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Preconceptional motivational interviewing interventions to reduce alcohol-exposed pregnancy risk

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Abstract

Alcohol exposed pregnancy (AEP) is a leading cause of preventable birth defects. While randomized controlled trials (RCTs) have shown that multi-session motivational interviewing-based interventions reduce AEP risk, a one-session intervention could facilitate broader implementation. The purposes of this study were to: (1) test a one-session motivational AEP prevention intervention for community women and (2) compare outcomes to previous RCTs. Participants at risk for AEP ($N=217$) were randomized to motivational interviewing+assessment feedback (EARLY), informational video, or informational brochure conditions. Outcomes were drinks per drinking day (DDD), ineffective contraception rate, and AEP risk at 3 and 6 months. All interventions were associated with decreased DDD, ineffective contraception rate, and AEP risk. Participants who received EARLY had larger absolute risk reductions in ineffective contraception and AEP risk, but not DDD. Effect sizes were compared to previous RCTs. The one-session EARLY intervention had less powerful effects than multi-session AEP prevention interventions among community women, but may provide a new option in a continuum of preventive care.

Keywords

Alcohol-exposed pregnancy; Motivational interviewing; Fetal alcohol spectrum disorders (FASD); Prevention; Brief intervention

1. Introduction

Most United States women of childbearing age drink alcohol [Substance Abuse and Mental Health Services Administration (SAMHSA), 2011]. While the majority limit or cease drinking when planning pregnancy, nearly half of pregnancies in the United States are unplanned and unrecognized for weeks or months after conception (Henshaw, 1998). Women who drink with unrecognized pregnancy are at high risk for exposing developing fetuses to alcohol during vulnerable periods, resulting in alcohol exposed pregnancy (AEP; Denny, Tsai, Floyd, & Green, 2009; Floyd, Decoufle, & Hungerford, 1999). Alcohol exposed pregnancy can adversely affect developing organ systems, resulting in mild to

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severe fetal alcohol spectrum disorders (FASD; Abel, 1990; Centers for Disease Control & Prevention, 2009; National Organization on Fetal Alcohol Syndrome (Producer) & National Organization on Fetal Alcohol Syndrome (Director), 2011).

Given the effects of drinking on fetal health, effective preconception interventions are needed that help drinking women prevent unintended pregnancy and/or help women who might become pregnant to stop or reduce drinking (Floyd, Weber, Denny, & O'Connor, 2009; Mengel, Searight, & Cook, 2006). Such interventions could be deployed in a variety of community settings (i.e., women's health clinics, community centers, college health centers, jails, etc.) to reduce the public health burden of AEP. A continuum of preconception AEP prevention interventions ranging from brief, low-cost interventions, to more intensive, interventions is needed. With such a continuum, non-responders to brief interventions could be referred for more intensive treatment in a stepped care model (Bower & Gilbody, 2005) or individuals could be matched to an appropriate level of care based on their presenting level of severity (Madras, Compton, Avula, Stegbauer, Stein, & Clark, 2009). In a stepped-care model for women at risk due to risky drinking and ineffective contraception, brief, one-session interventions could be administered in health care and other opportunistic settings while more intensive multi-session interventions could be administered in counseling and other settings.

Two counseling interventions, CHOICES (Floyd et al., 2007; Ingersoll, Floyd, Sobell, Velasquez, & Project CHOICES Intervention Research Group, 2003) and BALANCE, (Ceperich & Ingersoll, 2011; Ingersoll, Ceperich, Nettleman, Karanda, Brocksen, & Johnson, 2005), have been tested in randomized controlled trials (RCTs) and found efficacious. Both interventions targeted risky drinking and ineffective contraception behavior in women at risk for AEP. Both were based on assumptions that women vary in readiness for change and require counseling strategies tailored to their specific level of motivation, as specified in the transtheoretical model (McConaughy, Prochaska, & Velicer, 1983; Prochaska & Velicer, 1997). Both used a motivational interviewing (MI) (Miller & Rollnick, 2002) plus assessment feedback counseling intervention, considered an adaptation of MI due to specifying the number of sessions and strategies used, including the provision of personalized feedback of risk drawn from a baseline assessment. MI has demonstrated efficacy in the treatment of alcohol use disorders and misuse (Hettinger et al., 2005) and is an evidence-based practice [National Registry of Evidence Based Programs & Practices (NREPP), 2012] that uses reflective listening and evocation techniques to elicit the person's own motivations for change.

CHOICES is an MI plus assessment feedback counseling intervention to reduce risk for AEP in community women. It is delivered as four 30–75 minute sessions of counseling plus a medical contraception counseling appointment. The CHOICES intervention was tested against an informational brochure condition in a multisite RCT. Reductions in AEP risk (due to decreases in risky drinking, increases in contraception effectiveness, or both) were significantly more likely among participants who received CHOICES than participants who received informational brochures. The absolute risk reduction (the decrease in risk from baseline to follow-up of the intervention condition relative to a comparison condition) was 18%.

Nationally funded dissemination of CHOICES is underway in selected public health, tribal, and hospital system settings (National Center on Birth Defects and Disabilities, 2011). However, these dissemination efforts have revealed that a barrier to implementation of CHOICES is the number of sessions and resource intensity of the intervention. Prevention and treatment services for women at risk are most needed in public sector settings with limited resources to provide intensive multi-session interventions. Clinicians in these

settings want briefer interventions that require fewer sessions and fewer resources, are cost-effective, and represent the lower end of the intervention continuum in a stepped care model (CDC, personal communication). To this end, CHOICES data were examined for any evidence that CHOICES could be reduced in session number or intensity while retaining its effect. Analyses indicated those who attended two CHOICES sessions obtained the same benefit as those who attended three or four (Floyd et al., 2007).

CHOICES was modified for college women into a single session preconception MI plus assessment feedback counseling intervention (BALANCE) that contained the same components of the original intervention. In an RCT, BALANCE was tested among college women ages 18–25 at risk for AEP by comparing one 60-minute session (BALANCE) to an informational brochure condition (Ceperich & Ingersoll, 2011; Ingersoll et al., 2005). The BALANCE intervention was focused on both targeted behaviors (drinking and contraception effectiveness). A contraception counseling visit with a medical care provider through student health services was encouraged by study counselors, but was not a formal part of the intervention as it had been in CHOICES. At a 4-month follow-up, 80% of participants who received BALANCE reported no past month AEP risk, compared to 65% of participants who received the informational brochure, representing a 15% absolute risk difference between conditions.

