

Motivational interviewing + feedback intervention to reduce alcohol-exposed pregnancy risk among college binge drinkers: determinants and patterns of response

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Abstract Many college women are at risk for pregnancy, and binge drinking college women are often at risk for alcohol-exposed pregnancy. Brief interventions with sustainable outcomes are needed, particularly for college women who are binge drinking, at risk for pregnancy, and at increased risk of alcohol-exposed pregnancy. Two-hundred-twenty-eight women at a Mid-Atlantic urban university at risk for alcohol-exposed pregnancy enrolled in the randomized clinical trial, and 207 completed the 4 month follow-up. The BALANCE intervention used Motivational Interviewing plus feedback to target drinking and contraception behaviors. Main outcome measures included (1) the rate of risk for alcohol-exposed pregnancy, (2) the rate of risk drinking, and (3) the rate of pregnancy risk. At 4-month follow-up, the rate of alcohol-exposed pregnancy risk was

significantly lower in the intervention (20.2%) than the control condition (34.9%), ($P < .02$). Assignment to the intervention condition halved the odds of women remaining at risk for alcohol-exposed pregnancy, while not receiving the intervention doubled the odds of continued alcohol-exposed pregnancy risk (OR = 2.18; 95% CI = 1.16–4.09). A baseline history of blackouts, continued high blood alcohol drinking days at 1 month, and continued risk for pregnancy at 1 month independently contributed to a multivariate model of continued alcohol-exposed pregnancy risk at 4 month follow-up. BALANCE reduced alcohol-exposed pregnancy risk, with similar outcomes to longer interventions. Because early response predicted sustained alcohol-exposed pregnancy risk reduction, those who fail to achieve initial change could be identified for further intervention. The BALANCE intervention could be adopted into existing student health or university alcohol programs. The risks of unintended pregnancy and alcohol-exposed pregnancy among binge drinking women in college merit greater prevention efforts.

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Introduction

Alcohol-exposed pregnancy risk in university women

Binge drinking combined with pregnancy risk due to absent, intermittent, or ineffective contraception among fertile, sexually active women results in the risk of alcohol-exposed pregnancy. A recent survey at one university found that most sexually active university women (74%)

were risk drinkers who consumed more than 3 standard drinks over a 2 h period (defined as a binge) and/or drank more than 7 drinks per week (Dawson et al. 2005), and many (21%) were ineffective contraceptive users, with a combined risk for alcohol-exposed pregnancy evidenced in 17% of those who were sexually active (Ingersoll et al. 2008). This rate of alcohol-exposed pregnancy risk is comparable to that seen in high-risk community women, (between 10 and 26% depending on setting) (Project CHOICES research group 2002). While these data indicate that some college women are at risk for alcohol-exposed pregnancy, it is possible that most would not carry a fetus to term. Thus, having an alcohol-affected child may be less likely for these women than facing real physical and emotional risks of unplanned pregnancy, sexually transmitted infections, unintended sex, and a variety of negative consequences from drinking including blackouts and injuries, reviewed next. The consequences of unintended alcohol-exposed pregnancy may include increased abortion rates (Sihvo et al. 2003) or, if the fetus is carried to term, a range of neurobehavioral effects known as Fetal Alcohol Spectrum Disorders, including the most severe form, fetal alcohol syndrome (American Academy of Pediatrics 2000; Eustace et al. 2003).

Binge drinking in university women

College binge drinking results in numerous problematic outcomes including higher total volume of alcohol consumed, higher consumption of illicit drugs and cigarettes, and more unplanned sex, accidents, rape, driving while intoxicated, and deaths (Howard and Wang 2004; Jones et al. 2001; Wechsler and Isaac 1992; Wechsler et al. 1994) than occur in students who do not binge drink. College women may have a higher probability of new onset binge drinking during their first year of college than men, who often begin a pattern of binge drinking earlier (Reifman and Watson 2003).

Pregnancy risk in university women

Many college women are sexually active and at risk for pregnancy due to no contraception or ineffective contraception. While 29% of women 18–44 from the general U.S. population are at risk for unplanned pregnancy, (Xaverius et al. 2009), a much higher proportion of college-age women are at risk. Vahratian et al. (2008) found that between 60 and 80% of pregnancies in women ages 18–24 were unintended. Over 80% of adolescent pregnancies are unintended (Ayoola et al. 2006). Finer and Henshaw (2006) found that the rate of unintended pregnancy among women aged 18–24 is double that of other age groups, with a rate of one unintended pregnancy for every 10 women in that age group.

There are no strong epidemiology studies of pregnancy risk among college women specifically, but data from related studies suggest that many college women are at risk. For example, in a study assessing awareness of emergency contraception among college women, Hickey (2009) found that among the 15% of college women who had ever been pregnant, 87% reported that these pregnancies were unplanned. Over a third (37%) of college women presenting for pregnancy testing at student health services reported that they had used no contraception, while 60% had contraception methods available but did not use them consistently (Sawyer et al. 1998). While some college women become more effective contraceptive users after counseling following a pregnancy scare (ni Riain 1998), many college women fail to maintain effective contraception use (Kusseling et al. 1995). The term “ineffective contraception” as we use it here includes sexual activity and (1) no use of contraceptive methods during sexual intercourse, (2) incorrect or inconsistent use of effective methods (common examples are condoms used during some intercourse episodes and not others, or condoms used improperly, or taking birth control pills but missing too many doses for pregnancy prevention), or (3) use of methods considered ineffective (using withdrawal, douching, etc.).

Interventions to reduce alcohol-exposed pregnancy risk

The high rates of risk drinking, ineffective contraception use, and alcohol-exposed pregnancy risk among college women suggest a need for preventive interventions that could reduce risk drinking, reduce pregnancy risk, and reduce alcohol-exposed pregnancy risk. There has been one efficacious preventive intervention to reduce alcohol-exposed pregnancy risk. A 5-session counseling intervention CHOICES, was based on Motivational Interviewing (Miller and Rollnick 2002) plus personalized feedback with a contraception consultation. It reduced alcohol-exposed pregnancy risk in a randomized clinical trial among community women from six high risk settings (Floyd et al. 2007). The odds of being at reduced risk 9 months after the intervention concluded were doubled in the intervention versus the information control condition. In the CHOICES study, reduced risk resulted from three changes women could make: (1) adopting an effective contraceptive method and using it consistently, (2) reducing drinking to be below the risk drinking threshold consistent with NIAAA recommendations for women (no binges, and no more than 7 drinks per week), or (3) changing both of the behaviors that placed her at risk of having an alcohol-exposed pregnancy. (The authors used the term “reduced risk” because even consistent use of effective contraception, or very low level drinking, can still result in alcohol-exposed pregnancy, though the likelihood is greatly reduced).

