Preventing Alcohol-Exposed Pregnancies: A Randomized Controlled Trial of a Self-Administered Version of Project CHOICES with College Students and Nonstudents

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Background: Alcohol-exposed pregnancies (AEPs) are a preventable cause of birth defects and developmental disabilities for which many women are at risk. The initial 5-session Project CHOICES intervention was found to prevent AEPs. In the ensuing decade, there have been several additional CHOICES-like studies. This study, Project Healthy CHOICES, had 2 objectives: (i) to compare outcomes for students versus nonstudents; and (ii) to test a self-administered mail-based version of the Project CHOICES intervention.

Methods: A randomized controlled trial (RCT) compared 2 interventions for women of childbearing age (18 to 44) who were at risk of an AEP: (i) motivational feedback based on Project CHOICES and (ii) information only. Advertisements recruited 354 women (145 college students; 209 nonstudents) at risk of an AEP. Intervention and study materials were available in English and Spanish. Of the 354 women, 44% were minorities (25% identified as Hispanics).

Results: At the 6-month follow-up, the interventions did not differ and there was no Intervention by Student Study interaction. However, over the entire 6-month follow-up, significantly more students (68%) than nonstudents (46%) were not at risk of an AEP (2.1 odds ratio; confidence interval = 1.47 to 2.95). For all groups, risk reduction occurred primarily through effective contraception.

Conclusions: There was no significant difference between the 2 interventions. However, over the entire 6-month follow-up interval, college students were significantly more likely than nonstudents to not be at risk of an AEP and to use effective contraception. While the student groups had significantly higher reduced risk of AEP outcomes, there was also substantial risk reduction for women in the information only condition. These results suggest that the most effective AEP prevention efforts would be to inform women at risk that they could become pregnant. Because about half of all pregnancies are unplanned, identifying women at risk and preventing the risk of AEPs should be a public health priority.

Key Words: Preventing Alcohol-Exposed Pregnancies, College Students, Early Identification of Risk, Alcohol Use, Project CHOICES.

ALTHOUGH THE REPORTED negative effects of women's drinking on their unborn children date to biblical times (Astley, 2011; Royal College of Physicians of London, 1726), scientific interest about the effects of alcohol on unborn children was lacking until 1973 (Jones and Smith, 1973). Today, alcohol, a well-established teratogen, is known to cause adverse physical and behavioral effects on the fetus (Gupta et al., 2016). These adverse effects lie on a continuum known as fetal alcohol spectrum disorders (FASD) and range from mild to moderate to the most severe condition, fetal alcohol syndrome (FAS; Floyd et al., 2009; Gupta et al., 2016; Tan et al., 2015).

While the amount of alcohol that can place an unborn child at risk of developmental disabilities has not been clearly established, several studies have shown that ≥8 standard drinks (SDs) per week (1 SD = 14 g of absolute ethanol) or ≥4 SDs per day (i.e., binge drinking) poses a significant risk for an alcohol-exposed pregnancy (AEP; Floyd et al., 2009; Tan et al., 2015). The amount of drinking that places women at risk of an AEP does not always meet criteria for an alcohol use disorder (American Psychiatric Association, 2013), and many women drink at risky levels (Astley, 2011; Tan et al., 2015). Further, the critical period for some malformations is early after conception (Cole, 1994; Ernhart et al., 1987). Probability sample data from the 2002/2003 National Survey of Family Growth "found during a 1-month period, nearly 2 million women were at risk of an AEP," with

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Received for publication October 17, 2016; accepted April 1, 2017.

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Trial Registration. clinicaltrials.gov Identifier: NCT00219336; Protocol Identifier: U50/CCU30086; www.clinicaltrials.gov). Registration date: September 14, 2005.

DOI: 10.1111/acer.13385

600,000 engaging in binge drinking (Cannon et al., 2015, p. 776). Because about half of all pregnancies are unplanned (Finer and Henshaw, 2006), women can be drinking at risky levels before learning they are pregnant (Floyd et al., 1999; Naimi et al., 2003). Identifying such women and preventing the risk of AEPs should be a public health priority.

To develop effective AEP prevention programs, the Centers for Disease Control and Prevention (CDC) funded a multisite randomized controlled trial (RCT), Project CHOICES, that compared a 5-session motivational intervention using healthcare specialists with an information only group (Floyd et al., 2007; Velasquez et al., 2016). Project CHOICES differed from earlier efforts to prevent AEPs as it allowed women to make a *CHOICE* of changing 1 of 2 behaviors (effective contraception, drinking below AEP risk levels, or both). In Project CHOICES, the women who received the experimental intervention had significantly greater reductions in their risk of an AEP than those in the control intervention (Floyd et al., 2007).

