 0.1	0.058
Pregnancies (number previous)	2.0 ± 0.1	1.9 ± 0.2	2.2 ± 0.2	0.293
Wants more children (%)	61.2	63.8	59.1	0.459
Cohabitating (%)	45.7	41.4	49.2	0.224
Employed (%)	42.8	43.1	38.9	0.511
Religious (%)	86.6	88.6	85.0	0.431
Current smoker (%)	29.7	26.8	32.1	0.364
Current use of illegal drugs (%)	12.1	11.9	12.2	0.946
Depression				
Treatment recommended (%)	35.7	35.1	36.2	0.869
Minor depressive syndrome (%)	29.4	26.8	31.6	0.412
Major depressive syndrome (%)	2.9	2.7	3.1	0.855
Functionality impaired (%)	7.2	10.5	4.4	0.090
FASD awareness				
Heard of FASD (%)	71.5	72.3	70.9	0.161
Know someone affected by FASD (%)	32.2	28.8	35.1	0.531
Not sure if know someone affected (%)	9.4	9.0	9.7	

FASD, fetal alcohol spectrum disorders.

^aSample size varies due to inclusion of selected variables in the web-based survey and missing values.

^bComparing Intervention to Control using ANOVA for continuous variables and chi-square test for categorical variables.

Table 2. Alcohol Consumption and Related Parameters by Randomized Group

Alcohol consumption variable All women	Total population N = 247	Intervention N = 113	Control N = 134	<i>p</i> -Value
Ever drank alcohol (%)	94.7	94.7	94.7	0.993
Currently consume alcohol (%)	50.0	48.7	51.1	0.700
Age at first drink	15.2 ± 0.2	14.8 ± 0.3	15.6 ± 0.3	0.076
Drinks per week	3.80 ± 0.52	4.11 ± 0.94	3.53 ± 0.53	0.576
Drinks per occasion	2.22 ± 0.25	2.01 ± 0.33	2.40 ± 0.38	0.443
Binge episodes per 2 weeks	1.22 ± 0.21	1.40 ± 0.42	1.06 ± 0.16	0.415
Current binge drinker (%)	42.9	42.0	43.7	0.793
Current risky drinker (%)	42.0	42.5	41.7	0.898
Perception of other w	omen's drinkin	g		
Drinks per week	7.40 ± 0.63	7.04 ± 0.92	7.71 ± 0.87	0.599
Drinks per occasion	3.40 ± 0.21	3.28 ± 0.27	3.50 ± 0.32	0.614

Current drinkers	N = 122	<i>N</i> = 55	<i>N</i> = 67	
Age	29.0 ± 0.7	27.8 ± 1.0	30.0 ± 1.0	0.118
Drinks per week	7.60 ± 0.92	8.38 ± 1.74	6.94 ± 0.84	0.436
Drinks per occasion	4.39 ± 0.41	4.06 ± 0.53	4.66 ± 0.62	0.476
Binge episodes per 2 weeks	2.34 ± 0.38	2.78 ± 0.78	1.98 ± 0.25	0.299
Current binge drinker (%)	83.6	85.5	82.1	0.617
Current risky drinker (%)	84.4	87.3	82.1	0.432
Age at first drink	14.8 ± 0.3	14.6 ± 0.5	15.0 ± 0.3	0.450
Perception of other				
women's drinking	<i>N</i> = 114	<i>N</i> = 51	N = 63	
Drinks per week	8.70 ± 0.89	8.90 ± 1.55	8.53 ± 1.00	0.837
Drinks per occasion	3.85 ± 0.26	3.85 ± 0.36	3.85 ± 0.36	1.000
Difference between other women's and				
own drinking	N = 111	N = 50	N = 61	
Drinks per week Drinks per occasion	$\begin{array}{c} 2.85\pm0.88 \\ 0.17\pm0.28 \end{array}$	$\begin{array}{c} 3.79 \pm 1.14 \\ 0.51 \pm 0.38 \end{array}$	$\begin{array}{c} 2.02\pm1.31 \\ -0.10\pm0.41 \end{array}$	0.315 0.288

was contraceptive use (Table 3) or vulnerability to AEP (Table 4). Half of participants reported not currently drinking any alcohol. Among those currently consuming alcohol, there was a high proportion of binge drinkers (84%). The social norm, that is, perception of other women's drinking, on average was reported as 4 drinks per drinking occasion.

