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

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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.

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.

Alcohol and tobacco are among the most commonly used substances by women of childbearing age.\(^1,5\) Alcohol-exposed pregnancies (AEPs) are associated with a range of adverse birth outcomes, including observable facial and organ system anomalies, perinatal 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\(^8\) and ineffective contraception\(^1\) 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.\(^31\)

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-Control-Contraception#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).

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.
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