Journal of Substance Abuse Treatment 46 (2014) 382–389

Contents lists available at ScienceDirect

Journal of Substance Abuse Treatment

Brief motivational enhancement intervention to prevent or reduce postpartum alcohol use: A single-blinded, randomized controlled effectiveness trial☆

Doris McGartland Rubio, Ph.D. [a,b,*], Nancy L. Day, Ph.D. [c], Joseph Conigliaro, M.D., M.P.H. [d], Barbara H. Hanusa, Ph.D. [e], Cynthia Larkby, Ph.D. [c], Melissa McNeil, M.D., M.P.H. [a], Elan Cohen, M.S. [b], Bobby Jones, Ph.D. [c], Margaret Watt-Morse, M.D., M.P.H. [f], Carol Gilmour, M.D. [g], Michelle Lancet, B.S. [a], Kevin L. Kraemer, M.D., M.Sc. [a]

[a] Division of General Internal Medicine, Department of Medicine, University of Pittsburgh School of Medicine, Pittsburgh, PA, USA
[b] Data Center, Center for Research on Health Care, University of Pittsburgh School of Medicine, Pittsburgh, PA, USA
[c] Department of Psychiatry, University of Pittsburgh School of Medicine, Pittsburgh, PA, USA
[d] Department of Medicine, New York University, New York, NY, USA
[e] Center for Health Equity Research and Promotion, VA Pittsburgh Healthcare System, Pittsburgh, PA, USA
[f] Department of Obstetrics and Gynecology, Magee Women's Hospital, Pittsburgh, PA, USA
[g] Neonatology, UPMC Hamot Women's Hospital, Erie, PA, USA

ARTICLE INFO

Article history:
Received 7 March 2013
Received in revised form 4 September 2013
Accepted 4 October 2013

Keywords:
Brief motivational enhancement
Postpartum alcohol use
Comparative effectiveness
Randomized trial

ABSTRACT

Aims: The aim of this study is to assess the effect of brief motivational enhancement intervention postpartum alcohol use.
Design: This study is a single-blinded, randomized controlled effectiveness trial in which pregnant women were assigned to receive usual care or up to 5 face-to-face brief motivational enhancement sessions lasting 10–30 minutes each and occurring at study enrollment, 4 and 8 weeks after enrollment, 32 weeks of gestation, and 6 weeks postpartum.
Setting: The setting is in a large, urban, obstetrics clinic.
Participants: Participants were women who were ≥18 years old, <20 weeks of gestation, and consumed alcohol during pregnancy. Of 3438 women screened, 330 eligible women were assigned to usual care (n = 165) or intervention (n = 165). Due to missing data, we analyzed 125 in the intervention group and 126 in the usual care group.
Measurements: The measurements were the proportion of women with any alcohol use and the number of drinks per day, reported via follow-up telephone interviews at 4 and 8 weeks after enrollment, 32 weeks of gestation, and 6 weeks, 6 months, and 12 months postpartum.
Findings: In random effects models adjusted for confounders, the intervention group was less likely to use any alcohol (odds ratio 0.50; 95% confidence interval [CI], 0.23–1.09; P = 0.08) and consumed fewer drinks per day (coefficient −0.11; 95% CI −0.23–0.01; P = 0.07) than, the usual care group in the postpartum period but these differences were non-significant. Missing data during the prenatal period prevented us from modeling prenatal alcohol use.
Conclusions: Brief motivational enhancement intervention delivered in an obstetrical outpatient setting did not conclusively decrease alcohol use during the postpartum period.

1. Introduction

Alcohol use by women in the prenatal period is the most preventable cause of mental retardation in the United States (Maier and West, 2001). Fetal alcohol spectrum disorder (FASD), a cluster of infant abnormalities including growth retardation, central nervous system impairment, and craniofacial anomalies, is the most severe manifestation of prenatal alcohol exposure. Alcohol-related birth defects and alcohol-related neurodevelopemental disorders represent effects that do not meet criteria for FASD but are associated with alcohol use during pregnancy (Sokol, Martier, and Ager, 1989; Stratton and Battaglia, 1996). Although the risk of adverse fetal effects rises with heavy and binge-drinking, there is no evidence to confidently support a safe, lower-limit of alcohol intake during pregnancy. As such, even light-to-moderate drinking during pregnancy is a recommended target for intervention (ACOG, 2020).

☆ Declarations of interest: None.

* Corresponding author. Center for Research on Health Care, Division of General Internal Medicine, Department of Medicine, University of Pittsburgh School of Medicine, 200 Meyran Avenue, Suite 200, Pittsburgh, PA 15213, USA. Tel.: +1 412 692 2023; fax: +1 412 246 6954.
E-mail address: rubiodm@upmc.edu (D.M. Rubio).

0740-5472/$ – see front matter © 2014 Elsevier Inc. All rights reserved.
http://dx.doi.org/10.1016/j.jsat.2013.10.009

Despite considerable attention from public health agencies over several decades, alcohol use during pregnancy continues to exceed Healthy People 2010 and 2020 targets. Although most women stop drinking during pregnancy, approximately 11–13% of pregnant women continue to drink and 2–5% binge drink (Floyd and Sidhu, 2004; Morris et al., 2008; Control, 2009). More effective public health and clinical interventions, targeting both non-pregnant women of childbearing age and pregnant women, are needed to reduce the prevalence of alcohol use during pregnancy and improve fetal outcomes.