Figure 3A-C show changes over time in various measurements: (i) number drinks consumed per week, (ii) number binge episodes in past 2 weeks, and (iii) at high risk for AEP. Regardless of variable, all outcomes show a statistically significant time effect but no intervention effect. Full data for primary outcome variables over time, mean (SE) or %, may be accessed in Table S1.

Predictors of change (variables associated with a decrease in alcohol consumption) are shown in Tables 4 and 5: needing treatment for depression (or feeling that their functional-

Table 3. Baseline Contraceptive Use by Randomized Group (Nonpregnant Participants)

Contraceptive use	Total population $N = 219$	Intervention N = 99	Control N = 120	<i>p</i> -Value ^a
Use birth control (%) ^b Abstinent (%)	61.2 8.7	65.7 11.5	57.5 6.3	0.218 0.183
Birth control effectivene	ess N = 19	90 N = 85	N = 105	
High (%)° Medium high (%) Medium low (%) Low (%) No birth control (%)	13.7 30.5 24.2 0.5 31.1	40.0 24.7	15.2 22.9 23.8 1.0 37.1	0.073

^aComparison between Intervention and Control using chi-square test. ^bExcludes abstinence.

ity was impaired), thinking other women drink more, and experiencing more binge episodes in the past 2 weeks, were associated with reduced alcohol consumption. Table 5 shows predictors of change when model is adjusted for baseline alcohol consumption. In this study, depression and functionality variables often functioned similarly in analyses. Many women in our study expressed surprise regarding both other women's drinking (that half do not drink) and their own (that they were engaging in binge drinking).

DISCUSSION

In this randomized controlled study, risky drinking behavior and vulnerability to AEP were reduced in both the intervention and control groups. For each primary outcome variable (number drinks per week, number binge episodes per 2 weeks, vulnerability to AEP), there was evidence of a time effect but no statistically significant treatment effect. Effects were sustained over the 6-month follow-up period.

Assessment reactivity (particularly in participants already considering change), regression to the mean, and effects related to our mixed mode design may have contributed to the reduction in alcohol consumption in the control group. Our findings emphasize the need to include control groups in similar studies. In controlled studies, similar effects are not uncommon observations (Bernstein et al., 2010). The finding that assessment, in and of itself, is associated with a positive change in behavior has important implications for future interventions in this population. An assessment strategy may prove appropriate in situations where more time-intensive approaches are impractical.

American Indian/Alaska Native tribes vary significantly in alcohol consumption (May and Gossage, 2001a; Spicer et al., 2003). Our findings regarding the pattern of drinking among our participants supports previous work by May and Gossage (2001b), among others, where binge drinking is the primary pattern of drinking among a

 $^{^{\}rm c}$ Comparison between intervention and control for highly effective birth control or not: p=0.302.

MONTAG ET AL.

Fable 4. Variables Associated with a Decrease in Drinks Per week from Baseline to 6 Months (n=164)

	Correlations	Correlations between predictor variabl	ables					
Predictor variables	Binge	Functionality	Other women	Cohabitation	$eta^{\mathbf{a}}$	$B^{\mathrm{b}} \pm \mathrm{SE}$	Sig.	Partial R ²
Binge		0.042	0.277*	-0.093	0.563	1.31 ± 0.15	0.000	0.575
Functionality			0.203*	-0.164*	0.171	5.13 ± 1.89	0.008	0.210
Other women				-0.085	0.127	0.11 ± 0.06	0:020	0.154
Cohabitation					0.093	1.52 ± 1.02	0.139	0.118
R Adjusted R² ANOVA sig.								0.000 0.000

Binge = Binge episodes per 2 weeks at baseline (number); Functionality = Functionality (impaired vs. not impaired); Other Women = Perception of other women's drinking (number drinks per veek); Cohabitation = Cohabitating (yes vs. no).

