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Preventing Alcohol and Tobacco Exposed Pregnancies: CHOICES Plus in Primary Care

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Abstract

Introduction—Alcohol and tobacco use are common among U.S. women, yet if used during pregnancy these substances present significant preventable risks to prenatal and perinatal health. Because use of alcohol and tobacco often continue into the first trimester and beyond, especially among women with unintended pregnancies, effective evidence-based approaches are needed to decrease these risk behaviors. This study was designed to test the efficacy of CHOICES Plus, a preconception intervention for reducing the risk of alcohol- and tobacco-exposed pregnancies (AEPs and TEPs).

Study design—RCT with two intervention groups: CHOICES Plus (n=131) versus Brief Advice (n=130). Data collected April 2011 to October 2013. Data analysis finalized February 2016.

Setting/participants—Settings were 12 primary care clinics in a large Texas public healthcare system. Participants were women who were non-sterile, non-pregnant, aged 18–44 years, drinking more than three drinks per day or more than seven drinks per week, sexually active, and not using effective contraception (N=261). Forty-five percent were smokers.

Intervention—Interventions were two CHOICES Plus sessions and a contraceptive visit or Brief Advice and referral to community resources.

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Main outcome measures—Primary outcomes were reduced risk of AEP and TEP through 9-month follow-up.

Results—In intention-to-treat analyses across 9 months, the CHOICES Plus group was more likely than the Brief Advice group to reduce risk of AEP with an incidence rate ratio of 0.620 (95% CI=0.511, 0.757) and absolute risk reduction of −0.233 (95% CI= −0.239, −0.226). CHOICES Plus group members at risk for both exposures were more likely to reduce TEP risk (incidence rate ratio, 0.597; 95% CI=0.424, 0.840 and absolute risk reduction, −0.233; 95% CI= −0.019, −0.521).

Conclusions—CHOICES Plus significantly reduced AEP and TEP risk. Addressing these commonly co-occurring risk factors in a single preconception program proved both feasible and efficacious in a low-income primary care population. Intervening with women before they become pregnant could shift the focus in clinical practice from treatment of substance-exposed pregnancies to prevention of a costly public health concern.

Trial registration—This study is registered at clinicaltrials.gov NCT01032772.

INTRODUCTION

Alcohol and tobacco are among the most commonly used substances by women of childbearing age.[1,2] Alcohol-exposed pregnancies (AEPs) are associated with a range of adverse birth outcomes, including observable facial and organ system anomalies, prenatal and postnatal growth impairment, and behavioral and developmental deficits. Even small amounts of alcohol during pregnancy may result in negative outcomes.[3,4] Tobacco-exposed pregnancies (TEPs) are associated with stillbirth and miscarriage, placenta previa, placental abruption, and preterm birth.[5,6] The infant mortality rate from a TEP is 40% higher than in non-TEP infants, and 23%–34% of deaths due to sudden infant death syndrome are attributable to a TEP.[7,8] The combined effects of alcohol and tobacco use during pregnancy are synergistic rather than additive, further increasing the risk of preterm labor, low birth weight, and growth restriction. Modification of either behavior can produce a large reduction in risk for an adverse fetal outcome.[9]

Nearly half of all U.S. pregnancies are unintended[10] and the number may be even higher for alcohol[11] and tobacco users.[12] Many women not aware of their pregnancy continue drinking or smoking cigarettes well into their first and even second trimesters—critical periods of fetal susceptibility.[13,14]

Although preconception health care has been a subject of inquiry since the mid-1980s,[15] the importance of addressing preconception health behaviors, such as alcohol and tobacco use, has been increasingly emphasized in recent years.[16–20] Additionally, although AEPs and TEPs are considered healthcare priorities by several major groups, including the National Academy of Medicine (formerly the Institute of Medicine) and the U.S. DHHS,[16,20] most intervention trials among women of childbearing age have focused on cessation during pregnancy,[21–23] rather than in the preconception period.[24,25]

Project CHOICES is an efficacious four-session intervention developed through a Centers for Disease Control and Prevention–funded series of studies to prevent AEPs in various

settings, including primary care.[13,26,27] The CHOICES intervention uses motivational interviewing[27,28] and content aimed to increase participants' motivation and commitment to change risky alcohol use[a] and ineffective contraception[a] together with a visit for contraception education and services. CHOICES Plus halves the number of sessions and adds tobacco as a target behavior, thus addressing the need for an efficacious bundle of preconception services in primary care settings where non-pregnant women of childbearing age are most likely to present for services when substance-exposed pregnancy is preventable. Women using alcohol and tobacco are more likely to seek general primary care than to present to alcohol treatment or smoking-cessation programs.[29,30] Thus, the current trial tested CHOICES Plus in a safety net healthcare system compared to Brief Advice and informational and referral brochures, using outcome measures and analytic methods similar to those used in the original CHOICES trial.