Development and initial testing of a university intervention for alcohol-exposed pregnancy risk

In order to develop a briefer alcohol-exposed pregnancy risk reduction intervention, we conducted a randomized trial and tested the short term effects of a one-session MI plus personalized feedback intervention, BALANCE, to reduce the risk of alcohol-exposed pregnancy due to risk drinking and ineffective contraception among sexually active college women (Ingersoll et al. 2005). A brief report of our preliminary findings during the ongoing study showed that the intervention had promise; 1 month after the baseline assessment, 74% of women receiving the intervention and 54% of participants in the control condition were no longer at risk for alcohol-exposed pregnancy ($\chi^2_{1,df} = 8.15, P < .005$), a difference favoring the intervention condition. 25% of intervention and 15% of control participants reported no binge drinking, a significant difference also favoring the intervention group. Additionally, at 1 month, 64% of intervention and 48% of control participants reported effective contraception, a significant difference favoring the intervention condition. Alcohol-exposed pregnancy risk at 1-month follow-up was associated with a higher number of standard drinks per day with higher peak blood alcohol concentration in the month prior to baseline, (OR 1.1) and assignment to the control condition, (OR 2.9).

Purpose of the study

In this study, we investigated the longer term outcomes of the BALANCE intervention in the full sample, both to determine whether this brief intervention resulted in maintained change, and whether it yielded comparable effect sizes to the 5 session CHOICES intervention. Further, as a unique contribution to this emerging literature, we sought to understand what behaviors or other determinants including psychological characteristics predicted longer term alcohol-exposed pregnancy risk by examining participant characteristics and post-intervention behaviors. Lastly, in this report, we provide a full description of measures and intervention components that extend our previous report significantly.

Methods

Participants

Two-hundred-twenty-eight female students at risk for alcohol-exposed pregnancy at a Mid-Atlantic urban university age 18–24 enrolled in the trial. Eligibility criteria were: university enrollment, age 18–24, not planning or

seeking pregnancy in the next year, at risk for pregnancy, and drinking at risk levels. Women were considered to be at risk for pregnancy if they (1) had sexual intercourse with a man in the past 90 days, (2) used contraception ineffectively (defined as any or all of the following: (a) no use, (b) incorrect or inconsistent use of an effective method, determined by manufacturer's instructions for each method, or (c) use of an ineffective method only). Women were considered to be drinking at risk levels if they consumed more than 4 standard drinks per occasion (5 drinks or more constituted a binge) at least once in the past 90 days, or consumed more than 7 standard drinks per week on average. Note that when the study began, the number of drinks that constituted a binge for women was defined as more than four per occasion, such that five or more drinks constituted a binge. During the study, the binge threshold for women changed to more than 3 drinks on one occasion, such that four or more drinks constituted a binge (NIAAA 2004), but we retained our original definition to ensure consistency in data collection over time. Women were considered at risk for alcohol-exposed pregnancy if they were at risk for pregnancy and drinking at risk levels during the same 90 day period. Because there is a lag between insemination, fertilization, and implantation of the egg into the uterus following sexual intercourse, women were at risk for an alcohol-exposed pregnancy even if they did not consume alcohol on the night they were impregnated. Drinking during weeks 3–10 of gestation are particularly concerning because the flow of alcohol to the fetus is well-established and critical brain, heart, and facial structures are developing during this time. Therefore, our selection of the 90 day window was designed to reflect the potential risk to a developing fetus of alcohol exposure if a woman were to become pregnant and drink any time following the onset of pregnancy.

Measures

The assessment battery was designed to assess the behaviors that placed a woman at risk for alcohol-exposed pregnancy and other factors that might relate to treatment response. Baseline assessment occurred immediately before randomization, and generally required 90 min. Follow-up assessments at 1 and 4 months were much shorter, requiring approximately 15 min.

The *BALANCE Core Assessment* was a 41 item questionnaire adapted from other studies assessing alcohol-exposed pregnancy risk including the Project CHOICES feasibility study (Ingersoll et al. 2003). Many items branched and included sub-questions if endorsed. The assessment was administered by the interviewer, who was usually a study counselor, and covered demographic characteristics (7 items), sexual behavior and contraception

(11 items), obstetric history (4 items), drinking and illicit drug use (12 items), health behaviors and knowledge (e.g., folic acid functions, multivitamin use), and attitudes such as the belief that drinking daily has health benefits (7 items).

The *BALANCE CORE Assessment* included questions that measured all of the component behaviors of the primary outcomes at baseline. For example, in the sexual activity and contraception section of the measure, women reported information that would be used to assess baseline pregnancy risk. They responded to questions such as “In the past 3 months, how many males have you had intercourse with?”, and “When you had intercourse during the past 3 months, what were you or your partner(s) using to keep you from getting pregnant or getting a sexually transmitted disease? I am going to read a list of methods. For each one, please let me know if you have used the method in the past 3 months”. Following the participant’s responses, the interviewer further inquired about the effective use of each method endorsed, asking, “Please review this card describing the use of (METHOD). During the past 3 months, have you had intercourse and NOT used (METHOD) as described in this card?”

Following these inquiries the interviewer coded her contraception as ineffective if the following criteria applied: “Used one method effectively for part of 3 months but not entire 3 months” or “Used several methods effectively for part of 3 months but not entire 3 months” or “Used method effectively, but failed to use a backup method in unusual circumstance (ex: took antibiotics when on birth control pills and did not use a condom)”. They also reported how many alcoholic drinks, if any, that they consumed per week over the past 90 and 30 days, how many drinks containing alcohol consumed on a typical day when drinking, how many times in the past 90 and 30 days they had five or more drinks in 1 day, and the most they had to drink on any 1 day in the past 90 and 30 days.

In addition to the *BALANCE Core Assessment*, we used standard psychological measures to assess normal personality, psychological distress, and psychiatric functioning as potential covariates at baseline. Normal personality variables were measured with the *Five-Factor Inventory* (FFI, Costa and McCrae 1992). The FFI is a 60-item instrument to assess adults on five major dimensions of normal personality: neuroticism, extraversion, openness, conscientiousness, and agreeableness. Responses are on a five-point scale from strongly disagree to strongly agree. The FFI is based on decades of factor analytic research and its five major domain scales have high internal consistency (.86–.95) and can be considered personality traits. The FFI takes about 10–15 min to complete.

Psychiatric distress was measured with the *Brief Symptom Inventory* (BSI, 20 Derogatis 1993) that assesses

psychological symptoms and state distress experienced in the past 2 weeks by self-report responses to 53 questions on a five-point scale. It has 9 symptom scales and 3 general adjustment scales. Because it measures state psychiatric distress, it is expected to change over time. While widely used and well-validated, the BSI is more typically used with clinical samples than with college students, who score predominantly in the non-pathological range. The BSI requires 5 min to complete.