Comparison of the magnitude of effects between CHOICES and BALANCE is challenging because of the different durations of time that AEP risk was assessed (past 90 day for CHOICES, past month for BALANCE). Interestingly, while many BALANCE participants changed contraception behaviors but maintained their risky drinking behaviors (Ceperich & Ingersoll, 2011), CHOICES participants most commonly changed both drinking and contraception behaviors (Floyd et al., 2007).

While BALANCE was briefer and required fewer resources, making it potentially more scalable, it was tested in a college sample, not representative of the broader spectrum of community women. College women are typically younger, less likely to have already given birth and less likely to have other psychosocial characteristics that are related to a greater odds of AEP risk in community women, including recent drug use, a history of smoking, a history of inpatient treatment for addiction or mental illness, multiple sexual partners, or recent physical abuse (Project CHOICES Research Group, 2002). While BALANCE showed efficacy, the homogenous nature of the study sample limits the generalizability of findings to community women. In contrast, CHOICES showed efficacy with community women, but its length and staffing requirements are challenges to implementation.

To address these issues, we developed and tested a brief, low resource intensity, one-session MI plus assessment feedback counseling intervention without contraception counseling (EARLY) for a community sample at risk for AEP. Our study design adds several novel contributions to the AEP prevention literature. First, while previous studies primarily assessed binary outcome variables (risk or no risk) for alcohol, contraception, and overall AEP, we sought to provide more sensitive estimates of the impact of intervention by analyzing changes in the continuous outcome variables drinks per drinking day (DDD) and ineffective contraception rate (percentage of sexual encounters that were unprotected). In addition to power gained from a continuous outcome measure, DDD is also a desirable primary outcome because it is an alcohol phenotype that is strongly related to behavioral and biological markers of addiction such as binge drinking and genotypes (Agrawal et al., 2009; Ray, Mackillop, & Monti, 2010; Strat, Ramoz, Schumann, & Gorwood, 2008). Secondly, it is highly desirable to compare the efficacy of various AEP intervention studies using a common metric to provide clinicians and policy makers with information with which to make informed decisions about adopting AEP interventions.

Unfortunately, cross-study comparison of outcomes has previously been inhibited by varying definitions of risk behaviors and analytic methods unsuited to comparing study outcomes. Therefore, we selected common variables and used meta-analytic techniques to compare results of the current EARLY trial to those of CHOICES and BALANCE. An additional novel contribution of the current study is its inclusion of a time and attention equivalent informational control condition. Previous studies compared CHOICES and BALANCE to informational brochure conditions and did not account for AEP-specific motivational information (such as education about how even moderate drinking can affect the fetus), time or attention. Using two comparison conditions enabled us to examine the potential unique effects of counseling in the EARLY counseling condition to a time equivalent provision of AEP-relevant information in the informational video condition, and to potential assessment reactivity plus minimal information in the informational brochure condition.

2. Methods

2.1. Study design

In this three arm RCT, non-treatment-seeking community women at risk for AEP were recruited, screened for eligibility, consented to participate, assessed at baseline, randomly assigned to treatment condition, and followed-up up 3 and 6 months after baseline. Results were then compared to those of two previous AEP studies using meta-analytic techniques. The Institutional Review Board at the University of Virginia approved the study. Data were collected from 2007 to 2010 and analyses were conducted in 2011–2012.

2.2. Participants

Participants were women at risk for AEP from two cities and surrounding areas in central Virginia. AEP risk was defined as: (1) at least one unprotected episode of vaginal sex with a male partner and (2) drinking alcohol at risky levels (more than three standard drinks on one occasion or more than an average of seven drinks per week); [National Institute on Alcohol Abuse and Alcoholism (NIAAA), 2004], during the past 90 days. Inclusion criteria were: sexually active women, ages 18–44, at risk for AEP, without confirmed infertility, speaking English, able to provide informed consent, and intending to reside locally for the next 6 months. Exclusion criteria were: current or intended pregnancy, opioid dependence without agonist treatment, active suicidality and/or homicidality, and cognitive problems (mental retardation, dementia, or active psychosis) that could interfere with the ability to consent to, understand, or benefit from the intervention.

2.3. Procedures

The study was advertised as a women's health study looking for women who could get pregnant and who drank alcohol. The advertisements mentioned that women could earn compensation for time and travel, prorated for time spent, up to a total of \$215 over 6 months. We placed newspaper advertisements in local weekly employment papers, on the Internet in a university's listing of research studies available for community member participation, and on *Craigslist*. Flyers were posted in grocery stores, laundromats, apartment bulletin boards, coffee shops, bars, public health clinics treating sexually transmitted infections, and university dormitories and cafeterias. Advertisements also were placed in movie theaters, on the radio, and in direct mail, but these yielded few responses and were discontinued. Women participated in a 10 minute telephone screening call to determine eligibility for the study. If eligible, they scheduled an individual, in-person study visit to complete the baseline assessment and intervention session in one visit. Transportation was provided if needed.

Participants completed an interview and self-report measures during the 75 minute baseline assessment with a study counselor. In a few cases, a research assistant conducted the assessment. After the baseline assessment, the study counselor opened a password-protected file containing the participant's assignment to EARLY, informational video, or informational brochure, then provided the appropriate intervention condition. Assessments were conducted 3 (3 M) and 6 (6 M) months after the baseline assessment, in person or on the telephone with a research assistant masked to assignment.

2.4. Measures

At baseline, participants completed a Core Questionnaire including questions about demographic characteristics, obstetric and gynecological history, sexual behavior and drinking history adapted from the Core Questionnaire in the BALANCE study (Ceperich & Ingersoll, 2011). They completed a 90-day timeline follow-back (TLFB; Sobell & Sobell, 1992) and the MINI Module J for alcohol use disorders (MINI-J; Sheehan et al., 1998). The TLFB provided several drinking variables including total drinks, drinking days, number of binges, mean drinks per week, and drinks per drinking day. Taken together as a scale, these variables had a standardized Cronbach alpha of .92. Additionally, the TLFB provided the primary contraception effectiveness variable, which as a single variable could not be evaluated as a scale. Contraception effectiveness at baseline had a mean of .29, a standard deviation of .30, and ranged from a minimum of 0 to a maximum of .92. Psychiatric distress was assessed with the Brief Symptom Inventory (BSI; Derogatis, 1993). The psychometric characteristics of the BSI are well-established, and in this sample, its nine primary and three summary scales generated a standardized Cronbach's alpha of .95. Measures of motivation including readiness and self-efficacy for drinking and contraception included the stages of change for both drinking and contraception (Floyd et al., 2007), the self-efficacy: temptation and confidence scales for drinking and contraception (Velicer, DiClemente, Rossi, & Prochaska, 1990), and scaling rulers of the importance, confidence, and readiness to change drinking and contraception (Rollnick, 1998). At 3 M and 6 M follow-up, participants completed an abbreviated version of the Core Questionnaire without demographics, history, BSI and MINI-J.

