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Depressive Symptoms Moderate Treatment Response to Brief Intervention for Prevention of Alcohol Exposed Pregnancy

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Abstract

The previously published randomized controlled trial, EARLY, tested the efficacy of a Motivational Interviewing (MI) plus Feedback condition against a Video Information (VI) condition and an Informational Brochure (IB) condition in reducing drinking and/or increasing contraception effectiveness, and found that drinking and rates of effective contraception improved in all conditions. In this reanalysis of the data from EARLY, potential moderating effects of depressive, global distress, and anxiety symptoms in response to the 3 brief interventions to reduce alcohol exposed pregnancy risk were examined. Women with higher levels of depression at baseline reported greater improvements in the MI plus Feedback condition versus the VI and IB conditions with depression moderating both drinking and contraceptive effectiveness. Global distress moderated only drinking behavior in the MI plus Feedback but not other groups and anxiety was not a moderator of outcome in any of the intervention groups. Depressed or distressed women at risk for AEP may benefit from an AEP risk reduction intervention that incorporates interaction with a treatment provider versus educational information provided via video or written materials.

Keywords

Depression; Fetal Alcohol Syndrome; Prevention; Brief Intervention: Motivational Interviewing

1. Introduction

Depression is one of the most common psychological problems in women of childbearing age. Epidemiologic data demonstrate that moderate to severe depression in women peaks

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during the childbearing years (Weissman & Olfson, 1995). Symptoms of depression in this age group are associated with numerous high risk behaviors, including inconsistent use of birth control (Berenson et al., 2003) and alcohol and substance use, abuse, or dependence (Gjestad et al., 2011; Merrill & Read, 2010; Graham et al., 2007; Ramsey et al., 2002). This combination of risky behaviors can lead to additional significant health risks in women, such as increased risk of alcohol exposed pregnancy (AEP), which in turn may damage the developing fetus.

Alcohol Exposed Pregnancy (EAP) is associated with extensive and significant physiological and neurobehavioral damage to the fetus. Alcohol exposure can cause impairments along a spectrum of fetal alcohol spectrum disorders (FASD; Stratton, Howe & Battaglia, 1996; Sokol, Delaney-Black & Nordstrom, 2003), can impede learning, emotional regulation, physical functioning and can lead to lifelong disability (Naimi, et al. 2003). The most severe cases resulting from AEP experience Fetal Alcohol Syndrome (FAS). Individuals affected with FAS have severe, permanent growth retardation, specific facial abnormalities, and neurocognitive as well as neurobehavioral impairments (Stratton et al., 1996) that last a lifetime.

Unfortunately, the percentage of women at risk for AEP, although slightly decreased over the past few years, has remained unacceptably high (CDC, 2012; Stratton et al., 1996; CDC, 2002). In fact, FAS and FASD are the leading causes of preventable birth defects and mental retardation in the United States and Western European countries, and the prevalence of both is likely to be higher than the estimated rates of 2-5% (May et al. 2009; Stratton, et al., 1996; CDC 2005). Reported rates of FAS are higher among certain subgroups of women. For example, infants born to American Indian, Alaska Native, or African American women, or infants born to women who are unmarried, of low income, from rural areas, have lower levels of education, and have a history of previous drug use or mental health problems such as depression are at higher risk of FAS (CDC, 2002; May & Gossage, 2001, May et al. 2009).

Preventing an AEP can be accomplished through either abstinence from alcohol use during pregnancy or prevention of pregnancy by use of effective contraception or abstinence. Risk for AEP can be decreased by targeting change in risky behaviors such as drinking or absent or ineffective use of contraception in women of child-bearing age prior to conception. A number of preconception AEP prevention interventions have been found efficacious for preventing AEP, but not all women respond well to these interventions (Floyd, et al., 2007; Ceperich & Ingersoll, 2011). For example, in one randomized controlled trial, Manwell et al. (2000; TrEAT) targeted risky drinking in non-pregnant women of child bearing age through the use of a two-session 15 minute educational counseling intervention conducted by physicians in primary care offices. These physician-delivered counseling visits utilized a scripted workbook and included advice, education, a booklet on general health issues, and contracting for behavior change. Subjects assigned to the control group received the booklet on general health issues and were instructed to address any health concerns in their usual manner. The researchers found a significant treatment effect in reducing both 7-day alcohol use and binge drinking episodes over the 48 month follow-up period in the counseling intervention versus the group receiving only the booklet. An important finding was that among women who became pregnant during the 48-month follow-up period, those who received the brief intervention significantly reduced their drinks per week and number of binges compared to those who did not receive the intervention. Furthermore, these decreases were sustained in the intervention group. Manwell, et al. conclude that “the combination of brief intervention and pregnancy appears to have a sustained effect on alcohol use in young women” (2000, p. 1522).