Changes in psychological adjustment were evaluated with the *Outcomes Questionnaire 45.1* (OQ45.1 Lambert et al. 1994). The OQ45.1 is a 45-item self-report outcome/tracking instrument designed to assess change over time in three domains: symptom distress, interpersonal functioning, and social role and also generates a total score indicating psychosocial distress. The OQ-45.1 has strong test-retest reliability in college samples (ranging from .66 to .86), and its internal consistency reliability is excellent, generally above .90 in college samples for the total and symptom distress scales and ranging from .70 to .90 for the interpersonal functioning and social role scales. It requires 5 min to administer.

The *BALANCE 1* and 4 month follow-up assessments included the *Core Questionnaire*, the *BSI*, the *OQ-45.1*, and a locator form. The *1 month Core Questionnaire* was an abbreviated version of the baseline *BALANCE Core Questionnaire* that focused on behavior only in the past 1 month, and contained 4 branching questions about sexual activity and contraception and 3 branching questions about drinking that were designed to assess pregnancy risk and risk drinking. Women could select 0 sexual partners in the past month to indicate sexual abstinence. The *4 month Core Questionnaire* contained 7 branching questions about sexual activity and birth control that guided women to respond for the past 3 months and for the past 30 days, as well as 6 branching questions about drinking that also requested responses for the past 3 months and the past 30 days.

Some measures were used to develop personalized feedback and these were administered to women randomized to the intervention group only at the beginning of the counseling portion of the session. These included 90 days of drinking and contraception behavior recorded on a *Time-Line Follow-Back* (TLFB, Sobell and Sobell 1992), a calendar-based method that can enhance recall of drinking and other behaviors across time that was adapted to measure days of sexual intercourse, contraception, and drinking (Floyd et al. 2007). Additionally, women rated their temptation to drink or to skip using contraception and their confidence they would not drink and would use contraception in 8 situations on the *Brief Situational Confidence Scale*, (BSCQ, Breslin et al. 2000) modified to include contraception items (Floyd et al. 2007).

Procedures

Women were recruited for the study through mailings or flyers posted on campus and in the student health center, and were screened on the telephone or in person. Following screening, research assistants scheduled women to attend the project appointment, which was held at the university’s student health center, at a mutually convenient time. A research interviewer, usually a study counselor, verified eligibility and obtained informed consent, then administered the assessment battery. Following the assessment, the counselor opened a randomization envelope, and provided either the BALANCE counseling intervention, or the information-only control condition. Follow-up assessments were mailed or emailed to participants 1 and 4 months after the baseline and intervention based on their preferences for method of contact. Because participants were college students following an academic calendar, we chose a 4 month final outcome point to capture as many students as possible within a semester time frame. Women received gift cards in the amount of \$40 for the baseline session, \$35 for the 1 month follow-up, and \$50 for the 4 month follow-up. Figure 1 shows the study flowchart, showing screening, enrollment, and completion data for the study.

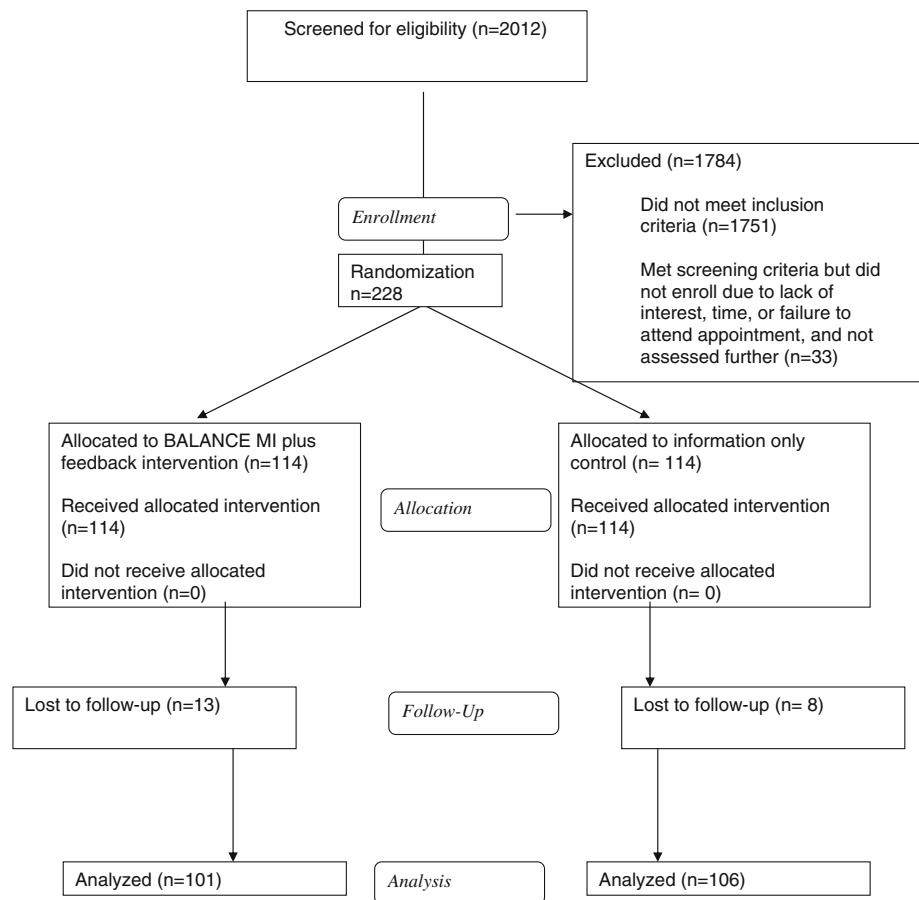
Study conditions

BALANCE intervention condition

The BALANCE counseling intervention was a single 60–75 min session of Motivational Interviewing (Miller and Rollnick 2002) plus personalized feedback following a semi-structured counseling manual. Counselors used a Motivational Interviewing counseling style throughout intervention activities. The intervention began with rapport building using open questions, affirmations, reflections, and brief summaries. After the participant had recorded TLFB data for her drinking, sexual intercourse, and contraception behaviors, she took a 10-min refreshment break while the counselor computed her feedback information. Following the break, the counselor provided personalized feedback of risks using the printed *BALANCE Feedback Form*. Risk information was based on the *TLFB* and *Temptation and Confidence* scales from the *BSCQ*.

Feedback forms were printed using color and symbols with national and local norms and her personal information depicted on pie charts and other graphics. Major headings on the *BALANCE Feedback Form* were drinking and pregnancy risk. Feedback components under drinking

Fig. 1 BALANCE study flowchart



included drinks per week, per occasion, and estimated peak blood alcohol concentration, categorization as a moderate or risk drinker (all participants met risk drinker criteria), including health risks associated with each category, and charts depicting her percentile rank compared to a nationally normative sample. Statistics for the feedback forms were gathered from National Institute of Alcoholism And Alcohol Abuse data in publications such as *Alcohol Alert* and National Institute Of Alcoholism And Alcohol Abuse websites. For example, participants viewed a pie chart showing that approximately 50% of U.S. women ages 18–24 do not drink, while 30% drink moderately and 20% drink at risky levels, then read a statement such as “You are currently drinking more than 80% of women your age”. Additionally, statistics from the participating university were shown for binge drinking, and the participant’s personalized feedback stated that “You are binge drinking more than xx% of university students”.