METHODS

Study Sample

A two-group RCT with a minimal intervention control and 1:1 allocation to study conditions was conducted from April 2011 to October 2013. Data were collected in person at baseline, 3 months, and 9 months, and by telephone at 6 months. The telephone interview at 6 months was used in place of an in-person interview because of cost considerations and based on previous experience, to ensure a high retention rate.[13]

Eligible women:

1. were aged 18–44 years;
2. were not sterile (e.g., tubal ligation, hysterectomy, menopause);
3. were not pregnant or planning to become pregnant in the next 9 months;
4. had vaginal intercourse with a man with no known fertility problems during the previous 3 months without using effective contraception (www.acog.org/Womens-Health/Birth-ControlContraception#Patient)[32]; and
5. drank at risky levels (more than three drinks per day or more than seven drinks per week, on average) in the previous 3 months. Tobacco smoking was not required for eligibility.

Participants provided written consent and received $75 for the initial baseline assessment interview, $30 for the 3-month interview, and $50 for the 12-month interview ($155 total). Women in the CHOICES Plus condition received an additional $30 if they attended the second intervention session ($185 total).

[a]Although even small amounts of alcohol may have negative effects on the developing fetus,[4,5] the CHOICES interventions are for women who are not pregnant but are at risk of pregnancy. Therefore, the CHOICES interventions aim to reduce the risk of AEP by targeting "risky drinking," defined as more than three standard drinks/day or more than seven standard drinks/week on average[31] and not using effective contraception. Effective contraception was determined by adherence to the guidelines published by American Congress of Obstetricians and Gynecologists.[32]

This intervention was specifically designed for women at risk of pregnancy. Participants' racial/ethnic composition was similar to women presenting to the clinics. IRBs at the University of Texas at Austin, Baylor College of Medicine, and the Harris Health System approved study protocols.

The study took place in 12 primary care clinics associated with a large urban safety net healthcare system in Harris County, Texas. Harris Health System, one of the largest public health systems in the U.S., serves approximately 4.25 million residents in metropolitan Houston. Participants were recruited using a brief screening instrument completed either in the clinics (60.0%) or by telephone (40.0%) in response to posters placed in clinic and hospital waiting rooms. Informed consent, baseline assessments, and intervention sessions were conducted in a participating clinic.

A randomization program using SPSS, version 20, generated unique identifiers and assigned each identifier to either the CHOICES Plus or Brief Advice condition. A card inside an opaque envelope indicated each participant's group assignment, and envelopes were opened after the baseline assessment.

The intervention was guided by a manual developed specifically for Choices Plus and delivered by trained masters' level Behavioral Health Specialists (BHSs). The manual delineated both the style and techniques to be delivered at each intervention session. The goals of the two 40-minute sessions were to encourage a contraceptive counseling visit, provide and debrief norms-based but personalized feedback of risk, motivate the woman to choose to change one or more of the target behaviors, decrease her temptation to engage in risk behavior and increase her confidence to avoid it, facilitate goal setting, and develop change plans. Discussions in each session were tailored to each participant's self-rated readiness to change and interest in discussing one behavior or the other. BHSs referred smokers to one or both of two evidence-based smoking-cessation programs that provide self-help materials and optional counseling: the American Cancer Society's Texas Quitline Fax Referral program and Fresh Start program offered by the Harris Health System.

The contraceptive counseling visit was separate from the counseling sessions and was provided by a family medicine physician or nurse practitioner. This visit included taking a medical history, discussing options for contraception, doing a physical exam and pregnancy test if requested, and providing contraception.

The BHS training was an intensive course that included didactics, role-plays, demonstrations, discussions, and practice. Although all counselors were already proficient in motivational interviewing, the trainings provided a thorough grounding in motivational interviewing theory and practice. To maintain consistent quality of treatment delivery, intervention sessions were audio recorded and reviewed by the supervisor for adherence to manual guidelines; level of skillfulness in motivational interviewing (using the Motivational Interviewing Treatment Integrity Scale 3.1.1[33]); maintenance of appropriate focus; and empathy and facilitation of the therapeutic alliance.

At least two thirds of each client's sessions were reviewed by a supervisor with expertise in the CHOICES Plus protocol and a member of the Motivational Interviewing Network of

Trainers. Individual supervision sessions were conducted weekly initially and then as needed. Group supervision sessions were held monthly.