2.5. Interventions

Eleven counselors (10 women and 1 man), with a master's or doctoral degree provided the interventions. Counselors were trained in MI through workshops, didactics, structured readings, role plays, and performance feedback. Counselors underwent weekly clinical supervision in both individual and group sessions, focusing on MI and protocol adherence. Supervision included review of tapes of sessions to monitor treatment fidelity.

Table 1 presents an outline of the three interventions conditions, each of which had a counselor manual to guide activities.

2.5.1. EARLY condition—EARLY was a 60-minute, face-to-face, individual, one-session, MI plus assessment feedback counseling intervention. EARLY was adapted from CHOICES and BALANCE by shortening the number of activities in the counseling session and removing the medical contraception consultation. Using the MI counseling style, counselors built rapport, provided personalized feedback on drinking, contraception, and AEP risk from the baseline assessment, and showed an informational video about AEP and FASD. They evoked participants' interest in changing one or both behaviors using MI strategies and techniques, and conducted an activity addressing ambivalence, readiness, tempting situations or goal setting (see Table 1). The activity addressed the issue (contraception or drinking) that appeared most relevant or was of highest interest to the participant. Participants usually completed an activity focusing on only one target behavior.

Counselors encouraged a contraception visit to explore options and referred participants to community women's health resources and offered informational brochures.

2.5.2. Informational video condition—Participants in the informational video condition viewed three videos about women and alcohol misuse, AEP and FASD, and general women's health. Participants spent approximately 45-minutes viewing these three videos, followed by a 5-minute debriefing with the counselor. Counselors focused on providing information, rather than reflective listening or counseling, and offered participants informational brochures.

2.5.3. Informational brochure condition—Participants in the informational brochure condition received informational brochures with content on FASD, contraception options, and local women's health, mental health, and substance abuse treatment agencies.

2.6. Data analysis

The three primary outcome variables were assessed over a 90 day period and included: (1) drinks per drinking day (DDD), (2) ineffective contraception rate (percentage of days with unprotected sexual encounters), and (3) AEP risk, calculated as the proportion of participants in each condition who had at least one unprotected episode of vaginal sex with a male partner and consumed alcohol at risky levels (more than three drinks on one occasion or more than seven drinks on average per week; (NIAAA, 2004). The raw data for these variables were obtained from the TLFB. We used descriptive statistics, *t*-tests, and chi-square tests to characterize the sample.

Robust estimators of effect were used to determine the impact of interventions on risk behaviors across time and between conditions because the study lacked sufficient power for traditional inferential analyses. Additionally, this approach allows comparisons of the magnitude of effects to the previous trials, CHOICES and BALANCE (see below). For aggregated categorical variables, such as percentage of participants at risk for AEP, risk reduction was calculated as the decrease in percentage of participants within a given condition who were at risk at baseline compared to follow-up. Absolute risk reduction (also known as risk difference) was also calculated for these variables. Absolute risk reduction is the decrease in risk from baseline to follow-up of the intervention condition relative to a comparison condition. In addition, for each primary outcome variable at each follow up, we calculated within-group and between-group unbiased estimators of effect size (*d*) and 95% confidence intervals (CIs) (Hedges & Olkin, 1985). These effect sizes represent changes in each condition from baseline to follow-up and differences between EARLY, informational video, and informational brochure conditions at each follow-up. Cohen's (1988) criteria for identifying the magnitude of *d* were used, where *d*=.2 is a small effect, *d*=.5 is a medium effect and *d*=.8 is a large effect. These analyses were conducted using *Comprehensive Meta-Analysis* (ver.2) software (Borenstein, Hedges, Higgins, & Rothstein, 2005).

2.6.1. Comparing EARLY to other AEP interventions—We used meta-analytic techniques to compare the effect sizes of common outcome variables in CHOICES, BALANCE, and EARLY to place the current study in context. The three available outcome variables common to all studies were: (1) percentage of participants with ineffective contraception in past 90 days (defined as one or more unprotected sexual encounter), (2) percentage of participants who reported risky drinking in the past 90 days (defined using previously applied cutoffs of more than four drinks in 1 day or more than eight drinks in a week), and (3) percentage of participants at risk for AEP in past 90 days (defined as risky drinking and ineffective contraception). While the primary report on BALANCE (Ceperich & Ingersoll, 2011) analyzed behaviors within past 30 days, data for the past 90 days from

that study were available for comparisons. Risk reduction, absolute risk reduction, and unbiased between-group estimators of effect size, d 's, were calculated for each study to compare effects.

3. Results

3.1. Study flow

Fig. 1A shows the study CONSORT diagram. We screened 1426 women; of 358 eligible women, 126 did not attend the scheduled baseline appointment. 232 participants consented, but 15 were mistaken enrollments who reported 100% contraception effectiveness on the TLFB at baseline, despite having reported lower effectiveness during screening. Their data were dropped from analysis, leaving a final sample of 217. No mistaken enrollments were due to lack of risky drinking; all participants drank at risky levels at baseline. Random assignment placed 73 participants in the EARLY condition, 70 in informational video condition, and 74 in informational brochure condition. Of the 217 participants enrolled, 183 (84.3%) completed 3 M and 165 (76%) completed 6 M follow-ups. Attrition did not differ across conditions.

3.2. Participant characteristics at baseline

Table 2 shows baseline demographic, contraception, drinking, and motivation characteristics of the sample. Participants were primarily Black (48.6%) and White (38.3%) with fewer biracial and Asian participants. Most (58.8%) were single, never married. Participants included those who were unemployed (25.6%), working full time (24.4%), and attending school full time (23%), with a minority working or attending school part time. On average, participants were 27.9 years old, with 13.6 years of education.