The Feedback Form showed how much money the participant had spent in the past year on drinking based on her own reported spending per drink, as well as how many “empty” calories and potential associated pounds she had accrued over the year. Regarding pregnancy risk, the Feedback Form showed whether the participant fell in the low risk or risky category (all participants were categorized as at risk for pregnancy) and provided the reasons why. For example, “You are at risk for pregnancy because you missed 4 pills in a row and had sex without a backup method such as condoms”, or “You are at risk for pregnancy because your contraception method is condoms, and you did not use them on every intercourse episode”. Lastly, the Feedback Form showed the chance of pregnancy with typical and imperfect use of various common contraception methods in an easy-to-read table adapted from data provided on the Planned Parenthood website. This table showed why some methods are considered medically inadequate for pregnancy prevention, having high pregnancy rates such as 21 for every 100 users over a year’s time.

The counselor used the elicit-provide-elicited conversational strategy for exchanging information (Rollnick et al. 1999, 2008). Throughout the feedback process, the counselor first asked the participant for her ideas about how her behavior compared to norms, then presented one portion of the Feedback Form, then queried the participant’s thoughts, reactions, and summaries of the information. The counselor used reflections to underscore the participant’s reactions and any change talk (statements indicating that she should or wanted to change, or how she might do it) that she expressed. Following the discussion of the feedback, the counselor asked the participant to rate the importance of, her confidence to, and her readiness to change drinking and

contraception behaviors, using a 0–10 scale for each. Using the participant’s ratings of the importance, her confidence, and her readiness to change each behavior, the counselor elicited change talk by asking follow-up questions such as “what makes it a 4 and not a 0” and “what would it take for you to feel one point more confident?” After this discussion, the counselor guided the participant to create a change or maintenance plan for both behaviors based on her own levels of interest in changing. At the end of the session, the participant received a copy of the feedback materials to keep.

Information control condition

When women were randomized to the control condition following the assessment, the counselor thanked them for their participation in the assessment, and oriented them to a brochure on women’s health that included recommendations for eating, drinking, health screenings, family planning, prevention of sexually transmitted infections, and exercise recommended for women of childbearing age. The counselor collected locator information and recorded the participant’s preference (mail or email) for follow-up contacts. This type of minimal control condition is consistent with recommendations for initial testing of a novel intervention (Rounsaville et al. 2001).

Counselor training and supervision

Four women served as counselors over the course of the BALANCE study. All counselors had master’s degrees in psychology or social work, and received training in Motivational Interviewing and the BALANCE counseling manual from the investigators. For quality control, all counseling sessions were audio-taped. Counselors reviewed the tapes in weekly individual supervision (with SDC) and weekly group supervision sessions conducted by the investigators (SDC and KSI), both members of the international Motivational Interviewing Network of Trainers and Licensed Clinical Psychologists with extensive Motivational Interviewing training and supervision experience. If drift was detected from the BALANCE counseling manual or from the Motivational Interviewing style, the supervisors elicited options for better handling this type of situation from the counselors, and often role-played specific situations with the counselors. In addition to reviewing specific BALANCE cases, counselors and supervisors reviewed and practiced Motivational Interviewing principles, techniques, and strategies at least twice a month during the group supervision time. Tapes were erased following their use in individual and group supervision sessions.

Analyses

We used descriptive statistics to characterize the sample demographics, contraceptive behaviors, drinking behaviors, and alcohol-exposed pregnancy risk. Outcome analyses focused on 4 month variables. *T*-tests and Chi-square analyses were used to assess whether intervention and control groups differed on secondary variables at baseline to check randomization, and at 4 months to assess outcomes. Chi-square analysis was used to determine whether the rates of risk drinking, ineffective contraception, and alcohol-exposed pregnancy risk (the primary outcome) differed between the two groups across time. We classified women as *non-responders* if they never achieved alcohol-exposed pregnancy risk reduction, *improvers* if they were at risk for alcohol-exposed pregnancy at 1 month but no longer at risk at 4 months, *relapsers* if they had achieved reduced risk status at 1 month but were again at risk at 4 months, and *maintained responders* if they achieved alcohol-exposed pregnancy risk reduction at 1 month and maintained it at 4 months, and used Chi-square analysis to determine if these patterns differed by group.

We used a simple logistical regression analysis to determine the impact of group assignment on alcohol-exposed pregnancy risk at 4 months. In order to explore how women had maintained (or not) reduced risk status, we considered demographic characteristics (age, year in university, employment and living status, etc.) personality (examples: normal personality, psychological distress, psychiatric functioning) and behavioral variables (examples: drinking and contraception behaviors at earlier timepoints, visiting a contraception provider following the intervention, number of sexual partners, methods of contraception) that we hypothesized could influence response to the intervention. We then examined univariate relationships among potential baseline or 1 month explanatory variables with 4 month alcohol-exposed pregnancy risk. When we found several conceptually overlapping variables that were related to outcome, we reduced the variable set to non-redundant variables by selecting those that represented distinct behaviors (rather than summary variables) with the smallest *P* values. We entered these variables, after assignment, into a stepwise logistic regression analysis to determine their effect on the primary outcome, alcohol-exposed pregnancy risk at 4 months.

Results

Retention

Four month outcome data were available on 207 of the 228 enrolled women, representing a follow-up rate of

90.8%. Twenty-one women (9.2%) were lost to follow-up. We compared the 207 completers to the 21 dropouts and found no significant differences between these categories on demographic, sexual history, contraception, or drinking variables at baseline. Because of this lack of difference between completers and dropouts, all subsequent analyses were conducted on the sample of 207 study completers. No significant differences were found between intervention and control conditions at baseline on demographic characteristics, sexual behaviors, contraception behaviors, or drinking behaviors, indicating that random assignment was successful in minimizing existing differences between the groups of women (see Table 1 for demographic characteristics, sexual, and drinking behaviors of women in the intervention and control conditions).

Four-month primary outcome: alcohol-exposed pregnancy risk

All participants were at risk for alcohol-exposed pregnancy at baseline due to risk drinking and risk for unintended pregnancy in the 3 months prior to the study. In contrast, at follow-up 79.8% of women in the intervention condition and 65.1% of women in the control condition were no longer at risk for alcohol-exposed pregnancy in the past month. This represents a *Risk Difference* (RD), one marker of the effect size in Chi Square analyses, (Gliner et al. 2002) of 14.7%, between the two conditions, which was a significant difference ($\chi^2_{(1,df)} = 5.51; P < .02$). Table 2 shows 4 month outcomes data for the sample.

