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Computer-Delivered Screening and Brief Intervention for Alcohol Use in Pregnancy: A Pilot Randomized Trial

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Abstract

Background—Although screening and brief intervention (SBI) for unhealthy alcohol use has demonstrated efficacy in some trials, its implementation has been limited. Technology-delivered approaches are a promising alternative, particularly during pregnancy when the importance of alcohol use is amplified. The present trial evaluated the feasibility and acceptability of an interactive, empathic, video-enhanced, and computer-delivered SBI (e-SBI) plus three separate tailored mailings, and estimated intervention effects.

Methods—We recruited 48 pregnant women who screened positive for alcohol risk at an urban prenatal care clinic. Participants were randomly assigned to the e-SBI plus mailings or to a control session on infant nutrition, and were reevaluated during their postpartum hospitalization. The

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primary outcome was 90-day period-prevalence abstinence as measured by timeline follow-back interview.

Results—Participants rated the intervention as easy to use and helpful (4.7-5.0 on a 5-point scale). Blinded follow-up evaluation at childbirth revealed medium-size intervention effects on 90-day period prevalence abstinence (OR = 3.4); similarly, intervention effects on a combined healthy pregnancy outcome variable (live birth, normal birthweight, and no NICU stay) were also of moderate magnitude in favor of e-SBI participants (OR=3.3). As expected in this intentionally under-powered pilot trial, these effects were non-significant (p = .19 and .09, respectively).

Conclusions—This pilot trial demonstrated the acceptability and preliminary efficacy of a computer-delivered screening and brief intervention (e-SBI) plus tailored mailings for alcohol use in pregnancy. These findings mirror the promising results of other trials using a similar approach, and should be confirmed in a fully-powered trial.

Introduction

Prenatal exposure to alcohol can have lasting effects on neurocognitive, social, and behavioral function, and is a major cause of intellectual disabilities (Sokol et al., 2003). Lifetime costs for each child born with full Fetal Alcohol Syndrome (FAS) are estimated at approximately $2,000,000 (Lupton et al., 2004). Despite widespread awareness of these risks and ongoing prevention efforts, National Survey on Drug Use and Health data suggest that 9.4% of pregnant women report alcohol use in the past month, and 2.3% report five or more drinks on one occasion (Substance Abuse and Mental Health Services Administration, 2014). However, few of those in need of treatment receive it: in 2013, only 7.9% of those needing treatment for alcohol use actually received specialized substance abuse treatment services, and 96.7% of those who needed but did not receive services felt that they did not need it (Substance Abuse and Mental Health Services Administration, 2014).

Screening, brief intervention, and referral for treatment (SBIRT) approaches proactively address substance use in primary care settings, and potentially reach those at risk regardless of willingness to seek treatment. Large proportions of at-risk groups can be reached with SBIRT, particularly in the perinatal period where most pregnant women seek prenatal care. Federal agencies and professional societies that promote the use of SBIRT in medical care settings include the American College of Obstetricians & Gynecologists (Sokol et al., 2006) and the National Task Force on Fetal Alcohol Syndrome/Fetal Alcohol Effect (NTFFASFAE; Barry et al., 2009).

Findings with regard to brief interventions for alcohol use in pregnancy are mixed. Some controlled trials have shown positive results (O'Connor and Whaley, 2007, Chang et al., 2005); others have not (Osterman et al., 2014, Osterman and Dyehouse, 2012, Handmaker et al., 1999). The results of recent large-scale implementation studies with general populations have failed to demonstrate the effectiveness of brief interventions (e.g., Kaner et al., 2013, Hilbink et al., 2012). Such findings may be in part explained by growing evidence that SBIRT approaches are challenging to implement due to the time, training, and commitment they require (Yarnall et al., 2003, van Beurden et al., 2012, Kaner et al., 2013, Aalto et al.,

2005, DePue et al., 2002). In prenatal care settings, many obstetricians report obstacles such as insufficient time and limited confidence in addressing alcohol use (Anderson et al., 2010).

Technology can address these limitations. Computer-delivered screening and brief intervention (e-SBI) can be used independent of medical staff. Increasing reach in this way may lead to a substantial population impact even with small magnitude effects; e-SBI could also be delivered at very low cost, and with high fidelity replication in the community. Reviews largely support the efficacy of technology-delivered interventions—many of them brief—in reducing alcohol and other substance use (e.g., Rooke et al., 2010, Portnoy et al., 2008, Moore et al., 2011, Khadjesari et al., 2011, Gainsbury and Blaszczynski, 2011).

In a randomized trial of an e-SBI for alcohol use in pregnancy, Tzilos et al. (2011) found that a computer-delivered brief intervention for alcohol use during pregnancy was seen as highly acceptable by participants and was associated with significant increases in infant birthweight. However, that study found no group differences on self-reported alcohol use, possibly due to floor effects observed with its phone-based follow-up interview (72% of participants reported drinking at baseline, and only 10% at follow-up). The objective of the present Stage I pilot trial (Rounsaville et al., 2001) was to build on Tzilos et al. by adding an in-person follow-up to avoid the possible floor effects seen in that study, and by enhancing the intervention through tailored videos and subsequent tailored mailings. As a Stage I trial, our goals were to evaluate feasibility and acceptability and to obtain effect size estimates; this trial was not powered to detect significant differences.