All participants had at least one unprotected sexual encounter during the previous 90 days. The majority (71.6%) of sexual encounters involved ineffective contraception, with more than one third of participants (35.7%) reporting no contraception during sexual encounters in the previous 90 days. All participants reported risky drinking in the past 90 days. They drank an average of 4.6 drinks per drinking day (DDD, $SD=4.0$), with 19.1 risky drinking days in the past 90. Scores on the MINI alcohol module indicated that 81 participants (38%) had a likely diagnosis of alcohol dependence, 53 (25%) had a likely diagnosis of alcohol abuse, and 81 (38%) did not meet screening criteria for either alcohol use disorder. Regarding motivational concepts, both readiness to change on a continuum and stage of change from the transtheoretical model (Prochaska & Velicer, 1997) were measured. In general, stage of change for contraception was higher than readiness to change drinking. While nearly 40% of participants were in the preparation stage of change for contraception, only 28% were in that stage for drinking. Consistently, 40% of participants were in precontemplation about drinking, while 21% were in precontemplation about contraception.

3.3. Analysis of main effects

There were main effects of the interventions on DDD, ineffective contraception rate, and AEP risk. Table 3 shows the descriptive statistics for primary outcome variables at each time by condition, along with effect size or risk reduction statistics on differences from baseline to each follow-up point. Across conditions, improvements in DDD were small. Within-group unbiased estimators of effect ranged from $d=.09$ to $d=.32$, representing overall changes of less than one standard drink per drinking day. Rates of ineffective contraception decreased across conditions, with small to medium ($d=.18$ to $d=.78$) estimators of effect size, representing an average decrease in the percentage of days with unprotected sexual encounters of approximately 17%. Across conditions, AEP risk decreased from 100% at

baseline ($N=217$) to 68.3% at 3 M ($n=183$) and 54.1% at 6 M ($n=159$), indicating overall AEP risk reduction of 45.9%.

3.4. Analysis of between-group differences

As shown in Table 3, no differences in DDD were observed between conditions at 3 M or 6 M. For ineffective contraception rates, small effect sizes were found when comparing EARLY and informational video conditions at 3 M ($d=.32$, 95% CI=-.05, .69) and 6 M ($d=.26$, 95% CI=-.16, .67). These conditions differed in percentage of days with unprotected sexual encounters by 12.7 and 11.4% at the two follow-ups. The magnitude of differences between EARLY and the informational brochure condition was much smaller (3 M $d=.05$, 95% CI=-.31, .40; 6 M $d=.14$, 95% CI=-.25, .53). Lastly, small between-group effects were found between conditions for overall AEP risk. At 3 M, fewer EARLY participants were at risk (63.3%) than informational video (69.6%) or informational brochure (71.6%) participants, representing a 6.3 and 8.3% relative reduction in risk. Effect sizes for the two comparisons were $d=.16$ (95% CI=-.27, .12) and $d=.21$ (95% CI=-.20, .62). Differences between EARLY and informational video participants in AEP risk were more robust (18.9% absolute risk reduction difference) at 6 M, ($d=.43$, 95% CI=-.03, .88). EARLY participants also had lower AEP risk than informational brochure participants with a relative risk reduction difference of 9.1% ($d=.20$, 95% CI=-.21, .62).

3.5. Comparison with outcomes from CHOICES and BALANCE

Comparison data are available for all three RCTs at three-month (3 M; CHOICES and EARLY) or four-month (4 M; BALANCE) follow-up points. Table 4 presents the results of a meta-analysis of these data. Common outcome variables include ineffective contraception (the percentage of participants who had one or more incidents of unprotected sex in the past 90 days), risky drinking (the percentage of participants who reported drinking more than four drinks in 1 day or more than eight drinks in a week in the past 90 days), and (3) risk for AEP. At baseline, 100% of the CHOICES and BALANCE sample were in the risky category for all three outcome variables. However, because EARLY used an updated definition of risky drinking for women (>3 /day or >7 /week; NIAAA, 2004) we transformed these data to the higher risky drinking cut-offs. This reduced the number of participants in the EARLY sample used for comparison because approximately 10% of participants were no longer in the risky drinking or AEP risk category. Conversion of CHOICES and BALANCE data to the currently defined risky drinking cut-offs was not possible because of limited access to raw data for CHOICES.

As shown in Table 4, at 3 M, CHOICES participants had significant improvements in ineffective contraception with almost half (45.8%) of participants no longer at risk for pregnancy. This represents a 17.4% absolute risk reduction compared to the informational brochure condition and a small between-groups effect size ($d=.43$, 95% CI=.26, .61). BALANCE participants showed greater absolute risk reduction, with 61.8% of participants no longer at risk for pregnancy at 4 M. However differences in improvement between BALANCE and informational brochure participants were smaller, with a relative risk reduction of 7.0%, representing a small between-groups effect size ($d=.17$, 95% CI=-.26, .61). Only 19.0% of EARLY participants were no longer at risk from ineffective contraception at 3 M, but this represents an 8.3% absolute risk reduction and small effect size compared to informational video participants ($d=.37$, 95% CI=-.22, .96) and a 5.4% absolute risk reduction and small effect sizes compared to informational brochure participants ($d=.22$, 95% CI=-.21, .75).

Reductions in risky drinking were greatest among CHOICES participants at 42.2%. Reductions in risky drinking among BALANCE and EARLY participants were 16.6 and

11.8% respectively. Improvements in risky drinking for CHOICES participants exceeded those in informational brochure by 11.9% ($d=.29$, 95% CI=.11, .47) and, despite the small improvements seen for BALANCE participants, their absolute risk reduction was 4% greater than informational brochure participants ($d=.21$, 95% CI=-.26, .61). EARLY participants, however, showed less improvement in risky drinking than informational video ($d=-.31$, 95% CI=-.78, .16) and informational brochure ($d=-.02$, 95% CI=-.42, .38) participants.