Since the initial Project CHOICES, which was a RCT, several CHOICES-like RCTs have been published. "While all the CHOICES or the CHOICES-like interventions (experimental groups) had higher success rates than the standard control interventions, an equally important finding was that all control groups showed substantial overall reduced risk outcomes" (Velasquez et al., 2016, p. 43). Remembering that all women in CHOICES studies were at risk of an AEP, the percentages of women in the control groups that reduced their risk is notable. While the results of all CHOICES studies are impressive, many not only require trained staff to deliver the intervention, but women must also attend clinic sessions. Given the seriousness of FASD, effective and accessible interventions are needed at a population level. Because not all women at risk of an AEP want to or can come to a clinic or healthcare setting, this study evaluated a brief mailed self-administered CHOICES-like intervention. College students were included in this study because several published studies have shown that they are likely to engage in risky sexual behaviors when drinking, particularly binge drinking (Cooper, 2002; Winograd and Sher, 2015). It was hypothesized that a self-administered mail-based motivational intervention based on Project CHOICES would significantly reduce AEP risks compared to an information only intervention.

Project Healthy CHOICES had 2 objectives: (i) to compare outcomes for college students versus nonstudents; and (ii) to test a self-administered mail-based version of the initial Project CHOICES intervention (Floyd et al., 2007).

MATERIALS AND METHODS

Recruitment, Screening, and Eligibility

This study included women who were at risk of an AEP from 2005 through 2009. All study materials (assessment/consent/follow-up/feedback) were mailed to participants through the United States Postal Service (USPS). Participants returned all materials to the project using prepaid USPS envelopes. The study was approved by the Nova Southeastern University's Institutional Review Board (Research Protocol #CPS02230510Exp). We obtained written informed consent from all participants.

Advertisements were used to recruit women of childbearing age (18 to 44) for a research study conducted by mail. Although the ads said, "If you drink alcohol, even small amounts you may be eligible," they did not specifically solicit women at risk of an AEP. English and Spanish ads were placed in media outlets in Florida (e.g., radio; local and college newspapers). Because Florida has a large Hispanic population, study and intervention materials, which are described elsewhere (Letourneau et al., 2017), were available in English and Spanish.

Callers were screened by phone for initial eligibility (i.e., AEP risk) for the 90 days before the call using the following criteria: (i) female; (ii) 18 to 44 years old; (iii) had heterosexual vaginal intercourse with ineffective contraception (i.e., based on participants' self-reported deviations from published guidelines for different birth control methods); (iv) consumed an average of ≥8 SDs per week and/or engaged in binge drinking (≥5 SDs on 1 occasion); and (v) returned their informed consent and assessment materials within 60 days after they were mailed to them. The binge drinking criterion of ≥5 drinks on 1 occasion used in Project CHOICES (Floyd et al., 2007) was based on epidemiologic data when that study started. It was later changed by the CDC to ≥4 drinks based on a broader perspective on women's drinking and not just an AEP (Bertrand et al., 2005; Dawson, 2000; Jacobson and Jacobson, 1999; Sayal et al., 2009). The 2 slightly different criteria do not affect the results as ≥4 drinks would include women who met the ≥5 drink criterion.

Figure 1 provides a summary of the participant flow in the clinical trial. Of the 3,796 women who responded to ads, 2,981 were prescreened and 815 (21.5%) could not be contacted. Of those prescreened, 82.5% were ineligible (46.0% insufficient or no drinking; 31.2% were effectively contracepting or had no vaginal intercourse). The 522 initially eligible were offered an opportunity to participate and sent an informed consent and assessment materials. A further 32.2% were then excluded, mainly for failure to return their assessment, yielding 354 women who consented to participate, returned all study materials, and entered the study.

Study Design and Intervention

Study procedures were identical for participants until they received the intervention. As in Project CHOICES (Floyd et al., 2007), women were offered a choice of how to prevent an AEP (reducing drinking below AEP risk levels, effective contraception, or both). All participants received a list of local programs that provided alcohol and birth control services.

After returning their informed consent and assessment materials, participants were blocked on student status (student, nonstudent) and randomly assigned to 1 of 2 interventions: (i) information only (IO; $n = 174$) or (ii) motivational feedback (MF; $n = 180$). Blocked randomization resulted in 145 students and 209 nonstudents assigned to the following groups: (i) student, MF ($n = 72$); (ii) student, IO ($n = 73$); (iii) nonstudent, MF ($n = 108$); and (iv) nonstudent, IO ($n = 101$). Participants who completed and returned their assessment materials received a $20 check for their participation.

Information Only. Women in the IO group were mailed a brochure developed by the CDC in either English (*Think Before You Drink: You Can Hurt Your Unborn Baby*) or Spanish (*Piénselo Antes de Beber: Puede Lastimar a Su Futuro Bebe*). The brochures, available at the CDC website, target women of childbearing age, discuss FAS and the negative effects of a mother's drinking on her unborn child, and recommend calling alcoholics anonymous or an alcohol