Project CHOICES was a feasibility pilot study that targeted non-pregnant women at high risk for an AEP (Project CHOICES Intervention Research Group, 2003). The CHOICES intervention focused not only on reducing risk drinking, but also pregnancy prevention. The intervention consisted of 4 brief intervention sessions using a counseling style called motivational interviewing (MI; Miller and Rollnick, 2002) and one consultation visit to a family planning provider. At the 6 month follow-up assessment, 68.5% were at reduced risk because they had either changed their risky drinking, instituted effective contraception, or both. Although conceptualized as successful overall, about a third of the women in the study did not respond to the treatment. In a randomized controlled trial (RCT) based on the CHOICES pilot study, Floyd et al. (2007) targeted both risky drinking and ineffective contraception with brief counseling interventions based on MI and found that a 4 session MI intervention compared to information – control condition produced significant reductions in risk for AEP in a community sample of women. Analyses of CHOICES data indicated that attending 2 counseling sessions provided the same benefit as 3 or 4, suggesting a potential to reduce intensity while retaining the impact of the intervention (Floyd, et al., 2007). Thus, in an RCT called BALANCE, a single 75-90 minute MI plus feedback session (BALANCE) was compared with an Informational condition among college women at risk for AEP (Ingersoll et al. 2005). Participants in both conditions improved risky drinking, effective contraception, and overall AEP risk. At 4 month follow-up, more BALANCE participants showed past month reductions in AEP risk, with a 14.7% risk difference between conditions, and effective contraception, with a 13.6% risk difference; however, differences in changes in risky drinking were not significant (Ceperich and Ingersoll, 2011).

In Project EARLY, the parent study for the current research, Ingersoll et al. (2013) compared a single session MI with Feedback intervention against video information (VI) on FAS and informational brochure (IB) on contraception and FAS. Analyses of changes across time and between treatment conditions revealed significant improvements in risky drinking in all conditions and no significant differences between groups regarding outcomes. Contraception and risk for AEP improved across time in all conditions, however the participants who received the MI plus feedback showed larger gains, as measured by meaningful absolute risk reduction differences and small to medium unbiased between-groups estimators of effect size. Overall there is a positive impact of brief interventions in the studies reviewed above, but these interventions are not effective for all women. Based upon the data listed above, there are still between a third to two-thirds of women across these studies who did not change the behaviors that compose AEP risk (Floyd, et al., 2007; Ingersoll et al. 2005; Ceperich and Ingersoll, 2011; Ingersoll et al, 2013).

It is important to determine who these women are and why they are not responding to interventions to reduce their AEP risk. It can be hypothesized that some women may respond differently to interventions based on their individual needs or perhaps due to other co-occurring symptoms such as depression, anxiety, or general distress. Females are known to have greater likelihood of psychiatric comorbidity than males (Zilberman et al. 2003). According to a recent study by Sánchez-Peña (2012), the percentage of women with psychiatric disorder associated with alcoholism is 47% (almost 1/1 in relation to men). Psychiatric disorders most frequently associated with alcoholism are personality disorders (30%), adjustment disorders (24%), depressive disorders (22%), and anxiety disorders (18%). For drinking women presenting with symptoms of depression, anxiety or distress, but who do not meet full criteria for a disorder, these numbers could be even larger.

In persons with co-occurring psychiatric disorders, such as depression or anxiety and alcohol use disorders, a comprehensive approach to treatment of both disorders is recommended (Thase et al., 2000). In fact, patients with significant affective symptomatology and alcohol use disorder may demonstrate extra symptomatic benefits when a form of psychotherapy for

substance use is added to medication treatment for affective symptoms (Thase et al., 2001). Determining effective AEP interventions for female drinkers presenting with depressive, distressful or anxious symptoms is imperative considering the long-term complications of both these disorders for the women and the potential negative impact on the lives of children. Women who are drinking excessively and are depressed may have a worsening of depression over time (Buu et al., 2011) and may be at increased risk for higher suicide ideation scale scores (Sher 2004). The long term complications for the children exposed to alcohol in utero are equally devastating, including FAS and FASD and lifelong and permanent impairments related to such. A recent study (Leis, 2012) of prenatal women assessed alcohol use and depressive and anxious symptoms during the first and third trimesters of pregnancy and found that 34% of women reported having at least one alcoholic drink at 32 weeks' gestation and 17% reported binge drinking. A weak association between elevated symptoms of anxiety and any alcohol use but not between elevated symptoms of depression and any alcohol use was found. Modest associations were found between both elevated symptoms of depression and anxiety at 18 weeks' gestation and binge drinking at 32 weeks' gestation. Leis et al. (201) concluded that elevated symptoms of depression and anxiety may increase risk for binge drinking during pregnancy.