CHOICES and BALANCE participants had more reduction in AEP risk compared to EARLY participants. Only 36.4% of CHOICES participants (compared to 54.4% of informational brochure participants) were still at risk at 3 M ($d=.43$, 95% CI=.26, .61). BALANCE participants had lower rates of AEP risk (31.3%) than CHOICES participants (36.4%) but AEP risk differences between BALANCE and informational brochure participants (37.5%) in that trial were smaller ($d=.15$, 95% CI=-.18, .52) than in CHOICES. EARLY participants had higher rates of continued risk for AEP (62.1%) and intervention participants were not at lower risk than informational video (60.7%; $d=.03$, 95% CI=-.45, .38) or informational brochure participants (61.2%; $d=-.02$, 95% CI=-.42, .38).

4. Discussion

All three brief interventions in the EARLY study reduced DDD, ineffective contraception, and AEP risk across time. Additionally, there was a slight advantage of the counseling condition. Specifically, the EARLY intervention condition decreased ineffective contraception and AEP risk, but not DDD, compared to the informational brochure or informational video conditions. We had hoped we would identify a one-session intervention option for AEP risk reduction at the low intensity end of the continuum of preventive interventions to be more transferable to and scalable in public health settings. While the EARLY intervention was associated with positive changes, meta-analytic techniques show that overall risk reductions were smaller than those achieved in earlier studies of more intensive interventions.

Specifically, when comparing the effects of all three interventions in the EARLY trial to the interventions in CHOICES and BALANCE, risk reductions were smaller in magnitude. Between-group differences favoring the intervention condition were comparable across the three trials for changes in ineffective contraception. However, unlike CHOICES and BALANCE, EARLY did not outperform comparison conditions for risky drinking or overall AEP risk when measured using the categorical variables available in CHOICES and BALANCE. It is possible that the brief EARLY intervention with community women was not powerful enough to influence both behaviors that compose AEP risk among community women, beyond the risk reduction achieved by the consciousness raising impact of assessment that all participants received regardless of condition assignment.

Interestingly, the EARLY intervention had a more positive effect than comparison conditions on ineffective contraception; however, the proportions of participants reporting unprotected sex in the follow-up period in all of the EARLY conditions were still much higher than in CHOICES or BALANCE. It is unclear why ineffective contraception risk reductions were so much smaller in the three EARLY conditions than in the CHOICES and BALANCE conditions. While a contraceptive counseling visit with a medical provider was included in CHOICES and was available through the university's medical services in BALANCE, this was not available in EARLY, and that might have reduced the uptake of effective contraception. While subset analyses showed that access to contraception alone is not likely responsible for the positive outcomes of CHOICES (von Sternberg, 2011, personal communication), providing an assessment plus a brochure listing women's community health resources is likely not equivalent to a contraceptive service embedded

within the intervention. Anecdotally, many participants in EARLY told researchers that cost of contraception and transportation were barriers to access.

The significantly lower risk reduction observed among participants who received informational brochures in this study compared to the CHOICES study, which both included similar samples of community women, also suggests that there may be important participant characteristics that moderate response to intervention that have not yet been identified. From patient characteristic data reported in the manuscripts, it appears that the CHOICES and EARLY samples are similar in some regards, including mean age (30 versus 28 years), percent African American (47 versus 49%), and unmarried status (51 versus 59%). However, other psychosocial factors appear more prevalent in the CHOICES versus EARLY participants, including having less than a 12th grade education (28 versus 11%) and alcohol dependence (56 versus 38%). While these variables did not qualify as covariates in the current analysis, future research should investigate the role that these and other psychosocial characteristics may have in moderating treatment responsiveness among specific subpopulations of women at risk for AEP.

There may be a role for a one-session intervention like those in the EARLY study in settings where more intensive intervention is not feasible, given that awareness-raising through assessment and either information or counseling can result in significant behavior change for many women. Moreover, these interventions might represent the lowest intensity interventions on the continuum of AEP risk reduction interventions and thus fill an important gap. Brief interventions in women's health settings where there is direct access to contraception may be a promising avenue to supplement current practice with a brief MI plus assessment feedback counseling intervention. The current evidence suggests that EARLY is a less potent intervention than were CHOICES and BALANCE. We recommend that when feasible to implement, the multi-session CHOICES be favored for community women and dissemination in public health settings over the less intensive one-session interventions tested in the EARLY study.

We evaluated two informational conditions: informational video and informational brochure. We were somewhat surprised that participants in the informational video condition fared worse than those in the informational brochure condition. We speculate that this difference could be due to varying content. Specifically, the informational video was focused on FASD, alcohol dependence, and general women's health issues, rather than the broader neurological risks of early alcohol exposure of risky drinking. It is possible that the relatively greater emphasis on FASD in the videos did not motivate participants to change, given that they may have perceived their own behavior as less extreme than that of women depicted in the videos. Therefore, the video condition may have inadvertently reinforced stereotypes of women at risk that led to less change.

This study extended the limited previous literature on interventions for AEP risk reduction, and was rigorously conducted with a sample size that was adequate to detect effects and to permit comparisons of effect sizes across conditions. However, the study had limitations. A potential limitation is that we did not have a non-TLFB assessment control. Results are consistent with previous research that suggests that thorough assessment of risk behaviors has an intervention effect (Clifford, Maisto, & Davis, 2007). Additionally, the counselors in this study provided all conditions, and it is possible that cross-training could have led to inadvertent contamination, in which elements of one condition were inappropriately provided in a different condition. While our quality assurance and supervision procedures moderate this concern, it is still possible that some contamination occurred, and this would have reduced our ability to detect between-group differences. Lastly, without an integrated contraception counseling visit, it is difficult to compare the EARLY intervention with the

CHOICES and BALANCE interventions. Even though a sub-analysis of CHOICES data suggested similar rates of change among participants who did and did not attend the contraception counseling visit, individual participants' behavior change could have been altered significantly by this visit. Comparing EARLY to CHOICES and BALANCE may be hindered by this difference across studies.

5. Conclusion

In the EARLY RCT, we found all three one-session interventions yielded significant reductions in drinking and contraception risk behaviors and AEP risk. Additionally, the EARLY intervention reduced ineffective contraception rates and AEP risk but not drinking when compared to informational brochure or informational video conditions. This implies that risk awareness-raising through assessment paired with non-personalized information (i.e., video or brochure) or more personalized MI plus assessment feedback counseling could reduce risk among women unable to access more potent AEP risk interventions. Previously, detailed assessment alone was found to be as effective at reducing drinking during pregnancy compared to a detailed assessment followed by a brief intervention for all those except heavy drinkers (Chang et al., 2005). Thus, the impact of assessment and brief treatments in subsets of preconception women should be investigated further. It is possible that a simple screening and brief intervention (SBI) paradigm similar to methods advocated for problem drinking among patients in primary care settings (Kaner et al., 2007) could be applied to AEP risk. Women in an early brief alcohol intervention study in primary care reduced their drinking by almost 50% and reduced episodes of risky drinking up to 1 year after the intervention (Fleming, Barry, Manwell, Johnson, & London, 1997). A strategy of widespread SBI adapted to include contraception as a targeted behavior could eventually serve as part of continuum of AEP risk reduction methods in public health settings (Mengel et al., 2006) with non-responders referred for more intensive or extensive treatment in a stepped care model (Bower & Gilbody, 2005).