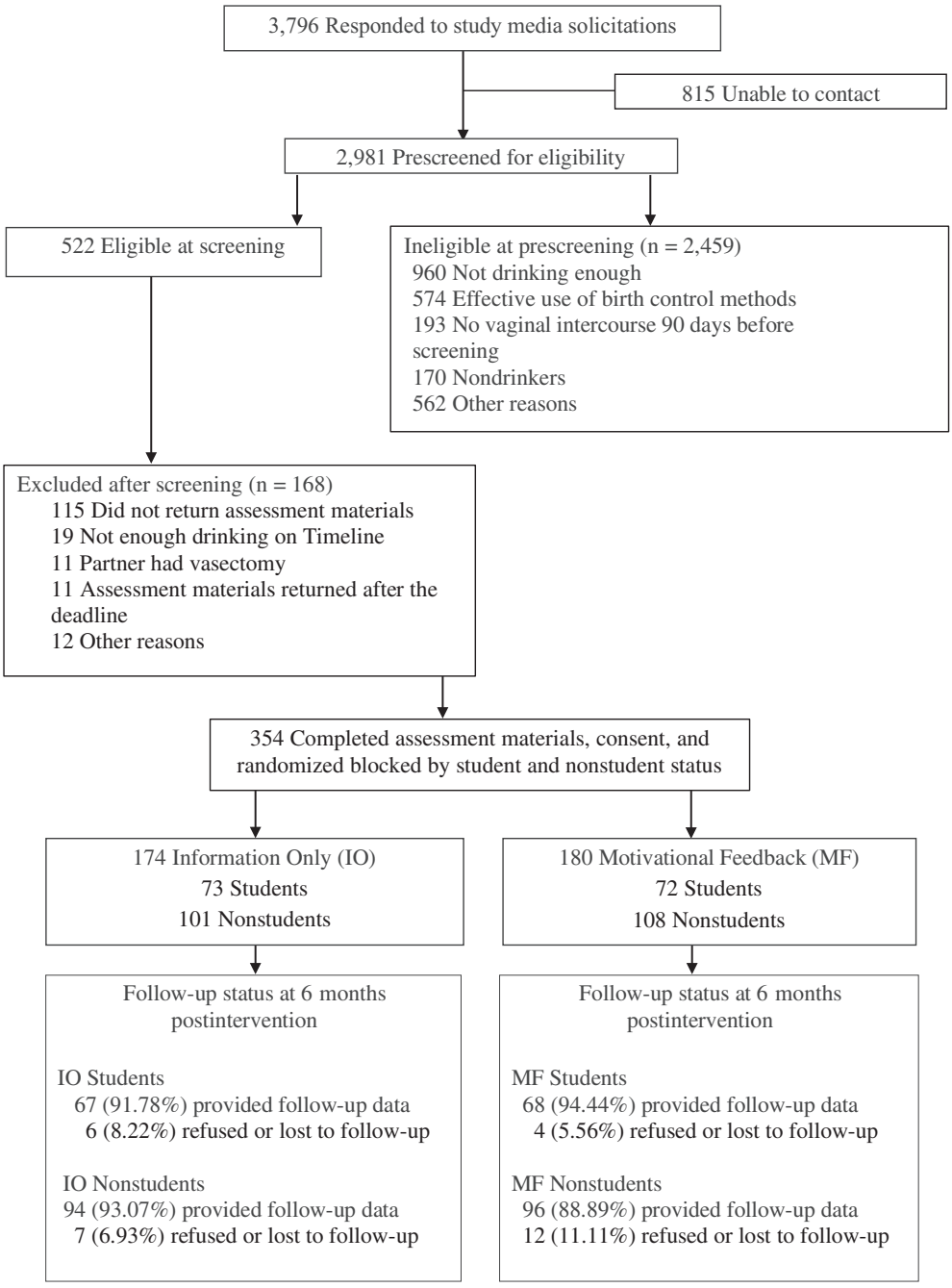

Fig. 1. Consort diagram of participant flow into the study.

treatment program for help to stop drinking. The CDC brochure did not contain information about how to contracept effectively.

Motivational Feedback. Women in the MF group were mailed a brochure prepared as part of the PHC study intervention in English (*Making Healthy Choices for a Healthy Baby*) or Spanish (*Mujeres y Salud Eligiendo Opciones Saludables*). This brochure (http://www.nova.edu/gsc/online_files.html) allows women to make informed decisions about preventing an AEP. The MF materials included nonstigmatizing messages about drinking and contraception embedded among other health messages. Like Project CHOICES, this group also received a brochure on birth control practices.

Measures

Assessment. The assessment included the following: (i) demographic questions; (ii) detailed inquiry about birth control practices; and (iii) ratings *at the present time* of changing 2 behaviors (i.e., "*to not become pregnant*," "*to reduce alcohol use*") on a 5-point importance rating scale (1 = not, 2 = slightly, 3 = somewhat, 4 = very, 5 = extremely).

Timeline Followback. The timeline followback (TLFB), a psychometrically sound measure for assessing daily drinking, collects reliable aggregate drinking data using a calendar format (Agrawal et al., 2008; Sobell and Sobell, 1992). Drinking is reported for each

day using a calendar format and a SD conversion (1 SD = 14 g absolute ethanol). Data were collected for the 90 days prior to the assessment and 6 months postintervention.