^aStandardized coefficient.
^bUnstandardized coefficient.
*Sign 1-toilog in 7,005

number of AIAN populations. Overestimation of other women's alcohol consumption may contribute increased drinking (Dunnagan et al., 2007) and increased perception of risks associated with drinking may reduce consumption (Testa and Reifman, 1996). Social norms that tolerate risky drinking may prevent women from recognizing and addressing problems. According to the 2007 National Survey of Drug Use and Health, the vast majority of people needing treatment for alcohol abuse were unaware that they needed it (Substance Abuse and Mental Health Services Administration, 2008). Nonetheless, attempts to shift social norms relating to alcohol consumption have been used in interventions among non-AIAN populations with mixed results (Clapp et al., 2003; Lewis and Neighbors, 2006). The present results indicate that, among AIAN women in our source group, interventions addressing social norms may prove effective. Findings support narrow social norms among variables such as drinks per occasion among drinkers, drinks needed to feel tipsy, and age at first drink. These variables were not different among groups with different vulnerability to AEP. The perception of how much other women drink was an important predictor of reduced drinking during follow-up.

In addition to perceiving social norms of higher alcohol consumption, the present study revealed 2 other predictors of reduction in alcohol use: testing positive for depression or impaired functionality and a greater number of binge drinking episodes over a 2-week period. Treatment for depression was recommended for a third of the women in our sample (36%). This proportion is striking when compared to the prevalence of depression among U.S. women (14% in 2006) (Farr et al., 2010) and among 2,289 adult Alaska Native women (20%) (Dillard et al., 2012) measured using the same PHQ-9 instrument. In women, as opposed to men, depression appears to predate alcohol problems (Helzer and Pryzbeck, 1988). Screening for depression may facilitate identification of women vulnerable to AEP. Furthermore, addressing depression in this population may be a helpful independent approach to preventing FASD.

The finding that a greater magnitude of change was predicted by higher number of binge episodes at baseline is somewhat unexpected in that the strategy of SBIRT is geared toward a broader population of relatively lower risk. However, recognition of the extent of one's binge drinking may be sobering (and motivating) for women who are more likely to frequently binge drink.

Controlling for baseline alcohol consumption only served to improve the predictive power of our model (adjusted R^2 increased to 78.9%). In addition, binge drinking, perception of social norms, and depression/functionality were consistently predictive of primary variable change at each follow-up time point. Variables that were, perhaps unexpectedly, not significantly predictive of change were age, smoking, income, illegal drug use, and religiosity.

0.789

0.000

Correlations between predictor variables Predictor variables Binge Cohabitation β^a $B^{b} \pm SE$ Partial R² Functionality Other women Sig. Binge 0.780 0.000 0.848 -0.0810.161 -0.282° $1.18\,\pm\,0.08$ Functionality 0.465° -0.373*0.468 19.70 ± 2.55 0.000 0.649 Other women -0.285*0.151 0.16 ± 0.06 0.010 0.279 Cohabitation 0.132 4.45 ± 1.92 0.023 0.248 0.798

Table 5. Variables Associated with a Decrease in Drinks Per Week from Baseline to 6 Months Controlling for Baseline Drinking (n = 164)

Binge = Binge episodes per 2 weeks at baseline (number); Functionality = Functionality (impaired vs. not impaired); Other Women = Perception of other women's drinking (number drinks per week); Cohabitation = Cohabitating (yes vs. no).

Adjusted R2

ANOVA sig.

Previous research has found that the effect of an intervention may be intensified or extended by multiple contacts (Longabaugh et al., 2001). In the present study, whether or not the 1-month follow-up contact was completed did not affect the 3- or 6-month follow-up results (data not shown). Similarly, missing the 3-month follow-up did not affect findings in the 6-month follow-up.

The present intervention did not include a contraceptive intervention component beyond assessment. Contraceptive use was not different among treatment groups or follow-up time points. As vulnerability to AEP may be decreased by preventing pregnancy as well as preventing risky drinking, this would be a valuable addition to future interventions. Relevant examples of such interventions are project CHOICES (Floyd et al., 2007) and EARLY (Ingersoll et al., 2013). It is of note that exposure to the EARLY intervention was associated with a greater change in contraceptive use than in alcohol consumption (Ingersoll et al., 2013).