However, while the one-session interventions in EARLY are promising and may fill a gap in the continuum of AEP prevention, all had less impact on AEP risk than interventions with more or longer sessions, easy access to contraceptive counseling, or in college settings. Until brief SBI innovations that include AEP risk components are developed and tested, we recommend using the AEP risk reduction interventions, CHOICES and BALANCE, with stronger evidence of promoting change.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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EARLY Study CONSORT Flow Diagram

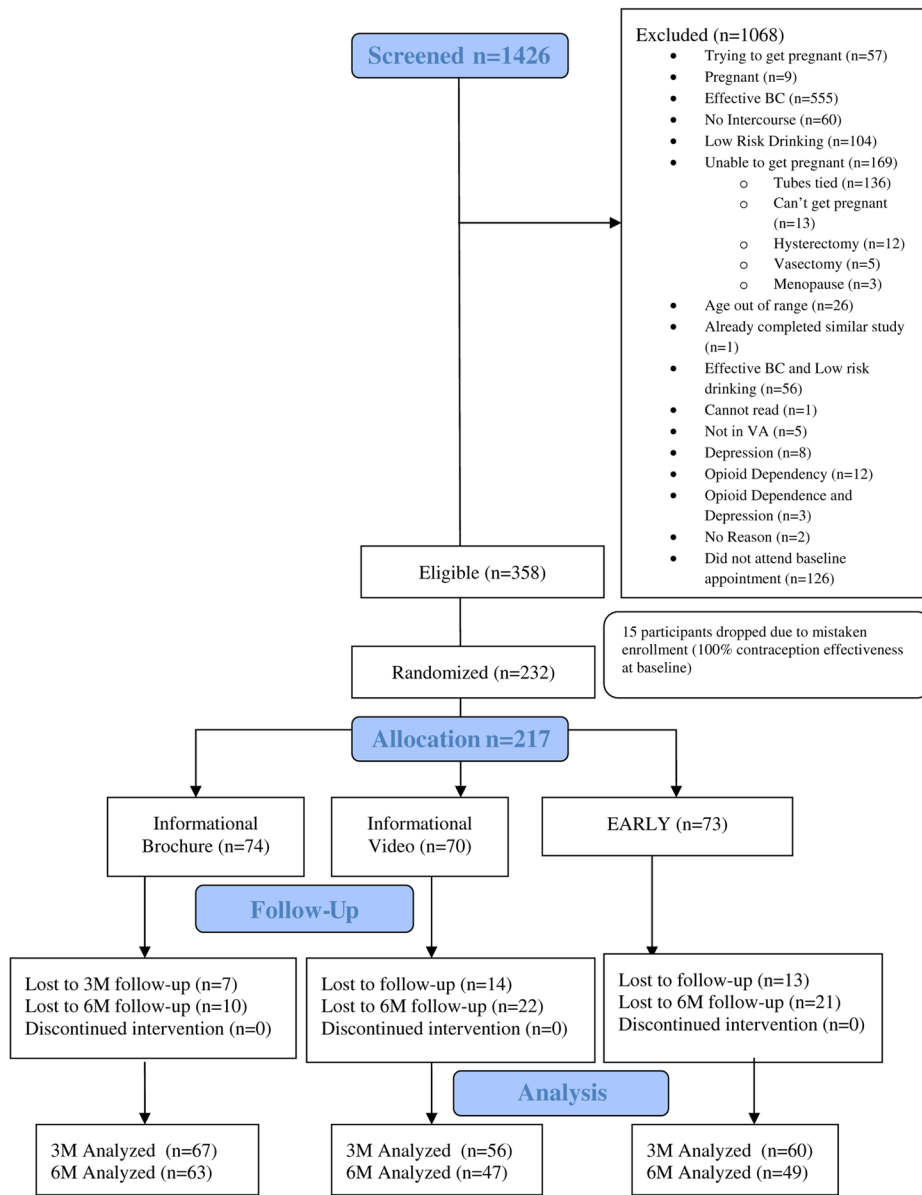


Fig. 1.
Study Flowchart.

Table 1

Intervention characteristics and components.

EARLY condition	Informational video condition	Informational brochure condition
<p><i>Counselors used a collaborative, evocative style to acknowledge autonomy and provide support while completing the following:</i></p> <ul style="list-style-type: none"> • Build rapport and induce role. • Provide overview of <i>EARLY</i>. • Discuss reactions to baseline assessment. • Elicit views of drinking and contraception use. • Provide personalized feedback including: <ul style="list-style-type: none"> – Summary of alcohol consumption and comparison to national average – Financial costs and health problems associated with drinking. – Specific reasons for pregnancy risk coupled with information about effective contraception methods. • Introduce and ask participant to view video [National Organization on Fetal Alcohol Syndrome, <i>Fetal Alcohol Spectrum Disorders: An Overview</i>]. • Elicit participant's response to video. • If relevant, discuss her other drug use and or other mental health issues in relation to AEP prevention. • Select and perform at least one intervention activity: <ul style="list-style-type: none"> – Use a <i>Decisional Balance</i> activity to explore ambivalence about change. – Use an <i>Importance, Confidence, and Readiness Ruler</i> activity to explore motivation to change and to elicit thoughts on next steps. – Use the <i>Temptation and Confidence</i> activity to elicit and explore the participant's thoughts about situational temptation to engage in risk behavior and confidence not to. – Use a <i>Change Plan</i> activity to create a goal statement and plans to achieve goal/s. • Encourage a contraception visit by encouraging the participant to schedule an appointment with her reproductive health practitioner to explore contraception options. Refer participants without practitioners to the list of community women's health resources. If relevant, refer participant to assessment+brochure with information about contraception. 	<p><i>Counselors used a neutral tone focused on providing information rather than using reflective listening while completing the following:</i></p> <ul style="list-style-type: none"> • Introduce and ask participant to view three videos [<i>Fetal Alcohol Spectrum Disorders: An Overview</i>, Alcohol misuse in women, and Women's Health]. • Elicit participant's response to video during a 5 minute long conversation. • Refer participant to assessment+brochure with information about contraception. • Refer participant to an assessment+brochure with a list of community women's health resources. • Summarize intervention. 	<p><i>Counselors used a neutral tone focused on providing information rather than using reflective listening while completing the following:</i></p> <ul style="list-style-type: none"> • Refer participant to assessment+brochure with information about contraception. • Refer participant to a assessment+brochure with a list of community women's health resources. • Summarize intervention.