Quick Drinking Screen. The quick drinking screen (QDS), a 4-item psychometrically sound drinking measure, collects reliable aggregate drinking data for major drinking variables (Dum et al., 2009; Roy et al., 2008; Sobell et al., 2003). During prescreening, the QDS was administered for the 90 days preceding the interview. A previous methodological publication using data from the present study found that participants' self-reports of their drinking on the QDS and the TLFB were very similar, with data collection separated by about 2 weeks (Dum et al., 2009). This suggests that on an aggregate basis, participants' reports of their pre-intervention drinking are reliable.

Follow-Up

Follow-up intervals for CHOICES-like RCTs have ranged from 4 (Ceperich and Ingersoll, 2011) to 12 months (Rendall-Mkosi et al., 2013). The current study used a 6-month follow-up interval because it has been shown that for reports of drinking follow-up windows as short as 3 months produce aggregate data consistent with those found for a 12-month posttreatment interval (Gioia et al., 2012). Also, the data collected in this study represent the entire 6-month interval (i.e., 180 days), whereas the other CHOICES studies collected data for the 90 days prior to the follow-up date (e.g., days 91 to 180 for a 6-month follow-up). One month prior to their 6-month follow-up, participants were mailed a reminder letter about the follow-up.

The follow-up asked participants about their birth control practices and alcohol use. The first 2 birth control questions asked whether participants had engaged in vaginal heterosexual intercourse and whether they had become pregnant. The effectiveness of birth control methods was evaluated using algorithms (e.g., *If you missed a pill during this time period, did you take both pills the next day and did you use a backup method other than rhythm or withdrawal until you started your next packet of pills?*) from Project CHOICES (Floyd et al., 2007; Project CHOICES Intervention Research Group, 2002). Participants who returned their 6-month follow-up were sent a $20 check for their participation.

Personalized Feedback After the Study

After completing and returning their follow-up questionnaires, participants were sent personalized feedback based on their answers to the follow-up. The feedback showed whether participants were at risk of an AEP and how much they had changed their alcohol and birth control use over the 6 months since the intervention. Although the personalized feedback sent to participants had no effect on their outcomes, it was included as an incentive for them to return their follow-up forms. Blank English and Spanish feedback forms used in this study are available at http://www.nova.edu/gsc/online_files.html.

Data Analysis

The definition and assessment of an AEP were the same used in previous CHOICES studies (Floyd et al., 2007; Velasquez et al., 2016). At the start of the study, all participants were at risk of an AEP. At the follow-up, risk was evaluated dichotomously for the entire 6-month interval as: (i) *At risk* if a woman had engaged in any risky drinking and/or ineffective or no contraception; (ii) *Not at risk* if a woman reported no risky drinking or contracepting effectively, or both. Even 1 binge drinking day (i.e., ≥5 SDs) without effective birth control would constitute an at-risk day and result in women being classified as at-risk over the 6 months.

Using SPSS version 22 (IBM, Somers, NY), several generalized linear models (GLMs) were constructed (McCullagh and Nelder, 1989). The main objective was to test for significant differences over the entire 6-month follow-up interval using the 3 primary reduced risk outcome variables that have been used in almost all Project CHOICES-like studies (Velasquez et al., 2016): (i) reduced drinking; (ii) effective contraception; and (iii) reduced drinking and effective contraception. Main and interaction effects of 2 factors, student status (student vs. nonstudent) and intervention group (experimental, MF vs. control, IO), were evaluated.

To capture true differences due to student status and intervention group, several independent GLMs were run to identify a potential set of covariates from the baseline characteristics in Table 1. For dichotomous variables, a logistic regression model is appropriate, so the GLM model was constructed with a (robust) binomial link function, and for continuous variables, a linear function was used based on multiple regression. Any variable showing a significant interaction or main effect of student status or intervention was considered as a potential covariate and included in the final GLM for outcome analysis. We base this on the p-value cutoff point of 0.05. Traditionally, in any significance testing one would use a lower cutoff value resulting from Bonferroni's correction of Type 1 error, but we still chose to use higher cutoff value of 0.05 because using lower p-values for cutoff can fail to identify variables known to be covariates and may affect the impact of groups on outcomes due to confounding with other covariates present in the full model.

Several univariate analyses were conducted to identify demographic and pretreatment factors associated with AEP outcomes. To maintain an $\alpha = 0.05$ family-wise error rate, Bonferroni adjustments were made for 4 drinking variables thought to be related a priori; the individual test α level became $\alpha = 0.013$ (Holland and Copenhaver, 1988). Any additional covariates identified in the univariate tests were added to the final GLM. This procedure was used to identify and control any variables that might provide alternative explanations for any findings related to student status or the interventions.

A set of GLMs using binomial link function was calculated to examine differences in the 3 outcomes by student status and intervention group without including covariates. Finally, to identify the true effect of student status and intervention, 3 final binomial link function GLMs (1 for each outcome) were run to see differences by student status and intervention after controlling for all potential covariates simultaneously. In all cases where the binomial link function was used, logit was the function student status. These analyses used an intent-to-treat (ITT) procedure where participants not found for follow-up were considered at risk. Analyses were also run for participants only found for follow-up. The more conservative ITT analyses were used because participants followed up ($n = 325$) and lost ($n = 29$) differed statistically on some of the potential covariates included in the final GLM. Nonoverlapping 95% confidence intervals for odds ratios were used to identify significant effects of student status, intervention, and interaction effects using 4 groups (student status by Intervention).