The BA intervention was provided by the study BHSs and consisted of brief advice about alcohol and tobacco use, a “Healthy Lifestyle” brochure addressing diet, exercise, and illicit drug use, a referral brochure to community services, and referrals to Harris Health Services (e.g., contraceptive, smoking, alcohol, and other drug services).

Measures

Participants were assessed in person at baseline, 3 months, and 9 months post-enrollment, and in a brief telephone assessment at 6 months. The baseline assessment included questions on sociodemographic and health information; alcohol, tobacco, and illicit drug use; sexual activity and contraception use; the Alcohol Use Disorder Identification Test,[34] and the Brief Symptom Inventory.[35] Readiness to change,[36] pros and cons for changing,[37,38] experiential and behavioral processes of change,[39] and temptation and confidence[40–42] were assessed for each behavior.

Alcohol and contraception outcomes were assessed using the timeline follow-back.[43] This produced a continuous record of daily drinking, vaginal intercourse, and contraceptive use from 90 days prior to enrollment to 9 months post-enrollment. The data were divided into 30-day segments within each 90-day period to calculate risk drinking (drinking at risk levels at any time during a 30-day segment) and risk of pregnancy (any occurrence of vaginal intercourse without effective contraceptive use[b] during a 30-day segment). Risk drinking and pregnancy risk occurring in any 30-day segment was categorized as at risk of an AEP for the full 90-day period.

Smoking was assessed using multiple criteria: 7-day point prevalence based on self-report of any smoking, number of quit days and date of cessation, and results of a NicAlert cotinine saliva assay kit.[44–47] All self-reported smokers at baseline were assessed for cotinine at 3 and 9 months. Cotinine readings >30 ng/mL were considered to indicate smoking (i.e., above what might be accounted for by secondhand smoke).[44–47] Using a conservative approach, self-report and cotinine test results were 85% congruent (i.e., eight self-reported smokers without cotinine test results counted as incongruent, six participants had phone assessment interviews, and two participants refused). For participants with both self-report and cotinine test results, congruence was 93% (i.e., seven self-reported quitters had positive cotinine results, and one self-reported smoker had a negative cotinine result). TEP risk was based on the combination of any current smoking and risk of pregnancy in the 30 days prior to assessment.

Primary outcomes from self-report were (1) AEP risk; (2) TEP risk; (3) risk drinking; (4) current smoking (7-day point prevalence); and (5) ineffective contraception. In addition, current smoking and TEP risk based on cotinine saliva test results were analyzed.

[b]Effective contraception when used as directed in the American Congress of Obstetricians and Gynecologists published guidelines[32] included: diaphragm/cervical cap, intrauterine device, hormonal patch, vaginal ring, birth control pills, Depo Provera shot, sponge, Implanon, male and female condoms, and the morning-after pill

Statistical Analysis

Sample size calculations were based on the outcomes of the CHOICES efficacy trial[13] and took into account an expected 20% attrition rate. The power analysis (logistic regression model approach) was conducted using GEESIZE.[48] An estimated 238 participants were needed for 80% power to detect an absolute difference of 17.0 percentage points for risk of AEP. Based on ineffective contraception risk reduction from the CHOICES efficacy trial and smoking abstinence rates from the U.S. Public Health Service Clinical Practice Guideline meta-analysis,[49] 51 smokers were needed in each condition to attain 80% power to detect an absolute difference of 21.5 percentage points for risk of TEP.

Baseline comparisons on sociodemographic and behavioral characteristics were conducted. Intention-to-treat longitudinal analyses of outcomes used Poisson multilevel models (SAS, version 9.3 Proc GLIMMIX) with Huber–White sandwich estimators[50] to evaluate the incidence rate ratio (IRR) of AEPs, TEPs, and the risk behaviors (risk drinking, current smoking, and ineffective contraception use) each as a function of time, condition, and the interaction of time and condition. Random effects accounted for the correlated data with repeated observations clustered within person and nested within site.

In complete case analyses, cross-sectional Poisson regression models with robust estimators[50] were used to calculate the IRR for risk of AEP or TEP as a function of the CHOICES Plus intervention compared to Brief Advice. Absolute risk reduction was calculated from the observed risk outcomes at each time point. AEP risk was determined for the 3-, 6-, and 9-month assessments. TEP risk was determined for the 3- and 9-month assessments. Analyses also included the individual risk behaviors: risk drinking, current smoking, and ineffective/no contraception. Potential confounders were identified a priori and selected using a backward elimination procedure that considered the significant relationship of the potential confounder to the behavioral outcomes in determining the most parsimonious model.