EARLY condition	Informational video condition	Informational brochure condition
• Summarize intervention.		

Table 2

Participant baseline characteristics.

Characteristics	Total (N=217)	EARLY (n=73)	Informational video (n=70)	Informational brochure (n=74)	Test
Demographics, mean and SD or <i>n</i> and %					
Age	27.9 (7.4)	29.0 (7.3)	26.1 (6.8)	28.4 (7.9)	$F_{(2,df)}=3.13^*$
Years of education	13.6 (2.3)	13.7 (2.7)	13.6 (1.9)	13.5 (2.1)	$F_{(2,df)}=.14$
Race					$\chi^2_{(8df)}=4.3$
Black	104 (48.6%)	34 (46.6%)	35 (50.7%)	35 (48.6%)	
White	82 (38.3%)	29 (39.7%)	26 (37.7%)	27 (37.5%)	
Other	22 (10.3%)	9 (12.3%)	7 (10.1%)	6 (8.3%)	
Asian	6 (2.8%)	1 (1.4%)	1 (1.5%)	4 (5.6%)	
Marital status					$\chi^2_{(8df)}=3.8$
Single	127 (58.8%)	41 (56.2%)	44 (62.9%)	42 (57.5%)	
Living together	49(22.7%)	15 (20.6%)	17 (24.3%)	17 (24.3%)	
Married	19 (8.8%)	7 (9.6%)	5 (7.1%)	7 (9.6%)	
Separated	12 (5.6%)	5 (6.8%)	3 (4.3%)	4 (5.5%)	
Divorced	9 (4.2%)	5 (6.9%)	1 (1.4%)	3 (4.1%)	
Unemployed	56 (25.6%)	15 (20.6%)	23 (32.9%)	18 (24.3%)	$\chi^2_{(14df)}=10.2$
Contraception behavior, mean and SD or <i>n</i> and %					
Ineffective contraception	71.6% SD=29.7%	74.6% SD=29.2%	72.2% SD=27.6%	68% SD=32.3%	$F_{(2,df)}=.87$
0% contraception	76 (35.7%)	27 (37.5%)	25 (36.2%)	24 (33.3%)	$\chi^2_{(188df)}=192.9$
Drinking behavior, mean and SD or <i>n</i> and %					
Drinks per drinking day	4.6 (4.0)	4.6 (3.9)	4.5 (3.2)	4.6 (4.7)	$F_{(2,df)}=0$
No. of risky drinking days in 90 days	19.1 (21.4)	18.7 (20)	21.5 (23.5)	17.1 (20.6)	$F_{(2,df)}=.76$
MINI alcohol use disorders					
None	81 (37.7%)	27 (37%)	24 (34.4%)	30 (41.7%)	$\chi^2_{(4df)}=1.1$
Abuse	53 (24.7%)	17 (23.3%)	19 (27.1%)	17 (23.6%)	
Dependence	81 (37.7%)	29 (39.7%)	27 (38.6%)	25 (34.7%)	
Motivation, <i>n</i> and %					
Stage of change, drinking					$\chi^2_{8df}=14.31$

Characteristics	Total (N=217)	EARLY (n=73)	Informational video (n=70)	Informational brochure (n=74)	Test
Precontemplation	87 (40.1%)	31 (42.5%)	31 (44.3%)	25 (33.8%)	
Contemplation	52 (24.0%)	17 (23.3%)	14 (20.0%)	21 (28.4%)	
Preparation	60 (27.7%)	31 (42.5%)	23 (32.9%)	25 (33.8%)	
Action	14 (6.5%)	6 (8.2%)	2 (2.9%)	6 (8.1%)	
Maintenance	4 (1.8%)	4 (5.5%)	0 (0%)	0 (0%)	
Stage of change, contraception					$\chi^2_{8df} = 5.13$
Precontemplation	46 (21.2%)	15 (20.6%)	14 (20.0%)	17 (23.0%)	
Contemplation	61 (28.1%)	19 (26.0%)	25 (35.7%)	17 (23.0%)	
Preparation	86 (39.6%)	32 (43.8%)	25 (35.7%)	29 (39.2%)	
Action	11 (5.1%)	4 (5.5%)	2 (2.9%)	5 (6.8%)	
Maintenance	13 (6.0%)	3 (4.1%)	4 (5.7%)	6 (8.1%)	

Table 3

Primary outcome results.