RESULTS

Participants

Table 1 shows demographic, alcohol use, and importance of change variables by student status (student, nonstudent) and intervention group (IO, MF) at baseline. Students compared to nonstudents were significantly younger, fewer were married, and significantly more had at least a bachelor's degree. Across the 4 groups, on average participants were in

Table 1. Baseline Characteristics of Participants (N = 354) by Student Status and Intervention Group

Variable	Students IO (n = 73) Mean ± SD or % (n)	Students MF (n = 72) Mean ± SD or % (n)	Nonstudents IO (n = 101) Mean ± SD or. % (n)	Nonstudents MF (n = 108) Mean ± SD or % (n)	Student status Wald χ^{2a} (df = 1)	p
Age, years	23.2 (3.2)	23.4 (3.5)	29.3 (7.5)	27.7 (6.6)	69.9	<0.001
White, %	63.0 (46)	54.2 (39)	59.4 (60)	49.1 (53)	0.7	0.42
Married,%	16.4 (12)	19.4 (14)	32.7 (33)	35.2 (38)	10.7	0.001
≥Bachelors degree, %	45.2 (33)	45.8 (33)	39.6 (40)	38.9 (42)	1.4	0.02
% Drinking past 90 days[b]	37.4 (20.0)	37.9 (19.3)	45.2 (23.8)	45.1 (24.7)	5.0	0.03
% Days drinking ≥5 SDs past 90 days[b,c]	11.1 (12.7)	10.7 (12.6)	14.7 (18.0)	16.5 (18.6)	3.7	0.05
SDs/drinking day past 90 days[b,c]	3.6 (1.5)	3.6 (1.8)	3.8 (1.7)	4.1 (2.1)	2.7	0.10
SDs/wk past 90 days[b,c]	9.6 (7.1)	10.1 (8.7)	12.3 (10.1)	13.7 (12.8)	5.4	0.02
Importance rating of not becoming pregnant[d]	4.5 (0.9)	4.7 (0.6)	4.2 (1.0)	4.1 (1.1)	10.0	0.002
Importance rating of reducing drinking[d]	1.6 (0.9)	1.8 (1.0)	2.4 (1.3)	2.2 (1.2)	16.31	<0.001

[a]Two tailed.
[b]Bonferroni adjustments for 4 variables thought to be related a priori to maintain an $\alpha = 0.05$ family-wise error rate; individual test α level set at $\alpha = 0.013$.
[c]1 standard drink (SD) = 14 g of absolute ethanol.
[d]5-point scale importance rating: 1 = not, 2 = slightly, 3 = somewhat, 4 = very, 5 = extremely.
There were no significant differences for intervention or for Intervention by student status interaction. Thus, all Wald χ^2 and probability values are for the student status variable. IO = Information Only (FAS brochure from the CDC); MF = motivational feedback (2 motivationally focused brochures—alcohol use and effective contraception).

their mid- to late 20s. The 2 intervention groups (MF and IO) did not differ on any of the 4 drinking variables. In the 90 days prior to the assessment, participants reported drinking, on average, 37 to 45% of all days, consuming a mean of 3.6 to 4.1 SDs per drinking day, 11 to 16.5% of all days were binge days (≥5 drinks), and on average, they consumed 10 to 14 SDs per week.

As shown in Table 1, at baseline, all groups felt it was very important to not become pregnant. However, students' mean ratings (4.5, IO group; 4.7, MF group) on a 5-point scale (5 = *extremely important,* 4 = *very important*) were significantly higher than nonstudents (IO = 4.2, MF = 4.1). In contrast, all groups rated the importance of reducing their drinking as less important, and in this case, students' mean ratings (IO = 1.6, MF = 1.8) on a 5-point scale (1 = *not important, 2 = slightly important*) were significantly lower than those of nonstudents (IO = 2.4, MF = 2.2). While there were no group differences in terms of ethnicity (i.e., white vs. other), 44% of all participants were minorities (24.9% Hispanic; 10.7% black; 8.5% other). Last, variables that were significant in Table 1 were used as potential covariates in the outcome analyses.

Follow-Up

As shown in Fig. 1, across the 4 groups the 6-month follow-up rates ranged from 89 to 94% and did not differ significantly [χ^2 (3) = 2.10, $p > 0.05$]. The 92% overall participant follow-up rate is very high and exceeds the 80% criterion viewed as optimal for substance use disorder studies (Hansten et al., 2000).

Participants not found (n = 29) compared to those found (n = 325) for follow-up differed in 2 significant ways: (i) less likely to have completed at least a bachelor's degree (20.7 vs. 43.7%; $\chi^2 = 5.79$, $df = 1$, $p = 0.016$) and (ii) heavier drinkers at baseline [(i) mean (SD) percent days drinking: 51.9 (25.1) vs. 41.2 (22.3), $t = 2.47$, df = 352, $p = 0.014$; (ii) mean (SD) d/wk: 17.2 (11.9) vs. 1.2 (10.1), $t = 2.96$, df = 352, $p = 0.003$; and (iii) mean (SD) percent binge days: 23.9 (21.3) vs. 12.8 (15.6), $t = 3.56$, df = 352, $p < 0.001$)]. As some significant differences were found between follow-up completers and noncompleters, an ITT analysis was used for outcomes.