Four month drinking and contraception outcomes

At 4 months post-treatment, over a third of intervention women (33.7%) no longer reported any risk drinking or binge drinking during the past month, compared to 22.4% of control women, RD = 11.3%, a trend but not a significant difference between the conditions ($\chi^2_{1,df} = 3.12, P < .08$). A greater proportion of women made changes in contraception, with 68.7% of intervention and 55.1% of control women reporting effective contraception behavior during the past month at the 4 month follow-up, RD = 13.6%, favoring the intervention condition as a trend ($\chi^2_{1,df} = 3.69, P < .06$).

Routes to reduced risk

Figure 2 shows the proportion of women in each condition who were at risk and at reduced risk for alcohol-exposed pregnancy at the 1 month and 4 month follow-ups, based on specific behavior changes that represent routes to

Table 1 Baseline demographic characteristics, sexual behavior, and drinking behavior of college women study completers at risk for alcohol-exposed pregnancy

Variable	Controls		BALANCE intervention	
	n = 106		n = 101	
	Mean or n	(SD) or %	Mean or n	(SD) or %
Age	21	(1.8)	20.19	(1.8)
Race				
Caucasian	77	72.6%	68	67.3%
African American	16	15.1	18	17.8
Other	13	12.3	15	14.9
Single	92	87.6%	86	86%
Employed	68	63.6%	64	63.1%
Age first sexual intercourse	16.3	(2.0)	16.2	(1.8)
Age first contraception	16.3	(1.9)	16.8	(1.6)
Sexual partners in 3 months	1.5	(.8)	1.4	(1.0)
Current contraception				
Withdrawal	48	44.9%	48	48%
Condoms	22	20.6%	22	22%
Pill	24	22.4%	19	19%
None	3	2.8%	5	5%
Rhythm	3	2.8%	3	3%
Spermicide only	2	1.9%	2	2%
Emergency contraception	2	1.9%	1	1%
Depo provera	2	1.9%	0	0
Age first full alcoholic drink	14.9	(2.4)	15.8	(8.5)
Most standard drinks in 1 day	7.3	(3.8)	7.8	(3.9)
# binges past month	4.1	(5.0)	4	(4.7)
# binges past 3 months	11.9	(12.0)	13.2	(15.6)
Average drinks per day				
None	1	.9%	4	4%
1–2	11	10.4%	15	15%
3–4	42	39.6%	38	38%
5–6	40	37.7%	29	29%
7–9	9	8.5%	10	10%
10+	3	2.8%	4	4%
Average drinks per week				
0	0	0	1	1%
1–7	50	47.2%	44	43.6%
8+	46	43.4%	40	39.6%
Had Blackouts	69	65.1%	70	69.3%
Have thought I should cut down on drinking	39	36.8%	46	45.5%
Ever used illicit drugs	84	79.3%	84	83.2%

There were no significant differences between groups on any of these baseline characteristics

reduced alcohol-exposed pregnancy risk. These figures clearly show that the proportion of women with reduced alcohol-exposed pregnancy risk improves in both groups from 1 to 4 months, but that at both times, the intervention condition improves more than the control condition. More

women in the intervention condition changed both behaviors and fewer of these women changed neither. Similar proportions of women in both intervention and control conditions changed only one behavior (either contraception or drinking).

Table 2 Four month outcomes of the BALANCE intervention versus the information control

Variable	Controls (N = 106)		BALANCE intervention (N = 101)		t-test or Chi-Square test
	χ or N	SD or %	χ or N	SD or %	
Average standard drinks per week	9.8	10.1	9.1	11.5	ns
Binges in past 3 months	7.7	8.7	6.5	12.2	ns
Most standard drinks per day	7.3	3.8	7.8	3.9	ns
Drink risk					
None	24	22.4%	34	3.7%	ns
Binge only	40	37.4%	35	34.7%	
Binge and 8+/week	42	39.3%	32	31.7%	
8+/week only	1	.5%	0	0	
Drink risk (binary)					$\chi^2_{1df} = 3.12, P < .08$
No	24	22.6%	34	33.7%	
Yes	82	77.4%	67	66.3%	
Contraception (most recent 30 days)					$\chi^2_{1df} = 3.69, P < .06$
Effective	59	55.7%	68	68.7%	
Ineffective	47	44.3%	31	31.3%	
Alcohol-exposed pregnancy risk					$\chi^2_{1df} = 5.51, P < .02$
No	69	65.1%	79	79.8%	
Yes	37	34.9%	20	20.2%	

Response patterns

What was the pattern of alcohol-exposed pregnancy risk over time? Were women at risk at one follow-up point also at risk at the other? Did women who reduced their risk stay that way, and vice versa? To answer these questions, we examined the rate of treatment response (*non-responders*, *improvers*, *relapsers*, and *maintained responders*) in intervention and control conditions. We could not assess the 1 month alcohol-exposed pregnancy risk status for 11% of intervention and 3% of control participants, due to missing data for some participants at 1 month.

Among the 190 who had data at both timepoints, χ^2 analysis showed that there were statistically significant differences between the conditions ($\chi^2_{(3df)} = 8.28, P < .05$). Figure 3 shows that the conditions differed in treatment response patterns. Specifically, more women in the intervention condition were in the maintained responder group than into any other category. While this was also true in the control condition, there were more non-responders in the control than the intervention condition. Only 11% of women in the intervention condition were non-responders, compared to over 25% of women in the control condition. Eighty-nine percent of women in the intervention condition but only 75% of women in the control condition responded to the intervention at one or both follow-up points ($\chi^2_{(1df)} = 6.14, P < .02$).

Determinants of continued alcohol-exposed pregnancy risk

Assignment to the intervention condition halved the odds of continued alcohol-exposed pregnancy risk at 4-month follow-up; put another way, being in the control condition and not receiving the intervention doubled the odds of continued alcohol-exposed pregnancy risk at 4-month follow-up (Odds Ratio = 2.12, 95% Confidence Interval = 1.13–3.99; Wald $\chi^2_{(1df)} = 5.41; P < .02$) in the simple logistic regression model. Secondary analyses were conducted to determine what specific behavior changes beyond group assignment were associated with continued risk for alcohol-exposed pregnancy. In addition, we examined the effect of early (1 month follow-up) treatment response on 4 month outcomes. In a logistic regression model including group assignment and 1 month alcohol-exposed pregnancy risk as the explanatory variables and 4 month alcohol-exposed pregnancy risk as the response variable, group assignment was no longer an independent predictor of 4 month outcome, but women who remained at risk for alcohol-exposed pregnancy at 1 month were more than six times more likely to be at risk for alcohol-exposed pregnancy at 4 months (OR 6.48, 95% CI 3.23–12.98; Wald $\chi^2_{(1df)} = 27.79; P < .0001$). Therefore, while the BALANCE intervention was more efficacious than the control condition at decreasing alcohol-exposed pregnancy