Limitations and Strengths

Participants in this study were self-selected volunteers so that it is unknown to what extent they represent the entire population of women of reproductive potential in these settings. However, we recruited potential subjects at various locations and publicized the study broadly. Our randomization procedure was flawed in that the number of binary choices that could be pulled by the research assistants was larger than the number of participants ultimately recruited. This may have contributed to the greater number of participants in the control group (n = 142) compared to the Intervention group (n = 121). Another limitation was that data were self-reported and therefore not feasible to validate. "Social presence" may have played a role as the self-administered paper-based and web-based questionnaires were completed with a researcher in the same room. Therefore, it is possible that participants may have under- or over reported sensitive behaviors due to social acceptability/ desirability.

In addition, a mixed mode design for data collection was used where baseline data was collected using a paper- and pencil-based format and follow-up data were obtained by telephone interview. Participants randomized to the intervention, completed an additional web-based survey where a subset of questions were repeated from the baseline survey. We compared responses on questions that occurred in both the paper-based and web-based modes and found no significant differences.

We sought to minimize these potential biases by assuring participants of confidentiality, using well-trained interviewers who were community members, establishing private environments for all data collection modes, using equivalent questions across modes, and ensuring that participants could ask questions or request clarification of questions in all modes.

Not all participants completed all follow-up interviews. Missing follow-up data may introduce bias but, whether data were analyzed using only complete data sets, all available data, or using multiple imputation methods, the results did not differ.

Alcohol consumption data were collected in increments of 2 weeks; a relatively short time period selected for obtaining the most precise data on daily drinking habits. As the number of drinks consumed per occasion (or drinking day) remained relatively consistent and reductions in risky drinking were largely due to changes in the frequency of drinking days, the brief assessment period may have introduced bias. This threat to validity could be lessened in future studies by expanding the assessment time periods.

As mentioned above with regard to the control group, regression to the mean may be a possible explanation for our findings. Possible distortion of results due to the Hawthorne effect could not be ruled out as participants were informed by the consent form that there would be follow-up calls within a 6-month period.

Initial and continuing efforts to gain the support of the community and to ensure confidentiality increased participation and retention. All recruitment and data collection were

^aStandardized coefficient.

^bUnstandardized coefficient.

^{*}Sig. 1-tailed, *p* < 0.05.

carried out by trusted community members trained as research assistants. Approval and support of the Tribal IRB was obtained. Efforts were made to adapt the SBIRT intervention to make it as relevant and understandable to this particular community as possible.

Implications for Prevention

Our finding that assessment alone, even without intervention, may be sufficient to decrease risky drinking and vulnerability to AEP indicate a value to providing assessment even if time constraints prevent an accompanying intervention. Furthermore, the study supports targeted interventions for AIAN women who currently drink alcohol that incorporate efforts to shift cultural norms, recognition of depression, and assessment of alcohol consumption and vulnerability to AEP.

ACKNOWLEDGMENT

This research was supported by the National Institute of General Medical Sciences grant U26IHS300292/01.