Sensitivity intervals, for those women lost to follow-up, were created for risk of AEP and TEP.[51] For one border of the interval, all women in the CHOICES Plus condition lost to follow-up were considered failures, and all women lost to follow-up in the Brief Advice condition were considered successes (at reduced risk). The other border of the sensitivity interval considered women lost to follow-up in the CHOICES Plus condition to be at reduced risk and women in the Brief Advice condition to be at risk.

RESULTS

Of 11,470 women screened, 4.9% were eligible, and 261 (46.7% consent rate) were randomized (Figure 1). Primary reasons for ineligibility included not drinking at risk levels (64.9%) and not being at risk of unintended pregnancy (27.7%). Follow-up continued until October 2013.

Trial participants had a mean age of 31 years, were largely Hispanic (47.1%) or non-Hispanic black (41.8%), with household incomes of <$20,000 (70.7%), and married/with a partner (40.6%). More than half (56.3%) were current illicit drug users (44.5% marijuana

users) and had a mean Alcohol Use Disorder Identification Test score of 11.6 (score >8 indicative of hazardous or harmful use).[52] Forty-five percent (n=118) were current smokers at risk of both TEP and AEP. Comparison of study conditions at baseline did not reveal statistically significant differences except that Brief Advice participants had significantly more ineffective contraception days (Table 1).

All women in the Brief Advice condition (n=130) received brief advice and referral (100%). Everyone assigned to CHOICES Plus (n=131) received the first session (100%), 87.8% completed both sessions, 53.4% attended the contraceptive visit, and 70.5% of the 61 smokers in the CHOICES Plus intervention accepted a referral to the Quitline (n=37) or Fresh Start program (n=6). Of those accepting a Quitline referral, 56.8% received services; 50.0% received Fresh Start services.

Intention-to-Treat Analyses

Initial intention-to-treat analyses revealed no treatment by time interaction effects; therefore, the authors ran main effects models. After controlling for time, multilevel Poisson regression identified a main effect of treatment, with more CHOICES Plus condition women than in the Brief Advice condition reducing their risk of an AEP (F[1,232]=22.58, p<0.001) (Table 2). The CHOICES Plus condition conferred a lower chance of being at risk for an AEP (IRR=0.620, 95% CI=0.511, 0.757). The main effects model for risk of TEP using self-reported smoking, after controlling for time, also demonstrated a statistically significant treatment effect (F[1,200]=8.84, p=0.003). Relative to Brief Advice, the CHOICES Plus condition conferred a decreased chance of being at risk for a TEP (IRR=0.597, 95% CI=0.424, 0.840). Similarly, main effects were demonstrated for reduction of risk (drinking (F[1,229]=13.31, p<0.001) and ineffective contraception (F[1,471]=20.13, p<0.001). Relative to Brief Advice, CHOICES Plus decreased the chances of being at risk for risk drinking (IRR=0.784, 95% CI=0.687, 0.894) and ineffective contraception (IRR=0.717, 95% CI=0.620, 0.830). There was no main effect of treatment on risk of smoking after controlling for time (F[1,82]=3.90, p<0.052).

Complete Case Analyses

At each outcome period, the CHOICES Plus condition risk for both AEP and TEP was significantly lower than the Brief Advice condition (Table 2). In the Poisson regression models with confounders, CHOICES Plus condition participants were more than twice as likely to reduce both AEP and TEP risk than the Brief Advice condition. For risk of TEP, similar outcomes were found when using self-reported cessation and results of the cotinine saliva assay. The CHOICES Plus intervention was also more likely to reduce the individual behaviors associated with risk of an AEP at each outcome period and to produce more self-reported smoking cessation at 9 months.

More women in the CHOICES Plus condition reduced both AEP risk behaviors (risk drinking and ineffective contraception) at 9 months (40.0%) than either risk behavior alone (Figure 2). Although there was significant smoking cessation at 9 months in the CHOICES Plus condition, reduced risk of TEP was reached primarily through the use of effective contraception (54.3%).