Other Potential Covariates Based on Reduced Risk Outcomes of an AEP

Further analyses were conducted to identify additional demographic and pretreatment factors associated with AEP outcomes. These analyses identified variables that were not significant in Table 1 (comparing groups on baseline variables) but needed to be included as potential covariates based on their relationship to AEP outcomes. Several significant differences in baseline variables were found between participants at risk of an AEP versus those not at risk over the 6-month follow-up interval. Participants no longer at risk: (i) were younger [not at risk mean (SD) = 25.6 (5.9) years; at risk mean (SD) = 27.4 (6.8) years, $t = -2.75$, $p = 0.006$]; (ii) felt it was more important not to become pregnant [not at risk mean (SD) = 4.5 (0.9) year, at risk mean (SD) = 4.1 (1.1), $t = 3.60$, df = 352, $p < 0.001$]; (iii) were more likely to be students [students not at risk = 69.0%, nonstudents not at risk = 49.8%, $\chi^2 = 12.93$, $df = 1$, $p < 0.001$]; and (iv) less heavy pre-intervention drinkers [mean (SD) percent days drinking: 39.3 (20.9) vs. 45.9 (24.5), $t = -2.77$, df = 352, $p = 0.006$; mean (SD) d/wk: 10.4 (9.3) vs. 13.6 (11.3), $t = -2.89$, df = 352, $p = 0.004$; mean (SD) percent days

binge drinking: 11.3 (13.3) vs. 16.9 (19.4), $t = -3.23$, df = 352, $p < 0.001$; mean (SD) drinks per drinking day 4.0 (1.9) vs. 3.6 (1.8), $t = 3.97$, df = 352, $p = 0.033$)]. Based on this analysis, the significant drinking variables were included as potential covariates.

Outcome Analyses

Outcome analyses were conducted for follow-up completers without including potential covariates, and as ITT analyses with and without potential covariates. Table 2 shows the percentage of 3 AEP reduced risk outcomes (reduced drinking, effective contraception, and both) by intervention condition (MF, IO) and by student status (student, nonstudent) for follow-up completers ($n = 325$). For women lost at follow-up, ITT procedures were used and considered these women still at risk of an AEP over the entire 6-month interval.

As shown in Table 2, for follow-up completers and using the ITT analyses, (i) the 2 interventions (MF and IO) did not differ in effectiveness; (ii) students were significantly less likely than nonstudents to be at risk of an AEP; (iii) the predominant way women reduced their AEP risk was through effective contraception; (iv) significantly more students than nonstudents engaged in effective contraception; and (v) there was no significant Intervention by student status interaction. When the ITT analyses were conducted using the potential covariates, student status remained statistically significant for reduced overall risk of an AEP ($p = 0.025$) and reduced AEP risk due to effective contraception ($p = 0.040$).

To better understand the impact of student status, the odds ratios and confidence intervals were calculated for the 2 outcome reduced risk variables where the outcomes differed significantly by student status. At the 6-month follow-up, the odds ratio (OR) for students versus nonstudents no longer at risk of an AEP due to reduced drinking, effective contraception, or both was 2.09 (CI = 1.47 to 2.95). The OR for students versus nonstudents no longer at risk of an AEP due to effective contraception was 1.50 (CI = 1.08 to 2.09).

DISCUSSION

For both intervention groups, motivational feedback and information only, a very high percentage of women were no longer at an AEP risk over the entire 6-month follow-up. Although there was no significant difference between the 2 interventions, students over the 6-month follow-up interval were significantly more likely (2.1 OR) than nonstudents to not be at risk of an AEP. Moreover, students also were significantly more likely to use effective contraception than nonstudents.

A possible explanation for college students having a significantly higher overall reduced AEP risk is because becoming pregnant would interfere with their immediate plans to finish their education and pursue a career. It would seem a reasonable inference that these young women gave a higher priority to not becoming pregnant than to avoiding an AEP should they happen to become pregnant. This interpretation is supported in Table 1 by the high ratings participants assigned to the *importance of not becoming pregnant,* and the lower ratings they gave to the *importance of reducing their drinking*. Given these findings, perhaps the most important aspect of this study was to inform these women that they were at risk of becoming pregnant. This explanation is consistent with the high rates of AEP risk reduction shown by the information only control group.

Although effective contraception was the main way women reduced their AEP risk, 16% also reduced their drinking below risk levels. Thus, while population approaches emphasizing birth control are very important for AEP prevention, some woman may also benefit from learning about the risk their drinking poses for an AEP.