REFERENCES

- Babor TF, McRee BG, Kassebaum PA, Grimaldi PL, Ahmed K, Bray J (2007) Screening, Brief Intervention, and Referral to Treatment (SBIRT): toward a public health approach to the management of substance abuse. Subst Abus 28:7–30.
- Bad Heart Bull L, Kvigne V, Leonardson G, Lacina L, Welty T (1999) Validation of a self-administered questionnaire to screen for prenatal alcohol use in Northern Plains Indian women. Am J Prev Med 16:240–243.
- Bernstein E, Bernstein J (2008) Effectiveness of alcohol screening and brief motivational intervention in the emergency department setting. Ann Emerg Med 51:751–754.
- Bernstein JA, Bernstein E, Heeren TC (2010) Mechanisms of change in control group drinking in clinical trials of brief alcohol intervention: implications for bias toward the null. Drug Alcohol Rev 29:498–507.
- Bezilla WA (2010) Assessing Fidelity and Use of Core Implementation Components in the Implementation of a Brief Motivational Intervention to Reduce Binge Drinking Among College Students: A Systematic Review of the Literature. University of Pittsburgh, Pittsburgh, PA.
- Clapp JD, Lange JE, Russell C, Shillington A, Voas RB (2003) A failed norms social marketing campaign. J Stud Alcohol Drugs 64:409–414.
- Coriale G, Fiorentino D, Kodituwakku PW, Tarani L, Parlapiano G, Scalese B, Ceccanti M (2014) Identification of children with prenatal alcohol exposure. Curr Dev Disord Rep 1:141–148.
- Delrahim-Howlett K, Chambers CD, Clapp JD, Xu R, Duke K, Moyer RJ, Van Sickle D (2011) Web-based assessment and brief intervention for alcohol use in women of childbearing potential: a report of the primary findings. Alcohol Clin Exp Res 35:1331–1338.
- Dillard DA, Smith JJ, Ferucci ED, Lanier AP (2012) Depression prevalence and associated factors among Alaska Native people: the Alaska education and research toward health (EARTH) study. J Affect Disord 136:1088– 1097
- Dunnagan T, Haynes G, Linkenbach J, Summers H (2007) Support for social norms programming to reduce alcohol consumption in pregnant women. Addict Res Theory 15:383–396.
- Ethen MK, Ramadhani TA, Scheuerle AE, Canfield MA, Wyszynski DF, Druschel CM, Romitti PA (2009) Alcohol consumption by women before and during pregnancy. Matern Child Health J 13:274–285.

- Farr SL, Bitsko RH, Hayes DK, Dietz PM (2010) Mental health and access to services among US women of reproductive age. Am J Obstet Gynecol 203:542.e1–9.
- Finer LB, Zolna MR (2011) Unintended pregnancy in the United States: incidence and disparities, 2006. Contraception 84:478–485.
- Floyd RL, Decouffé P, Hungerford DW (1999) Alcohol use prior to pregnancy recognition. Am J Prev Med 17:101–107.
- Floyd RL, Sobell M, Velasquez MM, Ingersoll K, Nettleman M, Sobell L, Mullen PD, Ceperich S, von Sternberg K, Bolton B (2007) Preventing alcohol-exposed pregnancies: a randomized controlled trial. Am J Prev Med 32:1–10.
- Gorman JR, Clapp JD, Calac D, Kolander C, Nyquist C, Chambers CD (2013) Creating a culturally appropriate web-based behavioral intervention for American Indian/Alaska Native women in Southern California: the healthy women healthy native nation study. Am Indian Alsk Native Ment Health Res 20:1–15.
- Havens JR, Simmons LA, Shannon LM, Hansen WF (2009) Factors associated with substance use during pregnancy: results from a national sample. Drug Alcohol Depend 99:89–95.
- Helzer JE, Pryzbeck TR (1988) The co-occurrence of alcoholism with other psychiatric disorders in the general population and its impact on treatment. J Stud Alcohol Drugs 49:219–224.
- Holmgren S (2009) Low Dose Alcohol Exposure During Pregnancy—Does It Harm? Swedish National Institute of Public Health, Stockholm. Available at: http://www.folkhalsomyndigheten.se/pagefiles/12314/R2009-14-low-dose-alcohol-exposure-pregnancy.pdf. Accessed January 10, 2015.
- Ingersoll KS, Ceperich SD, Hettema JE, Farrell-Carnahan L, Penberthy JK (2013) Preconceptional motivational interviewing interventions to reduce alcohol-exposed pregnancy risk. J Subst Abuse Treat 44:407–416.
- Jones KL, Smith DW, Ulleland CN, Streissguth AP (1973) Pattern of malformation in offspring of chronic alcoholic mothers. Lancet 301:1267– 1271.
- Kaskutas L (2000) Understanding drinking during pregnancy among urban American Indians and African Americans: health messages, risk beliefs, and how we measure consumption. Alcohol Clin Exp Res 24:1241–1250.
- Kesmodel US, Bertrand J, Støvring H, Skarpness B, Denny CH, Mortensen EL; Lifestyle During Pregnancy Study Group (2012) The effect of different alcohol drinking patterns in early to mid pregnancy on the child's intelligence, attention, and executive function. BJOG 119:1180–1190.
- Kroenke K, Spitzer RL (2002) The PHQ-9: a new depression diagnostic and severity measure. Psychiatr Ann 32:509–515.
- Lewis MA, Neighbors C (2006) Social norms approaches using descriptive drinking norms education: a review of the research on personalized normative feedback. J Am Coll Health 54:213–218.
- Longabaugh R, Woolard RF, Nirenberg TD, Minugh AP, Becker B, Clifford PR, Carty K, Sparadeo F, Gogineni A (2001) Evaluating the effects of a brief motivational intervention for injured drinkers in the emergency department. J Stud Alcohol Drugs 62:806–816.
- Madras B, Compton W, Avula D, Stegbauer T, Stein J, Clark H (2009) Screening, brief interventions, referral to treatment (SBIRT) for illicit drug and alcohol use at multiple healthcare sites: comparison at intake and 6 months later. Drug Alcohol Depend 99:280–295.
- Maier SE, West JR (2001) Drinking patterns and alcohol-related birth defects. Alcohol Res Health 25:168–174.
- Mallard SR, Connor JL, Houghton LA (2013) Maternal factors associated with heavy periconceptional alcohol intake and drinking following pregnancy recognition: a post-partum survey of New Zealand women. Drug Alcohol Rev 32:389–397.
- Marchetta CMEA (2012) Alcohol use and binge drinking among women of childbearing age—United States, 2006–2010. MMWR Morb Mortal Wkly Rep 61:534.
- May PA, Blankenship J, Marais A-S, Gossage JP, Kalberg WO, Joubert B, Cloete M, Barnard R, De Vries M, Hasken J (2013) Maternal alcohol consumption producing fetal alcohol spectrum disorders (FASD): quantity, frequency, and timing of drinking. Drug Alcohol Depend 133:502–512.
- May PA, Gossage JP (2001a) Estimating the prevalence of fetal alcohol syndrome: a summary. Alcohol Res Health 25:159–167.