	Within group effect sizes				Between group effect sizes: <i>d</i> (95% CIs)	
	EARLY		Informational video		Informational brochure	
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)		
Drinks per drinking day (DDD)	Baseline	4.6 (3.9) (<i>n</i> =73)	4.5 (3.2) (<i>n</i> =70)	4.6 (4.7) (<i>n</i> =73)		
	3 M	4.0 (2.1) (<i>n</i> =59)	3.9 (3.0) (<i>n</i> =56)	4.2 (4.3) (<i>n</i> =66)	EARLY vs. informational video: <i>d</i> =-.04 (-.40, .33)	
	6 M	BL to 3 M: <i>d</i> =.18 (-.09, .45)	BL to 3 M: <i>d</i> =.19 (.04, .35)	BL to 3 M: <i>d</i> =.09 (-.01, .19)	EARLY vs. informational brochure: <i>d</i> =.06 (-.24, .27)	
Ineffective contraception rate	Baseline	3.7(2.0) (<i>n</i> =44)	3.6 (2.4) (<i>n</i> =46)	3.7 (2.6) <i>n</i> =58	EARLY vs. informational video: <i>d</i> =-.05 (-.46, .37)	
	3 M	BL to 6 M: <i>d</i> =.28 (-.06, .61)	BL to 6 M: <i>d</i> =.32 (-.06, .69)	BL to 6 M: <i>d</i> =.19 (.02, .36)	EARLY vs. informational brochure: <i>d</i> =.00 (-.39, .39)	
	6 M	74.6% (29.2%) (<i>n</i> =73)	72.3% (27.6%) (<i>n</i> =69)	68.0% (32.3%) (<i>n</i> =74)	EARLY vs. informational video: <i>d</i> =.32 (-.05, .69)	
AEP risk	Baseline	54.2% (39.7%) (<i>n</i> =57)	65.8% (40.3%) (<i>n</i> =55)	54.8% (40.0%) (<i>n</i> =62)	EARLY vs. informational brochure: <i>d</i> =.05 (-.31, .40)	
	3 M	BL to 3 M: <i>d</i> =.58 (.27, .89)	BL to 3 M: <i>d</i> =.18 (-.07, .43)	BL to 3 M: <i>d</i> =.36 (.12, .60)	EARLY vs. informational video: <i>d</i> =.26 (-.16, .67)	
	6 M	44.7% (44.2%) (<i>n</i> =45)	55.8% (45.7%) (<i>n</i> =46)	50.7% (42.1%) (<i>n</i> =59)	EARLY vs. informational brochure: <i>d</i> =.14 (-.25, .53)	
AEP risk	Baseline	BL to 6 M: <i>d</i> =.78 (.40, 1.17)	BL to 6 M: <i>d</i> =.42 (.11, .72)	BL to 6 M: <i>d</i> =.46 (.16, .78)		
	3 M	% at risk	% at risk	% at risk		
	6 M	100% (<i>n</i> =73)	100% (<i>n</i> =70)	100% (<i>n</i> =74)	EARLY vs. informational video: <i>d</i> =.16 (-.27, .12)	ARR=6.3%
AEP risk	Baseline	63.3% (<i>n</i> =60)	69.6% (<i>n</i> =56)	71.6% (<i>n</i> =67)	EARLY vs. informational brochure: <i>d</i> =.21 (-.20, .62)	ARR=8.3%
	3 M	RR=36.7%	RR=30.4%	RR=28.4%	EARLY vs. informational video: <i>d</i> =.43 (-.03, .88)	ARR=18.9%
	6 M	44.9% (<i>n</i> =49)	63.8% (<i>n</i> =47)	54.0% (<i>n</i> =63)	EARLY vs. informational brochure: <i>d</i> =.20 (-.21, .62)	ARR=9.1%

Notes: *d* (95% CIs); RR=risk reduction, ARR=absolute risk reduction, 3 M=3 month follow-up, 6 M=6 month follow-up. We assessed whether patient characteristics (age, race, education, employment, alcohol use disorders, and history of unplanned pregnancy) varied by treatment condition, if they were related to outcome and should be considered covariates. The only variable differing by condition at baseline was age. EARLY participants were 2.9 years older than informational video participants. Age was unrelated in one-way ANOVAs to DDD, contraception effectiveness, and AEP risk at 6 M follow-up and therefore was not used as a covariate.

Table 4

Comparison with other randomized controlled trials at 3* or 4** month follow-up.

	CHOICES			BALANCE			EARLY			
	CHOICES % at risk	Brochure % at risk	Effect size <i>d</i> (95%CI)	BALANCE % at risk	Brochure % at risk	Effect size <i>d</i> (95%CI)	EARLY % at risk	Video % at risk	Brochure % at risk	Effect size <i>d</i> (95% CI)
Ineffective contraception+	54.2% (<i>n</i> =332)	71.6% (<i>n</i> =333)	CHOICES vs. Brochure: <i>d</i> = .43 (.26, .61)	38.2% (<i>n</i> =76)	45.2% (<i>n</i> =84)	BALANCE vs. Brochure <i>d</i> = .16 (-.19, .51)	81.0% (<i>N</i> =58) RR=19.0%	89.3% (<i>n</i> =56)	86.4% (<i>n</i> =66)	EARLY vs. video: <i>d</i> = .37 (-.22, .96) ARR=8.3%
	RR=45.8%	RR=28.4%	ARR=17.4%	RR=61.8%	RR=54.8%	ARR=7.0%		RR=10.7%	RR=13.6%	EARLY vs. brochure: <i>d</i> = .22 (-.31, .75) ARR=5.4%
Risky drinking+	57.8% (<i>n</i> =332)	69.7% (<i>n</i> =333)	CHOICES vs. Brochure: <i>d</i> = .29 (.11, .47)	83.4% (<i>n</i> =97)	87.0% (<i>n</i> =100)	BALANCE vs. Brochure <i>d</i> = .17 (-.26, .61)	80% (<i>n</i> =60)	69.6% (<i>n</i> =56)	73.1% (<i>n</i> =67)	EARLY vs. video: <i>d</i> = .31 (-.78, .16) ARR= -10.4%
	RR=42.2%	RR=30.3%	ARR=11.9%	RR=16.6%	RR=13.0%	ARR=3.6%	RR=11.8%	RR=17.5%	RR=17.4%	EARLY vs. brochure: <i>d</i> = -.02 (-.42, .38) ARR= -6.9%
Risk for AEP+	36.4% (<i>n</i> =332)	54.4% (<i>n</i> =333)	<i>d</i> = .41 (.23, .58)	31.3% (<i>n</i> =80)	37.5% (<i>n</i> =88)	BALANCE vs. Brochure <i>d</i> = .15 (-.18, .52)	62.1% (<i>n</i> =58)	60.7% (<i>n</i> =56)	61.2% (<i>n</i> =67)	EARLY vs. video: <i>d</i> = .03 (-.45, .38) ARR= -1.4%
	RR=63.6%	RR=45.6%	ARR=18.0%	RR=68.7%	RR=62.5%	ARR=6.2%	RR=29.7%	RR=26.4%	RR=29.3%	EARLY vs. brochure: <i>d</i> = -.02 (-.42, .38) ARR= -.9%

Notes: *CHOICES and EARLY **BALANCE+As explained in the text, not all participants in the EARLY study were defined as risky drinking at baseline when older definitions of risk were used to transform variables for comparison. Risky drinking and AEP risk rates were 91.8% for EARLY, 87.1% for informational video, and 90.5% for informational brochure in the present study. All other risk variables were 100% at baseline.