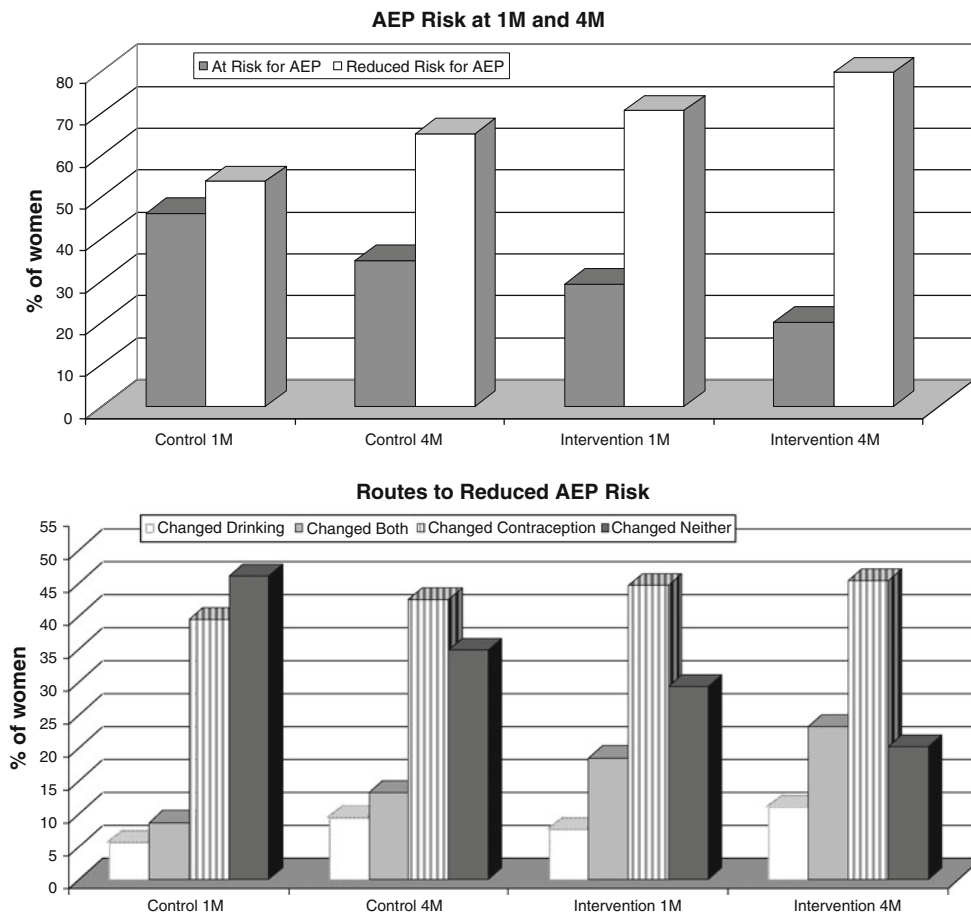


Fig. 2 Alcohol-exposed pregnancy risk and routes to reduced risk at 1 and 4 month follow-ups. Changed both means changed to 100% effective contraception AND no binge drinking nor more than 7 drinks/week. Changed contraception means changed from ineffective (absent, improper, inconsistent, or ineffective methods of contraception) to using an effective method on all episodes of vaginal

intercourse during the month prior to the 4 month follow-up. Changed drinking means changed from binge and/or more than 7 drinks per week to drinking below risk levels, with no binges and averaging fewer than 7 drinks per week during the month prior to the 4 month follow-up. Changed neither means that neither drinking nor contraception behavior improvements met the thresholds for risk reduction

risk, alcohol-exposed pregnancy risk status at 1 month strongly predicted maintaining that status at 4 months.

To better understand how women changed and/or maintained changes in alcohol-exposed pregnancy risk, we examined the components of alcohol-exposed pregnancy risk (drinking and contraception behaviors at 1 month) and other variables (demographic, personality, behavioral) that we hypothesized might be related to treatment response either at 1 month or subsequently. We examined the univariate relationships of this set of potential explanatory variables to treatment response (at risk or not at risk for alcohol-exposed pregnancy) at 4 months. In a first multivariate logistic regression model designed to identify a final, reduced variable set, we included treatment assignment, four sexual behavior variables (the number of sexual partners in the past month at baseline and at 1 month, whether they reported having sex in the past month at 1 month, whether their use of contraception was effective

or ineffective at 1 month), five drinking behavior variables (history of blackouts, the category of risk drinking at baseline and 1 month (binge only, binge plus more than 7 per week, more than 7 per week only without binges, neither), the number of drinks per week at 1 month, the number of drinks on the heaviest drinking day at 1 month), and seven *BSI* score variables, all of which had significant univariate relationships with 4 month alcohol-exposed pregnancy risk status. Examination of this model and the Odds Ratios and 95% Confidence Intervals for each variable retained led us to reduce the final variable set to five explanatory variables, 3 related to drinking and 2 related to sexual behaviors. None of the psychological variables were retained in the model.

This final multivariate model was significant (Likelihood Ratio $\chi^2_{(5,df)} = 58.24, P < .0001$) We provide a summary of the logistic regression analysis predicting alcohol-exposed pregnancy risk at 4 month follow-up in Table 3.

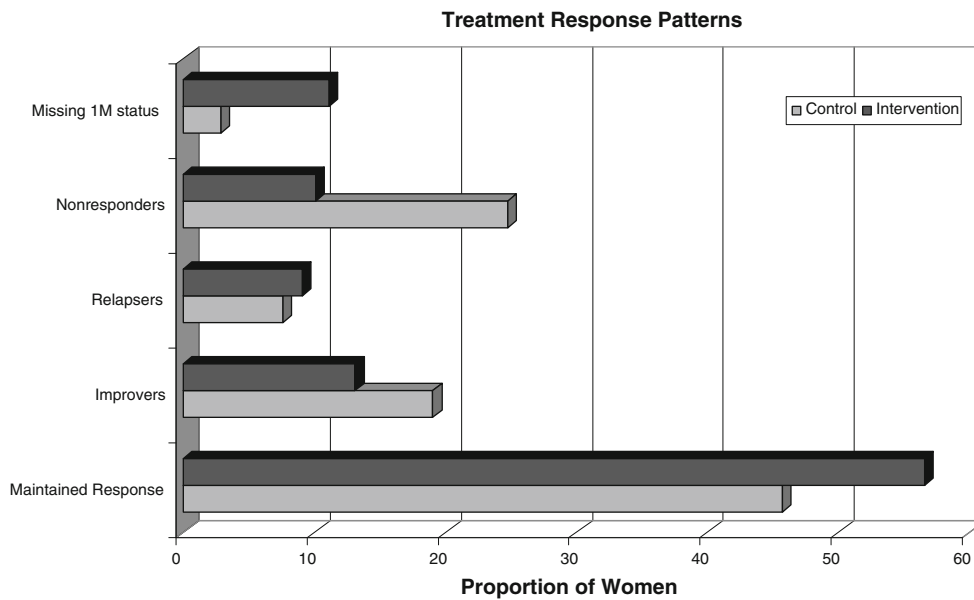


Fig. 3 Patterns of treatment response among control and intervention women. Non-responders never achieved alcohol-exposed pregnancy risk reduction. Relapsers achieved reduced risk status at 1 month but were at risk at 4 months. Improvers were at risk for alcohol-exposed

pregnancy at 1 month but no longer at risk at 4 months. Maintained responders achieved alcohol-exposed pregnancy risk reduction at 1 month and maintained it at 4 months