Brief motivational enhancement (ME) interventions to reduce unhealthy alcohol use are effective in some clinical settings (Wilk, Jensen, and Havighurst, 1997; Whitlock et al., 2004; Kaner et al., 2009). Such interventions have been studied in non-pregnant women of childbearing age (Floyd et al., 2007; Manwell et al., 2000), postpartum women (Fleming et al., 2008), and pregnant women (Handmaker, Miller, and Manicke, 1999; Chang et al., 1999; Chang et al., 2005; O'Connor and Whaley, 2007; Reynolds et al., 1995). The five randomized trials that delivered brief interventions during pregnancy to decrease alcohol use provided some mixed evidence of effectiveness of brief interventions. Two of the five studies found that brief intervention with a self-help component decreased alcohol use (O'Connor and Whaley, 2007; Reynolds et al., 1995). Interestingly, both of these studies were done in low income population. The other three clinical trials did not find any treatment effect when brief intervention was used (Chang et al., 1999; Chang et al., 2005; Handmaker, Hester, and Delaney, 1999). The brief interventions varied across the studies and included approximately 1 hour motivational interviewing (Chang et al., 1999; Handmaker, Hester, and Delaney, 1999), take home manuals (Chang et al., 1999; O'Connor and Whaley, 2007; Reynolds et al., 1995), and brief intervention with the pregnant woman and her partner (Chang et al., 2005). In a retrospective cohort study, Goler et al evaluated the "real-world" effectiveness of Early Start, a program of prenatal substance use screening and treatment linked to prenatal care visits in the Kaiser Permanente Northern California system (Goler et al., 2008). Of the 49,985 participants in Early Start, women who screened positive and received substance use treatment had better neonatal and maternal outcomes than women who screened positive but did not receive treatment. However, the analysis did not evaluate alcohol separately and address alcohol consumption outcomes.

Here, we report the results of a randomized controlled effectiveness trial of brief ME to reduce alcohol use during pregnancy and for 12 months postpartum. We hypothesized that pregnant women who received the brief ME in an obstetrical clinical setting would be more likely to abstain or significantly reduce their alcohol use during and after pregnancy than would women who received usual care in the same setting.

2. Methods

2.1. Study design, setting, and participants

This study was a single-blinded, randomized controlled effectiveness trial of a brief ME to prevent or reduce prenatal and postpartum alcohol use. It was implemented in a large, urban, obstetrics clinic in Pittsburgh, Pennsylvania. Women were eligible to participate in the study if they met the following criteria: (1) 18 years or older; (2) pregnant, planned to continue their pregnancy, and were not over 20 weeks of gestation; (3) spoke English; and (4) had consumed at least 3 drinks a week between conception and recognition of pregnancy, consumed at least 1 drink a week after recognition of pregnancy, or had at least one episode of binge drinking, defined as drinking ≥4 drinks on one occasion, after conception. While it would be beneficial to include all women who consumed any alcohol during pregnancy, we selected this level of alcohol use because a lower threshold would dilute any observed effect and would be insufficient for detecting intervention effects during and after pregnancy.

Study enrollment took place between April 2000 and October 2002, and study follow-up was completed on June 30, 2004. The institutional review boards of the University of Pittsburgh and the hospital that housed the clinic approved the project, and all participants provided written informed consent to be included in the study.

2.2. Study procedures

We recruited pregnant women from a large urban prenatal clinic who were attending their first or second obstetric visit in two phases. During the first phase, we collaborated with another ongoing study on preeclampsia and combined efforts for screening. We had an abbreviated screening instrument to determine the participants' initial eligibility for either study. The screening instrument was administered by clinic staff and consisted of two questions about pre-pregnancy frequency of alcohol intake and frequency of binge drinking. Women who were eligible for either study were approached by a research assistant for recruitment and informed consent. Patients who screened positive (initial screen was positive if patient used alcohol at least weekly before the pregnancy and/or reported any binge of 4 or more drinks on one occasion during the year before pregnancy) on the initial screen were given a brief informed consent to undergo a more complete assessment of eligibility. This eligibility assessment instrument was administered by the research assistant and took approximately 5–10 minutes to complete. Unlike the initial screen, this assessment focused on the inclusion and exclusion criteria listed above. Women who met complete eligibility criteria for the study were asked to complete informed consent for the clinical trial. The informed consent described the clinical trial as a study about whether advice and counseling about lifestyle changes, such as alcohol, drug, and tobacco use, during pregnancy can improve the health of pregnant women and their babies. Eligible women who gave their consent were randomized to receive usual care (usual care group) or to receive brief ME designed to decrease their alcohol use during and after pregnancy (intervention group). Women randomized to usual care received the standard warnings on alcohol use that are administered by the prenatal clinic staff but did not receive any other intervention.

Randomization was accomplished with the use of sealed envelopes that were prepared in 7 blocks of 64 by the study statistician according to standard randomization techniques and consecutively numbered in order to avoid temporal effects. Enrollment continued until the number of women assigned to groups reached 330. Our sample size calculations indicated that 150 subjects per group gave 80% power to detect a difference in abstinence of 14% (50% vs. 64%) at the 2nd trimester, 12% (15% vs. 27%) at 6 months postpartum, and 10% (9% vs. 19%) at 12 months postpartum (one-sided $\alpha = 0.05$ and $\beta = 0.20$).

2.3. Intervention

Participants in the intervention group were asked to attend 5 sessions that used motivational interviewing strategies (Miller and Rollnick, 1991). We specifically modified the motivational enhancement therapy (Miller, Zweben, DiClemente, and Rychtarik, 1992) of Project MATCH into a brief format suitable for an outpatient obstetrical setting and for a range of alcohol use. We used the FRAMES (feedback, responsibility, advice, menu, empathy, self-efficacy) structure for the brief intervention content (Miller and Rollnick, 1991; Samet, Rollnick, and Barnes, 1996). The content for the intervention was developed and approved by the investigative team which included expertise in motivational interviewing, psychology, internal medicine, addiction medicine, obstetrics–gynecology, and neonatology.