To assess the degree to which missing cases at the 9-month follow-up might influence conclusions, sensitivity analyses were conducted for risk of AEP and TEP. The optimistic scenario for risk of AEP in which all women in the CHOICES Plus condition who were lost to follow-up were considered to be at reduced risk of AEP and all women lost to follow-up in the Brief Advice condition were considered at risk at 9 months produced a significant treatment effect (IRR=0.612, 95% CI=0.467, 0.803). The pessimistic scenario for risk of AEP, in which all women in CHOICES Plus lost to follow-up were considered at risk of AEP and all women in Brief Advice were considered at reduced risk, still produced a reliable treatment effect (IRR=0.769, 95% CI=0.595, 0.994). For TEP, in the optimistic case, there was a significant treatment effect for the scenario in which women in CHOICES Plus lost to follow-up were considered to be at reduced risk and women in Brief Advice were considered at risk (IRR=0.424, 95% CI=0.265, 0.677). There was no treatment effect in the pessimistic case in which all women lost to follow-up in CHOICES Plus were considered at risk and women in Brief Advice were considered at reduced risk (IRR=0.657, 95% CI=0.425, 1.105). For TEP, of the potential combinations of risk status in the two treatment conditions for women lost to follow-up at 9 months, 67.7% resulted in a significant treatment effect for TEP.

DISCUSSION

The CHOICES Plus trial demonstrated the efficacy of a program to reduce risk for AEP and TEP among nonpregnant women at risk of unintended pregnancy attending safety net clinics in an intention-to-treat analyses at 9-month follow-up. In the complete case analyses, statistically significant decreases in the composite measures of risk for AEP and TEP were found at each time period. Reductions in risk drinking and increases in effective contraception for the CHOICES Plus women were comparable to those found in the original CHOICES efficacy trial[13] and were achieved typically by reducing both risky drinking and using effective contraception. Importantly, large and statistically significant differences were also found in smoking cessation at 9 months with CHOICES Plus.

These findings are important and very relevant, because binge drinking continues to increase among U.S. women of childbearing age,[1] and large numbers of women in this age group continue to smoke. Further, because many women who use alcohol and tobacco may continue to do so before realizing they are pregnant, they are unknowingly engaging in an AEP or TEP during a critical time for fetal development. Implementation of CHOICES Plus in primary care and other public health settings could dramatically reduce the risks of AEP and TEP. Given the personal, familial, and societal burden of caring for an individual affected by AEP or TEP over the lifespan, investing in prevention would likely result in substantial cost savings.

In light of the growing body of evidence that screening and brief intervention for illicit drugs may not be effective,[53,54] future clinical trials could evaluate the effectiveness of the CHOICES Plus intervention for reducing the use of specific drugs of abuse, such as marijuana. In this study, 44.5% of the enrolled women were also using marijuana. Because of recent societal and legal changes, marijuana use is on the rise, particularly in young people.[55] Several studies report deleterious effects of marijuana use during pregnancy,[56–59]

including a recent large-scale collaborative study funded by NIH that found that marijuana use during pregnancy resulted in 2.3 times greater risk of stillbirth.[60] The frequency of the concomitant use of alcohol, tobacco, and marijuana in women of childbearing age,[61] the increasing use of marijuana with legalization in many states, and the emerging evidence of harm caused by marijuana in the prenatal period suggest that future research should expand CHOICES Plus to include prevention of marijuana-exposed pregnancies.

Limitations

A potential limitation of the study was reliance on self-reported outcomes. In the case of tobacco use, the cotinine testing provided a reasonable validation for the reporting of smoking cessation and TEP. Regarding alcohol use, no efficient and accurate biomarkers currently exist to measure alcohol consumption on a daily basis. Validation studies of the timeline follow-back method used here for alcohol have consistently indicated reliable and valid reports of alcohol use.[62–64] The generalizability of the study may be limited by the 46.7% consent rate. The time commitment required of study participants was the most frequent reason given for declining participation, making it difficult to separate interest in participating in the intervention from the study and multiple follow-up sessions.

Strengths of this study are its streamlining of the original CHOICES intervention for busy urban healthcare settings by reducing the time commitment from four to two counseling sessions. Further, it demonstrated efficiency by expanding CHOICES to address tobacco use, effectively intervening to reduce both AEP and TEP risk in the reduced time frame. Here, bundling the risk factors could save money and time for both the interested consumer and the provider. Other notable strengths are the high retention rate across all time points and the effectiveness of CHOICES Plus when compared with Brief Advice, an active intervention which is an increasingly common practice in primary care. A novel aspect of the study was its use of posters designed to reach women of childbearing age, an inexpensive modification that expanded the reach of the intervention.

CONCLUSIONS

Given the promising outcomes, future research should focus on dissemination and translation issues related to its implementation, such as cost, training, and fidelity. An effectiveness trial is warranted in which existing clinic staff, rather than research staff, provides both screening and intervention services, without the influences on patient participation of compensation and study burden.