Variables that were independently related to continued alcohol-exposed pregnancy risk at 4 months included a history of blackouts (OR 2.98, 95% Confidence Interval 1.16–7.68), higher drinks/day at 1 month (OR 1.18, 95% Confidence Interval 1.04–1.35), and pregnancy risk/ineffective contraception at 1 month (OR 4.19, 95% Confidence Interval 1.91–9.20). Other variables retained in the model but that were not independent predictors were continued risk drinking at 1 month, and greater number of sexual partners at 1 month. The multivariate model in logistic regression uses “pseudo R square” estimates that are a generalization of the coefficient of determination, and that approximate the meaning of R^2 in a general linear model. This model was associated with a Cox-Snell R^2 of .27 and a Nagelkerke R^2 of .39. These values suggest that the logistic regression model accounts for between 27 and 39% of the variance.

BALANCE versus other alcohol-exposed pregnancy risk reduction interventions

BALANCE falls on the brief end of a hypothetical continuum of alcohol-exposed pregnancy risk reduction interventions from very brief to more intensive and extensive. Therefore, a possible advantage of BALANCE over the CHOICES (Floyd et al. 2007) intervention is shorter length; BALANCE could be delivered in one long (60–75 min) session, while CHOICES required 4 sessions of 45–60 min each, with a contraception consultation visit between sessions 2 and 3, held over a 6–12 week period. However, this advantage only holds if the results of BALANCE also compare favorably to those of CHOICES. In CHOICES, the follow-ups occurred at 3 months (a proxy for post-treatment), 6 months, and 9 months following baseline, while in BALANCE the

Table 3 Summary of logistic regression analysis predicting alcohol-exposed pregnancy risk at 4 month follow-up

Variable	β	SE	Odds ratio	95% Confidence interval	Wald statistic
Pregnancy risk reported at 1 month	.72	.20	4.19	1.91–9.20	12.76**
Number of sexual partners reported at 1 month	.75	.39	2.13	.99–4.53	3.81
Risk drinking reported at 1 month	.94	.56	6.61	.75–58.22	2.89
Higher drinks/day reported at 1 month	.17	.07	1.18	1.04–1.35	6.21*
Ever had a blackout	.55	.24	2.98	1.16–7.68	5.10*

* $P < .05$

** $P < .0005$

follow-ups occurred at 1 month and 4 months. The most comparable time point is the CHOICES 6 month and the BALANCE 4 month, representing 3 and 4 months post-intervention, respectively. Therefore, these longer term data from the BALANCE study can now be compared to those from the CHOICES study.

In CHOICES, 32.5% of control and 42.4% of intervention condition participants had achieved reduced risk drinking. In BALANCE, 22.6% of control and 33.7% of intervention condition women achieved reduced risk drinking, representing about 10% fewer of the women in each condition compared to CHOICES. In CHOICES, 32.8% of control and 47.7% of intervention condition participants achieved effective contraception, while in BALANCE, the comparable rates were 55.7 and 68.7%, about 20% more of the participants in each condition. In CHOICES, 46.9% of control and 63.9% of intervention condition participants achieved reduced risk for alcohol-exposed pregnancy, while in BALANCE, 65.1 and 79.8% of the women achieved reduced risk for alcohol-exposed pregnancy. Odds ratios for reduced alcohol-exposed pregnancy risk were comparable, approximately twofold greater in the intervention conditions in both CHOICES (OR 2.15, 95% CI = 1.52–3.06) and BALANCE (OR 2.18, 95% CI = 1.16–4.09). The outcomes appear quite similar, except that in CHOICES, improvements continued over time and did not diminish significantly, while in BALANCE, there was a decline in the statistical differences between groups for both risk drinking and pregnancy risk over time, without losing its effect on the primary outcome of alcohol-exposed pregnancy risk.

Discussion

BALANCE resulted in reduced alcohol-exposed pregnancy risk

We found that BALANCE, an individual MI plus feedback intervention, maintained its efficacy to reduce alcohol-exposed pregnancy risk among college women at the 4-month follow-up. The risk difference, an indicator of effect size, was small to moderate at 14.6%. More women improved their contraception than eliminated risk drinking. Thus, many of the women who achieved reduced alcohol-exposed pregnancy risk did so by improving their contraception, even if continuing to drink above recommended levels. Additionally, significantly more women in the intervention group than the control group maintained their response over time.

Initial responses and specific behavior changes are important determinants of outcome

Group assignment was an independent predictor of outcome at 4 months as it was in our preliminary findings at 1 month, increasing our confidence that reduction of alcohol-exposed pregnancy risk is related to the intervention. However, it seems that obtaining a positive treatment response by 1 month is crucial; most women who were non-responders at 1 month remained non-responders at the final follow-up. Moreover, specific behaviors at the 1 month follow-up predicted subsequent alcohol-exposed pregnancy risk at 4 months, including failure to improve contraception effectiveness, continued higher peak blood alcohol concentration days, and a baseline history of blackouts, another indicator of heavy drinking days.

Reductions in risk drinking

These results indicate that a brief MI plus Feedback intervention can reduce risk drinking initially, but these gains are not maintained over 4 months among college women. This is a concern, not just due to the potential harmful consequences of binge drinking itself, but also because the volume of drinking per day may be related to unprotected sexual behavior among college students. A recent study found a trend for lower odds of condom use related to more drinks on a given day (Patrick and Maggs 2009).

Reductions in pregnancy risk

The BALANCE intervention was more successful in promoting consistent effective contraception resulting in reduced pregnancy risk, but some of those improvements were also lost between the 1 and 4 month follow-ups. Some women who had reduced their risk of pregnancy resumed ineffective contraception, putting them at risk for pregnancy and in many cases, exposure to sexually transmitted infections. This pattern of response to the intervention suggests that offering feedback on pregnancy risk in addition to feedback on drinking may capitalize on college women's strong desire to avoid pregnancy. Additionally, while this intervention focused on preventing unplanned pregnancy, it is possible that a greater focus on sexually transmitted infection prevention might improve longer term contraception habits. This remains to be tested in future studies.