The initial Project CHOICES study (Floyd et al., 2007) was published almost a decade ago. Since that time, 6 RCT CHOICES-like interventions have been published, including this study. Although the results have all yielded a very high percentage of women who were no longer at an AEP risk, collectively there are some aspects of these studies worth noting. Figure 2 compares overall reduced risk outcomes for the present study and 6 other CHOICES-like studies (Ceperich

Table 2. 6-Month Postintervention AEP Reduced Risk Outcomes by Students Status and Intervention Group With and Without ITT Analyses, Without Inclusion of Potential Covariates

AEP risk outcome (ITT or no ITT)	Students, IO % (*n*/*N*)	Students, MF % (*n*/*N*)	Nonstudents, IO % (*n*/*N*)	Nonstudents, MF % (*n*/*N*))	Student Wald χ^{2a} (df = 1)	p^a
AEP reduced risk (no ITT)[b,c,]	65.7 (44/67)	79.4 (54/68)	51.1 (48/94)	51.0 (49/96)	12.87	<0.001
Reduced risk drinking (no ITT)[c,]	20.9 (14/67)	19.1 (13/68)	18.1 (17/94)	15.6 (15/96)	0.14	0.71
Effective contraception (no ITT)	56.7 (38/67)	72.1 (49/68)	44.7 (42/94)	42.7 (41/96)	12.13	<0.001
AEP reduced risk (ITT)[b,c,d]	60.3 (44/73)	75.0 (54/72)	47.5 (48/101)	45.4 (49/108)	15.56	<0.001
Reduced risk drinking (ITT)[c,d]	19.2 (14/73)	18.1 (13/72)	16.8 (17/101)	13.9 (15/108)	0.67	0.41
Effective contraception (ITT)[d]	52.1 (38/73)	68.1 (49/72)	41.6 (42/101)	38.0 (41/108)	14.02	<0.001

[a]There were no significant differences for Intervention or for Intervention by student status interaction. Thus, all Wald χ^2 and probability values are for the Student Status variable. IO = Information Only; MF = Motivational Feedback. All *p*-values are 2 tailed.

[b]Alcohol-exposed pregnancies (AEP) reduced risk includes both reduced risk drinking and/or effective contraception outcomes.

[c]Reduced risk drinking defined as ≤7 standard drinks (SDs) per week and ≤4 SDs on any day during the 6-month follow-up interval; 1 SD = 14 g absolute alcohol.

[d]Intent-to-treat (ITT) analysis considers participants not found for follow-up as still at risk.

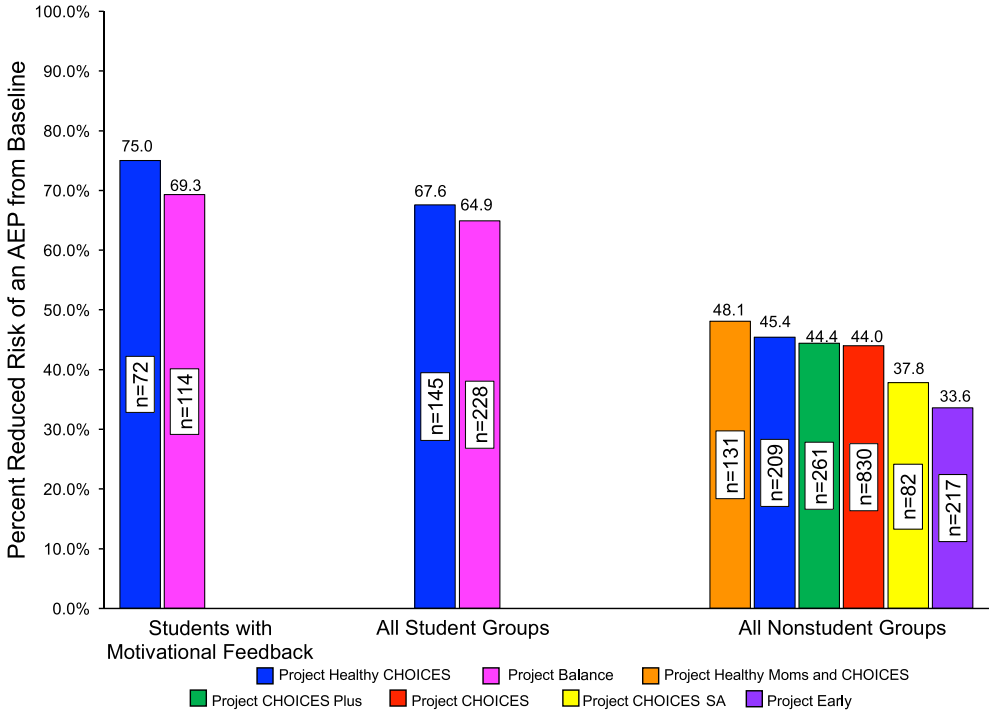

Fig. 2. Percent of women (based on intent-to-treat analyses) in CHOICES-like studies that reduced their risk of an alcohol-exposed pregnancy postintervention. CHOICES Studies: Project Healthy CHOICES (current), Project Balance (Ceperich and Ingersoll, 2011); Project Healthy Moms and CHOICES (Wilton et al., 2013); Project CHOICES Plus (Velasquez et al., 2016), Project CHOICES (Floyd et al., 2007); Project CHOICES, South Africa (Rendall-Mkosi et al., 2013); Project Early (Ingersoll et al., 2013).