This two-session intervention significantly improved multiple risk behaviors that could cause AEP and TEP in women attending public health clinics. Bundling a second behavioral risk (smoking) to prevent TEP to an evidence-based intervention for reducing AEP, and tailoring it for primary care, did not add counseling time to the intervention and did not decrease the effectiveness of the intervention for reducing AEP. Intervening with women before they become pregnant could shift the focus in clinical practice from the treatment of substance-exposed pregnancies to prevention of this costly public health concern.

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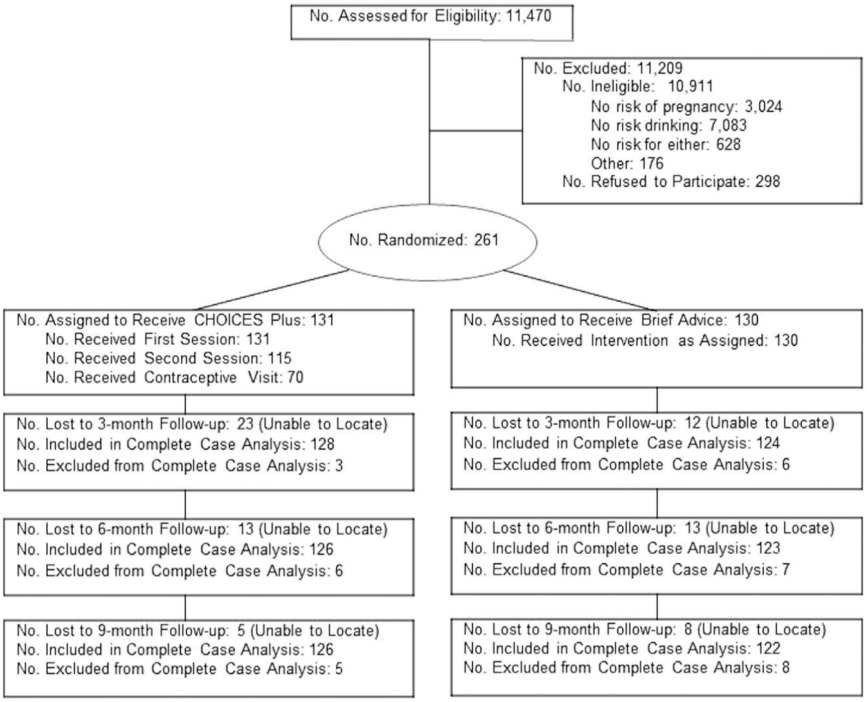

Figure 1.

CHOICES Plus - participant flow.

No., number.