- May PA, Gossage JP (2001b) New data on the epidemiology of adult drinking and substance use among American Indians of the northern states: male and female data on prevalence, patterns, and consequences. Am Indian Alsk Native Ment Health Res 10:1–26.
- May PA, Gossage JP (2011) Maternal risk factors for fetal alcohol spectrum disorders: not as simple as it might seem. Alcohol Res Health 34:15–26.
- May PA, Gossage JP, Kalberg WO, Robinson LK, Buckley D, Manning M, Hoyme HE (2009) Prevalence and epidemiologic characteristics of FASD from various research methods with an emphasis on recent in school studies. Dev Disabil Res Rev 15:176–192.
- May PA, Gossage JP, White-Country M, Goodhart K, Decoteau S, Trujillo PM, Kalberg WO, Viljoen DL, Hoyme HE (2004) Alcohol consumption and other maternal risk factors for fetal alcohol syndrome among three distinct samples of women before, during, and after pregnancy: the risk is relative. Am J Med Genet C Semin Med Genet 127C:10–20.
- May PA, Tabachnick BG, Gossage JP, Kalberg WO, Marais AS, Robinson LK, Manning M, Buckley D, Hoyme HE (2011) Maternal risk factors predicting child physical characteristics and dysmorphology in fetal alcohol syndrome and partial fetal alcohol syndrome. Drug Alcohol Depend 119:18–27.
- Montag A, Clapp JD, Calac D, Gorman J, Chambers C (2012) A review of evidence-based approaches for reduction of alcohol consumption in native women who are pregnant or of reproductive age. Am J Drug Alcohol Abuse 38:436–443.
- Naimi TS, Lipscomb LE, Brewer RD, Gilbert BC (2003) Binge drinking in the preconception period and the risk of unintended pregnancy: implications for women and their children. Pediatrics 111(Suppl 1):1136–1141.
- Nilsen P, Holmqvist M, Hultgren E, Bendtsen P, Cedergren M (2008) Alcohol use before and during pregnancy and factors influencing change among Swedish women. Acta Obstet Gynecol Scand 87:768–774.
- Paintner A, Williams AD, Burd L (2012) Fetal alcohol spectrum disorders implications for child neurology, part 1: prenatal exposure and dosimetry. J Child Neurol 27:258–263.
- Roussotte FF, Sulik KK, Mattson SN, Riley EP, Jones KL, Adnams CM, May PA, O'Connor MJ, Narr KL, Sowell ER (2012) Regional brain volume reductions relate to facial dysmorphology and neurocognitive function in fetal alcohol spectrum disorders. Hum Brain Mapp 33:920–937.
- Sawada Feldman H, Lyons Jones K, Lindsay S, Slymen D, Klonoff-Cohen H, Kao K, Rao S, Chambers C (2012) Prenatal alcohol exposure patterns and alcohol-related birth defects and growth deficiencies: a prospective study. Alcohol Clin Exp Res 36:670–676.
- Secretary of Health and Human Services (2000) U.S. Department of Health and Human Services (USDHHS). Tenth Special Report to the U.S. Congress on Alcohol and Health: Highlights from Current Research. USDHHS, Washington, DC.