Encouraging research suggests that reductions in drinking behavior after brief motivational interventions for alcohol use disorders may not be hindered by depressive or impulsive symptoms (Ryb et al., 2011). Ryb et al. reported that decreases in drinking in response to a brief behavioral intervention were found to be unaffected by the presence of impulsivity or depression indicators (Ryb et al. 2011). The impact of many other psychological symptoms, including anxiety and general distress, on the effectiveness of a dual-focused brief motivational intervention targeting AEP risk reduction is not yet known. Given the dearth of information about moderators of brief interventions, the high rates of comorbid depression and anxiety with alcohol misuse in women of childbearing years, and the significant negative impact of AEP, we conducted a retrospective investigation to explore whether or not depressive and anxiety symptoms moderated response to three preconception AEP prevention interventions using data from the parent study, EARLY (Ingersoll et al., 2013). We also examined whether global distress moderated response to the brief interventions to explore if there was a specific impact of depressive and anxiety symptoms or a more general impact of psychological distress.

2. Materials and Methods

2.1 Early

The data used for this secondary analysis is from the parent randomized control trial, EARLY, which tested the efficacy of a 1-session MI plus Feedback versus a Video Intervention (VI) versus an Informational Brochure (IB) to reduce AEP risk among community-based women of child-bearing age (18–44 years old). Alcohol-exposed pregnancy risk was defined as drinking at risky levels, which is defined as consuming on average more than 7 standard drinks per week or more than 3 drinks on one occasion (binge drinking) and having sexual intercourse with a male while using contraception ineffectively (i.e., no use at all, incorrect or inconsistent use of an effective method or use of an ineffective method). Examples of ineffective contraception use are: missing two birth control pills in any month without using an effective backup method, not putting the condom in place before the insertion of the penis into the vagina or not using a new condom with each penetration. The use of an ineffective method refers to the use of any method which results in 20 or more pregnancies in a year per 100 women (e.g.: the rhythm method, withdrawal, use of spermicides alone). Primary outcomes included drinking quantity (drinks per drinking day; DDD) and ineffective contraception use (percent unprotected sexual encounters). To allow comparisons with previous trials, categorical risky drinking and

ineffective contraception were calculated. The Institutional Review Board approved the study. Data was collected from 2007 to 2010 and analyzed and reported in 2011-2013.

2.2 Participants

Participants in the EARLY study were non-treatment seeking women at risk for AEP from 2 cities in central Virginia. They were recruited via newspaper ads and local university listings of research studies. Flyers were also posted in local gathering places such as laundromats. The study was advertised as a women's health study looking for women who could get pregnant and who drank alcohol. Participants ($N = 219$) were enrolled in the study if they met the following criteria: (a) 18-44 year-old fertile woman; (b) not pregnant or planning pregnancy in the next 6 months; (c) had vaginal intercourse with a man during the previous 90 days with ineffective contraception (see AEP risk definition above); (d) engaged in risky drinking during the previous 90 days (see AEP risk definition above); and (e) willing to be followed for 6 months. Participants were excluded from the study if they presented with untreated Major Depressive Disorder and untreated Opioid Dependence according to DSM-IV-TR criteria. Women with these conditions, if untreated, were excluded in this preliminary efficacy trial to avoid including women who were likely to have treatment needs beyond the scope of the study intervention. Such women were referred to care in the community.

2.3 Procedures

Interested women called a toll-free number and participated in a brief telephone call (5-10 minutes) to determine eligibility for the study. They were asked basic screening questions such as their age, if they consumed alcohol, etc. to determine if they would be invited to come to the research clinic for a screening visit. If eligible, they scheduled a study visit to complete the baseline assessment and intervention session at one of the two research clinics. Transportation was provided if needed. Women completed a baseline interview and the self-report measures listed in the measures section below during the 75 minute baseline assessment with a study therapist or research assistant. 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 & Savitz, 2000). 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 et al., 1990), and scaling rulers of the importance, confidence, and readiness to change drinking and contraception (Rollnick, 1998). At 3 month and 6 month follow-up, participants completed an abbreviated version of the Core Questionnaire without demographics, history, BSI and MINI-J.

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. Follow-up assessments were

conducted 3 and 6 months after the baseline assessment, in person or on the telephone with a research assistant masked to assignment.

Essential Features of Interventions—Details regarding the treatment conditions and therapists are presented below. The primary analysis paper also provides a detailed description of the 3 interventions in the EARLY study, including a table summarizing the intervention characteristics and components (Ingersoll et al., 2013).