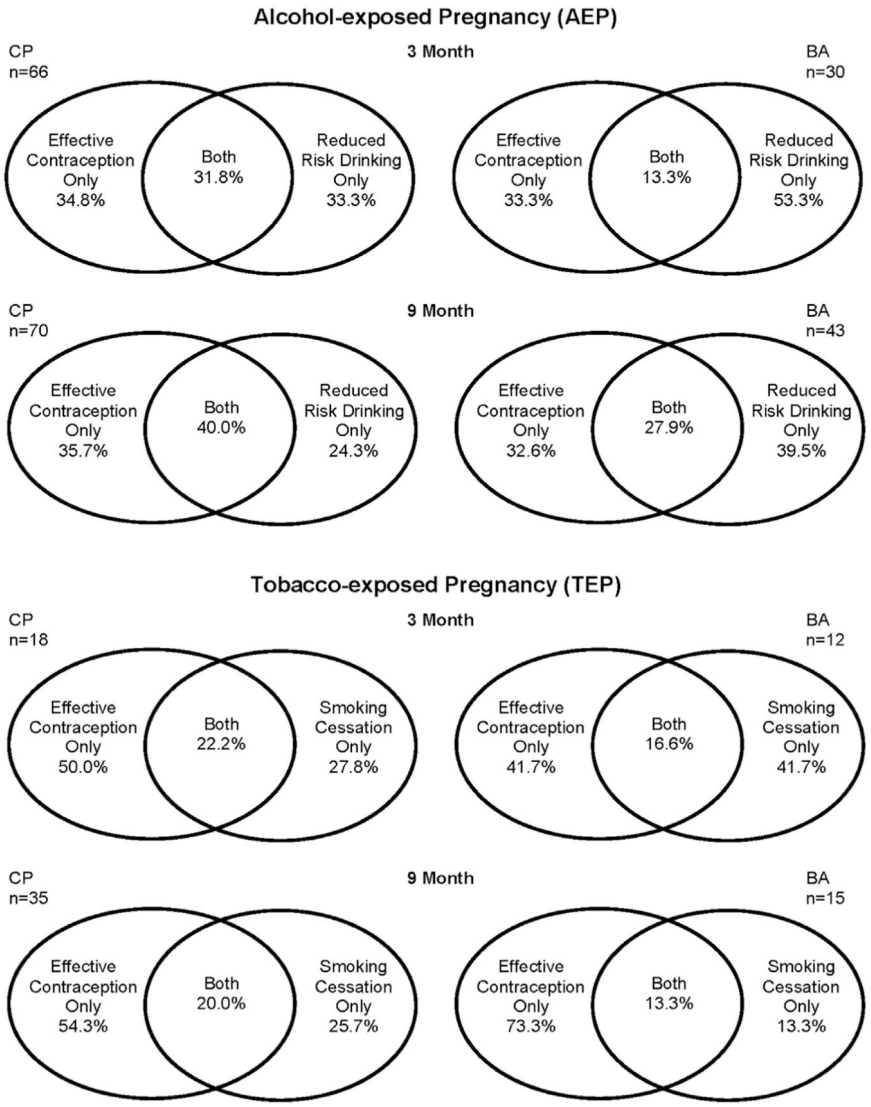

Figure 2.

Routes to reduced risk for those who successfully reduced their risk.

BA, Brief Advice; CP, CHOICES Plus.

Table 1.

Sociodemographic and Behavioral Characteristics of Participants at Randomization

Participant characteristics	BA (n=130)	CP (n=131)	*p*-value
Demographics			
Age (years), M (SD)	30.83 (6.8)	31.40 (7.6)	0.526
Married/living with partner	59 (45.4%)	47 (35.9%)	0.118
Race/Ethnicity[a]			
Hispanic	64 (49.2%)	59 (45.0%)	0.539
Non-Hispanic black	50 (38.5%)	59 (45.0%)	0.373
Non-Hispanic white	13 (10.0%)	13 (9.9%)	0.805
Other	3 (2.3%)	0 (0.0%)	0.477
Employed and currently working	44 (33.8%)	54 (41.5%)	0.201
Income <$20,000	92 (72.4%)	89 (69.6%)	0.609
Education (years), M (SD)	11.42 (3.1)	11.84 (2.8)	0.240
Homeless in the last 48 hours	10 (7.7%)	13 (9.9%)	0.393
Sexual activity			
Number of sex partners in last 3 months, M (SD)	1.52 (1.1)	1.46 (1.0)	0.602
Ever pregnant	89 (68.5%)	91 (69.5%)	0.828
Readiness for birth control, Range 1–10: M (SD)	5.65 (3.5)	6.37 (3.5)	0.096
Ineffective contraception days[b] in last 30 days, M (SD)	7.37 (7.0)	5.56 (6.3)	**0.029**
Alcohol and drug			
Current smoker	57 (43.8%)	61 (46.6%)	0.700
Days smoked per week, M (SD)	5.89 (2.0)	5.71 (2.0)	0.618
Drinks per week in last 30 days, M (SD)	12.44 (13.4)	15.29 (20.0)	0.143
Readiness for drinking below risk level[c] Range 1–10, M (SD)	6.15 (3.0)	6.87 (2.9)	0.051
Current illicit drug use in last 30 days	69 (53.1%)	78 (60.0%)	0.237
History of alcohol or drug treatment	2 (1.5%)	6 (4.6%)	0.154

Note: Boldface indicates statistical significance ($p<0.05$). Percentages were affected by missing data on some variables.

[a] Race was assessed by patient self-report to describe the sample. Reporting is required by Centers for Disease Control and Prevention and the IRB. Classifications were American Indian or Alaskan Native, Asian, black or African American, Native Hawaiian or other Pacific Islander, white, and other. Hispanic or Latina ethnicity was asked separately.

[b] Ineffective contraception days refers to any day on which the woman had vaginal sex without the use of effective contraception.

[c] Drinking Risk Level: >3 drinks/day or >7 drinks per week on average.

BA, Brief Advice; CP, CHOICES Plus

Table 2.