- Services UDoHaH (2005) US Surgeon General Releases Advisory on Alcohol Use in Pregnancy. US Department of Health and Human Services, Washington, DC. Available from: http://www.surgeongeneral.gov/news/2005/02/sg02222005.html Accessed February 21, 2014.
- Skagerstróm J, Chang G, Nilsen P (2011) Predictors of drinking during pregnancy: a systematic review. J Womens Health 20:901–913.
- Spicer P, Beals J, Croy CD, Mitchell CM, Novins DK, Moore L, Manson SM; American Indian Service Utilization, Psychiatric Epidemiology, Risk and Protective Factors Project Team (2003) The prevalence of DSM-III-R alcohol dependence in two American Indian populations. Alcohol Clin Exp Res 27:1785–1797.
- Streissguth AP, Herman CS, Smith DW (1978) Intelligence, behavior, and dysmorphogenesis in the fetal alcohol syndrome: a report on 20 patients. J Pediatr 92:363–367.
- Substance Abuse and Mental Health Services Administration (2008) Results from the 2007 National Survey on Drug Use and Health: National Findings. Office of Applied Statistics (SMA 08-4343), Rockville, MD.
- Testa M, Reifman A (1996) Individual differences in perceived riskiness of drinking in pregnancy: antecedents and consequences. J Stud Alcohol Drugs 57:360–367.
- Venner KL, Feldstein SW, Tafoya N (2007) Helping clients feel welcome: principles of adapting treatment cross-culturally. Alcohol Treat Q 25: 11–30
- Warren CW, Goldberg HI, Oge L, Pepion D, Friedman JS, Helgerson S, Edward M, Mere L (1990) Assessing the reproductive behavior of on and off-reservation American Indian females: characteristics of two groups in Montana. Biodemography Soc Biol 37:69–83.
- Whitlock E, Polen M, Green C, Orleans T, Klein J (2004) Behavioral counseling interventions in primary care to reduce risky/harmful alcohol use by adults: a summary of the evidence for the US Preventive Services Task Force. Ann Intern Med 140:557–568.
- WHO C (2011) Family Planning: A Global Handbook for Providers (2011 Update). CCP and WHO, Baltimore, MD and Geneva. Available at: http://whqlibdoc.who.int/publications/2011/9780978856373_eng.pdf. Accessed January 10, 2015

SUPPORTING INFORMATION

Additional Supporting Information may be found in the online version of this article:

Table S1. All available data for primary outcome variables over time—mean (SE) or %.

Copyright of Alcoholism: Clinical & Experimental Research is the property of Wiley-Blackwell and its content may not be copied or emailed to multiple sites or posted to a listserv without the copyright holder's express written permission. However, users may print, download, or email articles for individual use.