Therapists—Eleven therapists with a master's or doctoral degree provided the interventions using a counselor manual to guide activities. Therapists were trained in MI through workshops, didactics, structured readings, role plays, and performance feedback. Fidelity and integrity to the intervention was maintained through a variety of methods. Therapists underwent weekly clinical supervision by licensed therapists, in both individual and group sessions, focusing on MI and protocol adherence. Supervision included review of tapes of sessions to monitor treatment fidelity and coaching in MI skills for the counseling condition. All procedures were conducted utilizing appropriate study protocols and methodology with continuous ongoing oversight by the study PI.

MI plus Feedback (EARLY) Condition—The EARLY condition is a 60 minute, face-to-face, motivational enhancement therapy (MI plus feedback) intervention. EARLY was manualized and adapted from CHOICES and BALANCE by retaining their MI foundation but removing the medical contraception consultation and shortening the list of activities to be completed during the counseling session. Specifically, therapists built rapport, provided personalized feedback on drinking, contraception, and AEP risk based on baseline reporting, showed a brief informational video, and elicited women's interest in changing one or both behaviors. Therapists selected an exercise based on the therapist's assessment of the participant's interest and readiness in changing one of the two target behaviors. The exercise was selected by the therapist from a menu of options derived from the previous AEP risk reduction interventions. The menu of optional activities included: decisional balance exercises, scaling rulers, reviewing temptation and confidence, generating goal statements, and change planning, with each option applicable to either contraception or alcohol related change. Therapists used open questions, affirmations, reflective listening, and summaries to build rapport and to express empathy. They also used these skills to guide the participant to focus on a target behavior of drinking, contraception, or both, while minimizing any interpersonal resistance and seeking to spark participants' interest in and commitment to change. Therapists encouraged a contraception visit to explore options and referred participants to community women's health resources, but did not mandate that an appointment be made. In addition, therapists gave participants informational brochures with content on FASD, contraception options, and local women's health, mental health, and substance abuse treatment agencies.

Video Intervention (VI) Condition—To control for time and information about AEP, participants in the video condition viewed three videos about women and alcohol misuse, AEP and FASD, and women's health (*Fetal Alcohol Spectrum Disorders: An Overview*, *Alcohol misuse in women*, and *Women's Health*). The videos were obtained from professionally produced organizations and included diverse actors and contained personal narrative and didactic information. Participants spent approximately 45-minutes viewing these three videos, followed by a 5-minute debriefing with one of the study therapists. Therapists kept these conversations neutral and focused on providing information, rather than reflective listening. Therapists then offered participants the same brochures that they offered EARLY participants.

Informational Brochure (IB) Condition—Participants in the IB condition received informational brochures with content on FASD, contraception options, and local women's health, mental health, and substance abuse treatment agencies. These were provided to the participant by a study therapist, who again kept any conversation neutral and focused on providing information only.

Every effort was made to ensure that the VI and IB conditions did not receive any MI from the therapists by conducting ongoing monitoring, supervision and feedback from supervisors.

2.4 Measures

Drinking—Drinking over the past 90 days was assessed using the timeline follow-back (TLFB) technique (Sobell and Sobell, 1992) at screening, baseline, and both follow-up points. The TLFB provided several drinking variables including total drinks, drinking days, number of binges, mean drinks per week, days abstinent, and drinks per drinking day. Drinking quantity and frequency are important because of the risk for AEP in this population due to the fact that the women are not effectively using contraception. Drinks per drinking day (DDD) was the drinking measure used as the outcome measure because it is a index of risking drinking and binge drinking behavior and is typically used in the field and can thus be compared to other studies.

Contraception Effectiveness—Effective contraception use over the past 90 days was assessed using the TLFB at screening, baseline, and both follow-up points. Ineffective contraception use included (a) not using contraception at all, (b) incorrect or inconsistent use of an effective method, or (c) use of an ineffective method. Contraception effectiveness was calculated by dividing the number of days that women had intercourse and used contraception effectively by the number of total days they had intercourse, and multiplying the result by 100.