While a brief alcohol-exposed pregnancy risk reduction intervention like BALANCE is appropriate for college women, it could also be tested in community women, and

may be most likely to benefit those with relatively more education, and easy access to contraception services. In both CHOICES and BALANCE, there were substantial improvements in both drinking and contraception behaviors in the intervention group, but also in the control group. This suggests that repeated measurement of these behaviors in a clinical trial setting has some intervention effect, perhaps due to increasing women's awareness of and attention to the specific behaviors that compose alcohol-exposed pregnancy risk. Future studies that include an assessment-only comparison group could illuminate the effect size of these measurement procedures, and allow us to estimate the additional benefit of intervention conditions. This type of analysis could facilitate cost-effectiveness research in this area, which is currently absent from the published literature.

Advantages of dual focus interventions

Alcohol-exposed pregnancy prevention interventions provide another avenue for talking with women about binge drinking and ineffective contraception, and may result in fewer unintended pregnancies and a reduction of drinking-related hazards. The dual focus of an intervention like this one allows participants to choose what change they are more ready to make, while conveying risk reduction messages in both areas that could reduce the risk of alcohol-exposed pregnancy and unplanned pregnancy. Our data show that college women achieve alcohol-exposed pregnancy risk reduction by choosing all three methods of change: (1) changing both drinking and contraception behaviors, (2) changing contraception only (the most popular option), or (3) changing drinking only (the least popular option). Therefore, dual-focus interventions may have an important role in health promotion for college women.

Even the efficacious interventions for alcohol-exposed pregnancy risk like BALANCE and CHOICES may not be using the messages that would most help women make and sustain behavioral changes to prevent alcohol exposed pregnancies. College women especially may “tune out” messages about alcohol-exposed pregnancy risk, given that they typically do not plan or desire a pregnancy currently, and believe that they will reduce their drinking long before trying to become pregnant. In contrast, many community women may not be seeking pregnancy, but would accept and keep a pregnancy if it happened, so messages about the risk of alcohol-exposed pregnancy and potential damage to their child may resonate more strongly with them. College women might respond better to additional messages about the physical, emotional, and financial stresses of unintended pregnancy, sexually transmitted infections that could result from unprotected sex, as well as blackouts,

accidents, and unwanted sex that could occur as a result of binge drinking. Further studies that refine the messages used in dual focused interventions may increase their potency.

We were somewhat surprised that the psychological variables did not have relationships with drinking and pregnancy risk behaviors, or with outcomes, when considered in a multivariate model. One potential reason for this was the high rate of normal profiles on these instruments; in general, there was little variance in this non-clinical sample, and their risky behaviors were not associated with a high degree of psychopathology. It is possible that in a clinical sample at risk for alcohol-exposed pregnancy, there could be a relationship between risky behaviors and psychological distress.

Study limitations

This study has several limitations. Follow-up by mail resulted in some incomplete or indecipherable responses that rendered data for 14 participants unusable to assign an alcohol-exposed pregnancy risk status at the 1 month follow-up, but all of the 4-month follow-up responses were legible. Follow-up data may have been subject to distortions due to desire to please the researchers, or social desirability bias, but this concern is partially mitigated because while some in the control group changed, more women in the intervention group changed.

We did not collect event-level data on binge drinking and unprotected intercourse partially due to practical issues of data collection by mail, but also because of the nature of our study questions. Event-level data collected in a within-person design is recommended to help inform models of the association between drinking and sex and protective behaviors such as condom use or contraception, and are essential if the hypothesis is that drinking is causal in sexual or protective behavior (Cooper 2002). However, in this study, we were not positing that alcohol was a causal factor in ineffective contraception or that our intervention should target drinking as a method to influence contraception. Rather, we assumed that drinking and sex generally covary among college students at the global level as suggested by the literature (Wechsler et al. 1995). In this case, their combination creates a risk for alcohol exposed pregnancy, even if they do not occur on the same day. The risk of alcohol exposure in pregnancy may not necessarily relate to drinking on the day of conception, but clearly is related to drinking following conception and implantation of the fertilized egg into the uterine wall when mother's intake is fully available to the embryo. Similarly, our brief measures of outcome did not query the frequency of sex or the frequency of unprotected sex. Rather, women's answers were used to categorize them as at risk for pregnancy if

they reported even a single episode of unprotected sex. Therefore, our data cannot show gradations of change, but only risk categories. Event-level or frequency data about behaviors per day might have allowed us to explore the linkages among a constellation of daily behaviors that increase risk, and is desirable for future studies.

Another limitation is that while we employed four counselors across the study, one provided the majority of sessions. Thus, due to small cell sizes for the other three counselors, we are unable to examine the interesting question of therapist effects. It is therefore possible that the intervention's success depended on this single therapist rather than representing a treatment effect. However this concern is mitigated by the highly similar outcomes as those seen in CHOICES, a much larger multi-center study with many therapists, and by the fact that while BALANCE was a shorter intervention, its content and foundations were the CHOICES intervention.

Conclusions and public health implications

Significant numbers of college women are at risk for unintended pregnancy and alcohol-exposed pregnancy, and these risks merit prevention programming similar to that provided routinely for excessive drinking at colleges and universities. For risk-drinking college women who are not considering changing their drinking but who may be more interested in reducing their risk for pregnancy, a dual-focus intervention to promote alcohol-exposed pregnancy risk reduction may open discussion regarding risk drinking that otherwise might not happen. BALANCE may be most appropriate for the majority of college women binge drinkers whose drinking is moderately risky. The BALANCE intervention could be adapted for delivery to target women referred to alcohol harm reduction programs or presenting for pregnancy testing at student health centers, potentially capitalizing on the increased motivation some women feel following an alcohol violation sanctioned by the university or a pregnancy scare.

A history of heavy drinking with blackouts and continued binge drinking with high peak BACs during the study was related to ongoing alcohol-exposed pregnancy risk, and may require a more extensive intervention for the subset of college women who are the heaviest drinkers. However, because early failure to reduce heavy drinking or pregnancy risk predicts maintaining longer term alcohol-exposed pregnancy risk, this subset of non-responders could be targeted for further intervention, whether a more intensive intervention, or a booster intervention. Alternatively, women who present with a history of blackouts and relatively higher peak blood alcohol days (compared to their peers) could be offered a more intensive intervention rather than BALANCE from the outset. These women may

benefit from an intervention further along the continuum of intensity, more similar to CHOICES, with more sessions, an integrated contraception visit, and time to experience and debrief risk behaviors and make repeated attempts to reduce risk while engaged in counseling. Interventions that can help college women at risk for alcohol-exposed pregnancy to achieve and maintain changes in drinking and contraception remain highly desirable, especially for those women who are heavier drinkers.

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