



Preconceptional motivational interviewing interventions to reduce alcohol-exposed pregnancy risk

Karen S. Ingersoll, Ph.D. ^{*}, Sherry D. Ceperich, Ph.D., Jennifer E. Hettema, Ph.D., Leah Farrell-Carnahan, Ph.D., J. Kim Penberthy

University of Virginia Department of Psychiatry and Neurobehavioral Sciences, Center for Addiction Research and Education, 1670 Discovery Drive Suite 110, Charlottesville VA 22911, USA

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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.

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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 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

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^{*} Corresponding author. Tel.: +1 434 243 0581; fax: +1 434 973 7031.

E-mail address: kareningersoll@virginia.edu (K.S. Ingersoll).

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 (Hettema 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);

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