Mental health symptoms—Mental health symptoms were assessed via the Brief Symptom Inventory (BSI; Derogatis and Savitz, 2000). The BSI is a brief (53-item) psychological self-report symptom scale developed from its longer parent instrument, the Symptom Checklist-90-Revised (SCL-90-R; Derogatis and Savitz, 2000) and psychometric evaluation reveals it to be an acceptable short alternative to the complete scale. Both test-retest and internal consistency reliabilities are shown to be very good for the primary symptom dimensions of the BSI, and its correlations with the comparable dimensions of the SCL-90-R are high. The BSI has high internal consistency (Cronbach's alpha: 0.71-0.85), test retest reliability, discriminant validity. Several criterion-oriented validity studies have also been completed with this instrument. The 53-item self-report BSI scale measures nine primary symptom dimensions in patient and non-patient populations (somatization, obsessive-compulsive behavior, interpersonal sensitivity, depression, anxiety, hostility, phobic anxiety, paranoid ideation, and psychoticism), and three global indices [Global Severity Index (GSI), Positive Symptom Distress Index (PSDI), and Positive Symptom Total (PST)]. Examples of typical items from the depression subscales are: How much were you distressed by: “feeling blue,” and “feelings of worthlessness.” Examples of typical items from the anxiety subscale include: How much were you distressed by: “feeling fearful” and “feeling tense or keyed up.” The BSI measures the experience of symptoms in the past seven days including the day the BSI was completed. Answers to individual questions are on a 5-point scale, from 0 = “not at all”, to 4 = “extremely”. The Raw scores are converted to T-scores using age and sex appropriate non-patient norms. For the current study, we analyzed the global severity index, as well as the depression and anxiety scales. We used the

depression dimension to examine current depression in the population, the anxiety dimension to examine current anxiety levels and the GSI to assess global distress.

2.4 Data Analysis Strategy

The primary aim of this study was to determine if depression and anxiety moderated response to 3 one-session interventions to reduce alcohol consumption and increase contraception effectiveness in women at risk for AEP. We used multilevel modeling to examine individual growth trajectories in data collected via repeated measures (Raudenbush & Bryk, 2002). We built a two-level model with repeated measures (level 1) nested within individuals (level 2). The basic multilevel model took the following form:

$$\begin{aligned}\text{Level 1 (repeated measures): } & \text{DDD}_{it} = \pi_{0i} + \pi_{1i}(\text{Time}) + e_{it} \\ \text{Level 2 (individuals): } & \pi_{0i} = \beta_{00} + \beta_{01}\text{CONDITION} + r_{0i} \\ & \pi_{1i} = \beta_{10} + \beta_{11}\text{CONDITION} + r_{1i}\end{aligned}$$

where t indexes time (i.e., baseline, 3 months, 6 months) and i indexes individuals. We included a random intercept and random slope for time at the individual level, which allow individual-specific intercepts and slopes. In addition, a quadratic term for time was included to explore nonlinearity in outcomes. Condition and depression or anxiety (i.e., total score on the BSI depression or anxiety symptom dimension at intervention) were entered as level-2 covariates. Multilevel models assume normality and homoscedasticity of all error terms and conditional independence of the outcome, given the random effects. To evaluate whether the results of this study were specific to depression (rather than the effects of psychological symptoms in general), we conducted follow up analyses with anxiety and overall symptom severity as potential moderators using a similar multilevel model.

3. Results

Means, standard deviations, and the number of participants providing data on outcome measures at each time point are summarized in Table 1. There were a small number of outliers (fewer than 5% per variable) which we recoded to three standard deviations above (or below) the mean. We recoded outliers in order to maintain the participant's high (or low) score, but not allow outliers to disproportionately affect the analyses (Tabachnick & Fidell, 2007). The participants ranged in age from 18 to 44 years ($M = 27.90$, $SD = 7.49$). The sample was 47.5% Black, 37.4% White, and 15.1% other (i.e. Asian, Latino/a, bi/multiracial). On average, participants reported drinking 4.34 drinks per drinking day ($SD = 2.90$) in the 90 days prior to enrollment. Participants reported using contraception effectively only 10.16% of the time ($SD = 14.56$). We conducted a preliminary analysis to confirm that baseline DDD, contraception effectiveness, and BSI scores were similar across conditions; there were no differences on any dependent variable across conditions (all p 's $> .500$).

As reported in the parent study, EARLY (Ingersoll et al., 2013), within all participants, not separated by group, there was a negative linear effect of time on DDD ($p < .001$), indicating participants decreased DDD over the course of the study overall. The quadratic effect of time on DDD was not significant ($p = .211$), suggesting participants either maintained or further improved gains made at 3 months when assessed at 6 months. Specifically, at 3 months, participants drank approximately half a drink (.48) less per drinking day than they did at baseline. At 6 months, participants drank almost 1 drink (.87) less per drinking day than they did at baseline. This improvement from baseline to 6 months represents a Cohen's d of approximately .33, a small effect size (Cohen, 1988). No difference in improvement between participants in the MI plus Feedback condition and participants in the other conditions ($p = .927$) was detected (Ingersoll et al. 2013).