Treatment Outcomes for AEP, TEP, Risk Drinking, Risk of Pregnancy, and Smoking

Treatment outcomes	*n*	F-value		IRR (95% CI)	ARR (95% CI)	NNT	*p*-value
Intention-to-treat longitudinal analyses							
Risk drinking	261						
Condition		F(1,229)=13.31		0.784 (0.687, 0.894)	−0.174 (−0.178, −0.170)	5.75	<**0.001**
Time		F(1,238)=3.95		0.956 (0.914, 1.00)			**0.048**
Risk of pregnancy	261						
Condition		F(1,471)=20.13		0.717 (0.620, 0.830)	−0.233 (−0.239, −0.226)	4.29	<**0.001**
Time		F(1,471)=15.85		0.922 (0.885, 0.960)			<**0.001**
Risk of AEP	261						
Condition		F(1,232)=22.58		0.620 (0.511, 0.757)	−0.261 (−0.286, −0.255)	3.83	<**0.001**
Time		F(1,239)=9.69		0.910 (0.857, 0.966)			**0.002**
Smoking[b]	118						
Condition		F(1,82)=3.90		0.878 (0.770, 1.00)	−0.110 (−0.115, −0.107)	9.09	0.052
Time		F(1,82)=0.44		0.964 (0.863, 1.08)			0.508
Risk of TEP	118						
Condition		F(1,200)=8.84		0.597 (0.424, 0.840)	−0.233 (−0.243, −0.224)	4.29	**0.003**
Time		F(1,200)=4.52		0.879 (0.780, 0.991)			**0.035**
Complete case cross-sectional analyses[a]		CP	BA				
3 month		# at Risk (%)					
Risk drinking	252	84 (66.1)	99 (83.2)	0.817 (0.702, 0.951)	−0.171 (−0.159, −0.291)	5.85	**0.009**
Risk of pregnancy	252	83 (65.4)	105 (88.2)	0.755 (0.656, 0.872)	−0.228 (−0.120, −0.336)	4.39	<**0.001**
Risk of AEP	252	61 (48.0)	89 (74.8)	0.664 (0.535, 0.826)	−0.268 (−0.132, −0.404)	3.73	<**0.001**
Smoking[b]	105	40 (80.9)	45 (82.7)	0.986 (0.827, 1.174)	−0.018 (−0.111, 0.075)	55.56	0.872
Risk of TEP	107	24 (44.4)	34 (64.2)	0.618 (0.419, 0.911)	−0.198 (−0.071, −0.325)	5.05	**0.015**
6 month							
Risk drinking	249	77 (61.2)	102 (82.9)	0.754 (0.639, 0.889)	−0.217 (−0.093, 0.341)	4.61	**0.001**
Risk of pregnancy	249	73 (58.2)	100 (81.2)	0.749 (0.629, 0.893)	−0.230 (−0.102, −0.358)	4.35	**0.001**
Risk of AEP	249	53 (41.8)	86 (70.1)	0.639 (0.501, 0.815)	−0.283 (−0.137, −0.429)	3.53	<**0.001**

Treatment outcomes	*n*	F-value		IRR (95% CI)	ARR (95% CI)	NNT	*p*-value
9 month							
Risk drinking	248	78 (61.5)	91 (74.8)	0.821 (0.683, 0.987)	−0.133 (−0.017, −0.283)	7.52	0.035
Risk of pregnancy	248	67 (53.3)	94 (77.4)	0.699 (0.575, 0.853)	−0.241 (−0.105, −0.377)	4.15	<**0.001**
Risk of AEP	248	49 (39.2)	76 (62.6)	0.629 (0.480, 0.825)	−0.234 (−0.066, −0.402)	4.27	**0.001**
Smoking							
Self-report[b]	111	40 (69.0)	49 (85.9)	0.797 (0.652, 0.974)	−0.149 (−0.023, −0.321)	6.71	**0.026**
NicAlert	103	38 (75.4)	48 (86.5)	0.642 (0.414, 0.995)	−0.111 (−0.028, 0.288)	9.01	**0.048**
Risk of TEP							
Self-report[b]	109	16 (30.2)	32 (55.3)	0.502 (0.304, 0.828)	−0.251 (−0.019, −0.521)	3.98	**0.007**
NicAlert	101	19 (40.0)	34 (64.7)	0.544 (0.366, 0.808)	−0.247 (−0.126, −0.368)	4.05	**0.003**

Note: Boldface indicates statistical significance ($p<0.05$).

[a]Risk Drinking and AEP complete case analyses included the following confounders: married, income <$20k, white, drinks per week, Readiness for Change for contraception, Readiness for Change for alcohol, Confidence for alcohol, Confidence for contraception, Temptation for alcohol, and Behavioral Processes of Change for contraception. Smoking and TEP complete case analyses included the following confounders: Confidence for smoking, Confidence for contraception, Temptation for smoking, and Behavioral Processes of Change for contraception.

[b]Self-reported cessation with no cigarettes in the past 7 days.

AEP, alcohol-exposed pregnancy; ARR, absolute risk reduction; BA, Brief Advice; CP, CHOICES Plus; IRR, incidence rate ratio; NNT, number needed to treat; TEP, tobacco-exposed pregnancy.