and Ingersoll, 2011; Floyd et al., 2007; Ingersoll et al., 2013; Rendall-Mkosi et al., 2013; Velasquez et al., 2016; Wilton et al., 2013). All CHOICES studies in Fig. 2 had to use a RCT and present data for an experimental (i.e., CHOICES) and comparative (e.g., standard control information only) intervention. To allow for a fair and direct comparison of all studies, a common metric was used. For all studies, AEP rates were calculated using an ITT procedure that considered missing cases still at risk. Although counting missing cases as failures is a worst-case scenario and actual outcomes may have been higher, this allowed all studies to be evaluated using the same metric.

Of the 7 CHOICES studies in Fig. 2, the highest overall AEP reduced risk outcomes occurred for students in 2 different studies who received the motivational feedback intervention (current study; Ingersoll et al., 2013). For these 2 studies, their combined (i.e., control and experimental) student groups had higher (68%, current study; 65%, Ingersoll et al., 2013) AEP risk reduction rates compared to any of the 6 combined (i.e., control and experimental) nonstudent groups (34 to 48%). Considering that all women in all CHOICES studies were at risk of an AEP at the start of the CHOICES intervention, the collective results, even for the control groups, are impressive.

Further, the resources needed for the CHOICES-like intervention in both studies with college students were minimal compared to the 5-session CHOICES intervention. These results suggest that, at least with college students, a minimal CHOICES intervention, including a self-administered one, can be effective in changing behavior (s) to prevent an AEP.

The most notable strength of the current study is that all participants' reduced risk outcomes were cumulative; that is, participants with risk free outcomes maintained those outcomes over the *entire* 180-day follow-up interval (i.e., not even 1 AEP at-risk day during the 6 months was allowed). In contrast, 3 of the other 6 CHOICES studies in Fig. 2 used a partial follow-up interval (e.g., 3 months prior to the 12-month interval; Rendall-Mkosi et al., 2013), and all 6 reported collecting drinking data "for the 90 days prior to the follow-up interval" (see Velasquez et al., 2016, pp. 35–41). What this means is that for a study (e.g., Ingersoll et al., 2013) that collected follow-up data at 3 and 6 months, the data for months 1 through 3 and months 4 through 6 were reported separately. Thus, a woman could have been at risk for several days during months 1 through 3 and not at risk for months 4 through 6, and vice a versa. In other words, while all CHOICES like studies collected continuous drinking data using the Timeline Followback measure (Agrawal et al., 2008; Sobell and Sobell, 1992), their data presentations do not show whether women were free of risk over the entire follow-up period.

Other strengths of the present study include the following: (i) a large sample, (ii) 92% follow-up rate, (iii) 44% of participants were minorities (25% Hispanic), and (iv) the CHOICES motivational brochure in this study can be easily and inexpensively disseminated on a large-scale basis. This study also had a few limitations: (i) inability to generalize the

findings to women not recruited by ads and who are under the age of 18, (ii) results are limited to a 6-month interval, and (iii) there is a need to evaluate whether the MF brochure could be effectively disseminated and used in settings where women seek services for preventive or routine health care.

Because AEPs are avoidable and because their consequences are permanent and tragic, preventing them needs to be a national public health priority. The current findings suggest that low-cost population approaches could address this need. Although the CDC is freely disseminating the original Project CHOICES (Floyd et al., 2007) study materials on its website (Velasquez et al., 2016), these materials focused on a 5-session intervention delivered by healthcare practitioners (Floyd et al., 2007). Only 2 CHOICES-like studies, Project Balance (Ceperich and Ingersoll, 2011) and the current study, have specifically recruited and focused on college students. While the drinking of college students is the highest of all age groups (Winograd and Sher, 2015), discussions about extending CHOICES to college students have been rare.

In summary, the results of this study suggest that disseminating low-cost, informational brochures to prevent AEPs in settings where women seek services for preventive or routine health care (e.g., college and university campuses, community, and healthcare facilities) could help achieve the CDC's *Healthy People 2020* objective of mitigating the risk of AEPs among women of childbearing age (U.S. Department of Health and Human Services, 2012). This study strongly suggests that the most effective AEP prevention strategy is to simply communicate to those women at risk that they could become pregnant.

ACKNOWLEDGMENTS

The study was supported by grant U50/CCU300860 (LCS) from the Centers for Disease Control and Prevention (CDC) through a cooperative agreement with the Association for Prevention Teaching and Research (APTR). Portions of this paper were presented at the symposium "Advancing a Preconception Approach to Preventing Alcohol-Exposed Pregnancies" at the annual meeting of the Research Society on Alcoholism, Chicago, IL. The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the CDC or the APTR. No financial disclosures were reported by the authors of this manuscript. We want to thank Dr. Louise Floyd for all her support through this study and all CHOICES interventions.

CONFLICT OF INTEREST

The authors have no conflict of interests.

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