However, in our retrospective analysis of the data from EARLY, a moderating effect of depression on improvement in DDD across conditions was found; participants with higher levels of depression at baseline reported greater reductions in DDD over the course of the study in the MI plus Feedback condition versus the other conditions ($p = .029$). To further explore this three-way interaction, we examined the interaction between baseline depression and time in each condition separately (i.e., counseling, other conditions). In the MI condition, participants with greater levels of depression reported greater reductions in DDD over the course of the study than did participants with lower levels of depression ($p = .008$). However, in the other conditions, level of depression did not affect improvement ($p = .688$).

Within all participants, not separated by group, there was a positive linear effect of time on contraception effectiveness ($p < .001$). This indicates participants increased contraception effectiveness over the course of the study overall. The quadratic effect of time on contraception effectiveness was not significant ($p = .209$), suggesting gains made by 3 months were either maintained or improved between 3 months and 6 months. Specifically, at 3 months, participants used effective contraception on 8% more intercourse days than they had at baseline. At 6 months, participants used effective contraception on 13% more intercourse days than they had at baseline. This improvement from baseline to 6 months represents a Cohen's d of approximately .47, a medium effect size (Cohen, 1988). Consistent with findings from the parent study, EARLY, no differences in contraception effectiveness improvement between participants who received the MI condition and participants in the other conditions ($p = .811$) were found.

Turning to the questions of the impact of depression on intervention response, in our retrospective analysis, we found that depression moderated change in contraception effectiveness across conditions. Participants with higher levels of depression at baseline reported greater improvement in contraception effectiveness over the course of the study in the MI condition versus the other conditions ($p = .021$). To further explore this three-way interaction, we examined the interaction between baseline depression and time in each condition separately (i.e., counseling, other conditions). In the MI condition, participants with greater levels of depression reported a trend toward greater increases in contraception effectiveness over the course of the study than did participants with lower levels of depression ($p = .127$). However, in the other conditions, participants with greater levels of depression reported a trend toward lower increases in contraception effectiveness over the course of the study than did participants with lower levels of depression ($p = .081$).

We also explored the anxiety subscale score from the BSI as a potential moderator and conducted a secondary analysis with anxiety as a potential moderator variable. For DDD, level of anxiety did not moderate response to treatment in the different conditions ($p = .261$). Similarly, for contraception effectiveness, level of anxiety did not moderate response to treatment in the different conditions ($p = .734$). In order to evaluate if these finding regarding depressive and anxiety symptoms were specific to depression and anxiety or reflected a more general effect of any psychological symptom or overall distress level, we also assessed the global severity index. We also conducted a secondary analysis with the global severity index (GSI) as a potential moderator variable. For DDD, the results for GSI were similar to depression. Participants with a higher GSI score at baseline reported a trend toward greater reductions in DDD over the course of the study in the MI condition versus the other conditions ($p = .086$). To further explore this three-way interaction, we examined the interaction between baseline depression and time in each condition separately (i.e., counseling, other conditions). In the MI condition, participants with greater levels of GSI reported greater reductions in DDD over the course of the study than did participants with lower levels of GSI ($p = .006$). However, in the other conditions, level of GSI did not affect

improvement ($p = .526$). For contraception effectiveness, GSI did not moderate response to treatment in the different conditions ($p = .356$).

4. Discussion

In this secondary analysis of data from the EARLY study (Ingersoll et al., 2013), we conducted a retrospective investigation to explore the impact of depressive, anxiety, and general distress symptoms on response to 3 preconception AEP prevention brief interventions. As previously reported in the parent study, EARLY (Ingersoll et al., 2013), participants in all 3 conditions reduced their overall risk for AEP by decreasing DDD and increasing contraception effectiveness. However, the current secondary analysis of the EARLY data found a 3-way interaction, suggesting that depression symptoms moderated participants' response to the MI plus Feedback intervention. Specifically, participants who endorsed more depressive symptoms demonstrated greater AEP risk reduction than participants who did not endorse depressive symptoms in the MI plus Feedback condition relative to the other conditions. There was no such 3-way interaction when anxiety was evaluated as a moderator. For both DDD and contraception effectiveness, level of anxiety did not moderate response to treatment in the different conditions. In order to explore whether depression specifically moderated treatment outcome, the Global Severity Index was also evaluated as a potential moderator. A trend for participants with higher levels of GSI at baseline to report greater reductions in DDD over the course of the study in the MI condition versus the other conditions was found. However, for contraception effectiveness, GSI did not moderate response to treatment in the different conditions. It is unclear why GSI moderated drinking response and not contraceptive use behaviors. One possibility is that distressed individuals may have more control over their own drinking behavior and thus be able to differentially positively respond to the MI condition and make changes in their drinking behavior, but in situations where collaboration with others is involved, such as sexual intercourse, they may have less success in applying what was learned from MI, due to difficulties in negotiating effective contraceptive use. However, if this is the case, this could presumably apply as well to women with depressive symptoms, but our results indicate that depressive symptoms moderated both drinking and contraception.

Participants with increased depressive symptoms and global severity scores reported greater reductions in DDD over the course of the study if they were in the MI plus Feedback group, but not the other 2 conditions. Participants with increased depressive symptom scores also reported greater improvements in effective contraception use if they were in the MI plus Feedback group, but not the other 2 conditions. Increased anxiety did not appear to have a moderating effect on either drinking or contraception use. The implications of these results suggest that women who are depressed or endorsing global distress can benefit from an MI intervention by reducing their alcohol intake and that those with depression may also benefit by improving contraceptive use when provided a brief MI plus Feedback intervention.

Depressed and distressed women at risk for AEP can benefit from an MI-based intervention through reducing risky drinking and/or using effective contraception, extending previous findings that suggested depressed women with alcohol use disorders do benefit from MI-based interventions targeting drinking alone (e.g., Ryb, et al. 2011). The current findings suggest that women reporting depressive symptoms may benefit more from MI-based AEP interventions, when compared to other types of brief interventions such as watching educational videos or receiving educational written materials. Interestingly, increased anxiety symptoms did not appear to moderate outcome. These results suggest that it is depression or distress specifically that moderate treatment response rather than reflecting an effect of psychological difficulties in general.

It may be that interventions to reduce risk for AEP that incorporate an interpersonally interactive counseling component such as MI may be more beneficial for women struggling with depressive symptoms or psychological distress, than receiving information provided through a video or brochure. The person-to-person interaction associated with the MI-based AEP intervention may have forged a connection between the therapist and participant that either allowed the participant to more fully comprehend the information, remember it better, or perhaps increase motivation for change in the participant. For the non-depressed or less distressed participant, this interactive component may not be as important or necessary for effecting change. Additionally, anxiety symptoms may interfere with processing of such interpersonal information, clarification of ambivalence or strategies to increase change talk (all components of MI) thus negating the impact of MI and creating similar responses to all conditions in anxious participants.

Earlier research from the fields of social and cognitive psychology may also contextualize and at least partially explain these findings. Mildly to moderately depressed individuals may be “sadder but wiser” than their non-depressed counterparts (Alloy & Abramson, 1979). Specifically, mildly to moderately depressed or distressed individuals may make more accurate appraisals of personal risk for negative consequences associated with their behavior than do non-depressed individuals (Alloy & Abramson, 1979). Such depressed and distressed individuals may be more likely to accept and assimilate feedback containing information about personalized risk than non-depressed individuals who may discount information about personalized risk (DeMonbreun & Craighead, 1997; Nelson & Craighead, 1997). This is because non-depressed individuals may be subject to “cognitive illusions” or cognitive errors that make them prone to underestimate their real risk for harm (Beck, 1967; 1976).

Applying these seminal findings to the current study, mildly to moderately depressed women in the MI plus Feedback condition may have more accurately perceived and assimilated feedback and video content about their risky drinking, risky contraception behaviors, and risk for AEP. The process of exploring this personal risk through MI with counselors may have amplified their tendency to assimilate these risk messages and subsequently change their risk behavior. This does not fully account for the lack of a moderating effect of anxiety, but may suggest that anxious individuals did not process the information differently in the 3 conditions. Perhaps the presence of anxiety symptoms may indeed inhibit the processing of such information, even when presented in person via an interactive MI session.

There are several important limitations of this study. First, this study excluded potential participants with untreated Major Depressive Disorder according to DSM-IV-TR criteria; therefore the range of depression scores was restricted to those with milder symptoms. We do not know if the moderating relationship between depression and outcome would remain if participants with diagnosed major depression were included. Second, in the parent study, Project EARLY, depressive symptoms were assessed only at baseline; additional assessments of depressive symptoms were not obtained throughout the study period. Additionally, positive affect was not assessed. Findings regarding changes in depressive symptoms and/or positive affect over time may additionally illuminate the interpretations of the current results. Previous research shows that negative and positive affect may act as mechanisms of change across therapeutic behavioral interventions within treatment for alcohol dependence (Vaughan et al., 2012) and such complex interactions can be hypothesized to contribute to behavioral interventions targeting problematic drinking in combination with behaviors. Specifically, the interaction between reductions in negative affect symptoms and increases in positive affect may be particularly important in promoting new coping skills and reducing drinking. Positive affective states are thought to be

influential in producing short-term changes in thought and behavior, allowing individuals to think more creatively and use more adaptive problem-solving coping strategies, which may support the election of more low-risk behavior options. Unfortunately, data on affect was not collected throughout the study. In addition to the above limitations, because this study was conducted through secondary analyses of a parent study, it is important to note this study also shared limitations of the parent study (Ingersoll et al., 2013). These include not having a non-TLFB assessment control group. 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 reduce this concern, it is still possible that some contamination occurred, and this would have reduced our ability to detect between-group differences.

Future studies may benefit from evaluating whether there are moderators of effect both within EARLY and possibly within other large RCT of MI plus feedback interventions, and should include additional assessment of both positive and negative affect including depressive symptoms. Predictors of change in AEP risk and its component behaviors also should be evaluated across treatment conditions. Such analyses could reveal participant factors that should be addressed to increase the potency of brief AEP risk reduction interventions. In addition, given the variability in observed effects based on type of outcome variable and the cut-off point used to define risky drinking, future studies should make efforts to investigate outcomes using multiple end points.

Overall, results support that in the MI plus feedback condition, women with depressive symptoms had better outcomes than those who did not endorse depressive symptoms. In the other brief interventions there was no effect of depressive symptoms on improvement. Thus for many women who are not endorsing symptoms of depression or distress, providing information in the form of videos or written materials may be enough to facilitate change. This can then free up valuable time and resources to more effectively provide more intensive interactive interventions with women presenting with distress or depressive symptoms. Regarding improving contraception effectiveness, in the MI plus feedback condition there was a trend for women with depressive symptoms to demonstrate increased effective contraception more than those not endorsing depressive symptoms. However, in the other brief intervention conditions, there was a trend for women with depressive symptoms to do worse than non-depressed women. It appears that information alone was not enough of an intervention to help facilitate change in drinking or contraceptive behaviors in these depressed women and was not enough to effect changes in contraception use in distressed women. These findings suggest that depressed women at risk for AEP can benefit from an MI-based intervention through reducing risky drinking and/or using effective contraception. These results highlight the importance of screening for depression and distress level, since the presence of symptoms of such in women may be an important variable when considering prevention interventions. Women presenting initially with more depressive symptoms or higher levels of distress may benefit more from extra time with a counselor rather than receiving information via videos or brochures.

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Table 1
Descriptive Statistics for Main Outcome Variables

Variable	Timepoint	N	Mean (SD)
Depression	Baseline	213	56.23 (9.57)
Anxiety	Baseline	212	53.14 (11.01)
Global Distress	Baseline	214	58.85 (10.96)
DDD	Baseline	218	4.34 (2.90)
	3 months	181	3.86 (2.54)
	6 months	139	3.47 (2.19)
Contraception Effectiveness	Baseline	214	10.17% (14.56%)
	3 months	170	18.23% (28.07%)
	6 months	138	22.91% (32.45%)

<i>Descriptive Statistics for Main Outcome Variables Separated by Condition</i>			
Counseling	Timepoint	N	Mean (SD)
Depression	Baseline	70	56.13 (10.75)
Anxiety	Baseline	70	52.40 (11.06)
Global Distress	Baseline	70	58.11 (11.54)
DDD	Baseline	72	4.32 (2.69)
	3 months	59	3.92 (2.06)
	6 months	41	3.58 (1.88)
Contraception Effectiveness	Baseline	71	10.57% (16.21%)
	3 months	55	20.13% (29.67%)
	6 months	43	25.91% (37.04%)
Information	Timepoint	N	Mean (SD)
Depression	Baseline	73	55.96 (9.28)
Anxiety	Baseline	73	53.14 (11.73)
Global Distress	Baseline	74	58.50 (11.36)
DDD	Baseline	74	4.26 (2.93)
	3 months	64	3.82 (2.59)
	6 months	54	3.46 (2.43)
Contraception Effectiveness	Baseline	72	10.00% (13.39%)
	3 months	63	20.27% (29.17%)
	6 months	53	20.42% (30.31%)
Video	Timepoint	N	Mean (SD)
Depression	Baseline	70	56.63 (8.72)
Anxiety	Baseline	69	53.90 (10.27)
Global Distress	Baseline	70	59.96 (9.97)
DDD	Baseline	72	4.43 (3.09)
	3 months	58	3.85 (2.70)

<i>Descriptive Statistics for Main Outcome Variables Separated by Condition</i>			
	6 months	44	3.37 (2.20)
Contraception Effectiveness	Baseline	71	9.93% (14.13%)
	3 months	52	13.77% (24.79%)
	6 months	42	23.00% (30.52%)