Materials and Methods

Participants

Participants were pregnant women seeking services at a prenatal care clinic affiliated with the Henry Ford Health System (HFHS) in Detroit, Michigan; this clinic serves predominantly African-American women, over half of whom have incomes below $40,000, and approximately a third of whom are insured by Medicaid. Eligibility criteria included age 18 or older, understanding spoken English, 28 weeks gestation or less, intention to carry the pregnancy to term, willing to be sent tailored messages about alcohol use, and willing to allow access to their child's birth records. Finally, all participants had to test positive on the T-ACE alcohol risk screener (Sokol et al., 1989), while also reporting either (a) drinking weekly or more in the past month or (b) having four or more drinks at least monthly in the 12 months before becoming pregnant. Exclusion criteria included previous participation in other lab studies, plans to deliver outside of the HFHS system, cognitive impairment, or frank psychotic symptoms.

Procedures

Baseline data collection began July 19, 2012 and concluded November 21, 2013, ending when recruitment goals were met. Follow-up data collection took place between December 12, 2012 and March 22, 2014. Women were informed of the study by a clinic nurse at the conclusion of an initial intake appointment. Those expressing potential interest were introduced to a research assistant who evaluated participants for eligibility. Potential

participants were then given a tablet device which presented an informed consent information sheet on-screen and verbally, via headphones for privacy. Those providing consent used the tablet to complete a 28-item screen of alcohol use before pregnancy and in the past month. Participants received a small gift bag with infant-related items worth approximately $3 for completing the screen.

Following completion of the screen, eligible participants were told of the clinical trial. Those who provided written consent were given a tablet computer and headphones, with which they completed assessment and either the e-SBI or the control condition (a moderately interactive session on infant nutrition). Participants who completed all baseline research activities received a gift card worth $50 at Target stores. Given the importance of knowing when participants were hospitalized for labor and delivery, they were followed via daily checks of their electronic medical record (EMR) beginning at 28 weeks gestation, followed by twice daily checks beginning at 36 weeks gestation. Contact was made after childbirth but prior to discharge, at which time a blinded in-hospital follow-up evaluation was arranged. All follow-up evaluations took place in a private Henry Ford Health System childbirth and recovery room. Electronic medical records for infants delivered by participants were searched by a blinded evaluator who recorded live birth, birthweight, and whether the infant was admitted to the Neonatal Intensive Care Unit (NICU). All procedures for this study were approved by the Institutional Review Boards of Wayne State University and the Henry Ford Health System in Detroit, MI. The trial was registered with clinicaltrials.gov (NCT01643044).

Measures

The alcohol screening presented via the tablet included a series of 14 items measuring alcohol use before pregnancy and during the past month. It included the T-ACE screen (Tolerance, Annoyed, Cut down, Eye-Opener; Sokol et al., 1989), a single item from the NIAAA Task Force on Recommended Alcohol Questions (National Institute on Alcohol Abuse and Alcoholism, 2003) regarding binge drinking in the year before becoming pregnant, and a single item regarding frequency of drinking in the past month.

For participants who screened positive and provided consent, additional measures included the alcohol subtest of the MINI International Neuropsychiatric Interview, Version 5.0 (MINI; Sheehan et al., 2006) which measures DSM-IV criteria for alcohol use disorders; the Center for Epidemiological Studies Depression Scale-10 (Zhang et al., 2012); and additional items regarding demographics, treatment services received, and receipt of public assistance. All measures were completed using Audio Computer-Assisted Self-Interview (ACASI) software, also delivered via tablet computer. The same items were completed again at the postpartum follow up, also using the ACASI software and a tablet with headphones in the participant's private hospital room. At follow-up only, alcohol use was also measured via a timeline follow-back interview (Sobell and Sobell, 1996). As noted, pregnancy outcome (live birth, birthweight, and time spent in the Neonatal Intensive Care Unit, or NICU) was measured by review of participants' Electronic Medical Records. Acceptability was measured using items evaluating ease of use, overall liking, respectfulness, etc. on a 1 – 5 scale reflecting level of agreement (where 1 = "not at all" and 5 = "very much"). Feasibility

was considered in terms of recruitment to the study by clinic staff, and as the proportion of participants who were able to complete the brief intervention.

Intervention

The e-SBI intervention for this study was built on principles of Motivational Interviewing (Miller and Rollnick, 2002) and Self-Determination Theory (Ryan and Deci, 2000), and sought to facilitate self-change and/or treatment-seeking through a 20-minute interactive session, using techniques such as (a) brief education regarding alcohol-related pregnancy risks; (b) helping the participant evaluate the pros and cons of change and the extent to which the decision to avoid alcohol might align with deeply held values or goals; (c) feedback regarding how many women drink during pregnancy and the potential cost savings if they should avoid/continue to avoid drinking; and (d) eliciting a specific, participant-selected goal regarding drinking during the rest of pregnancy, with requests for details and proactive problem-solving for those who chose to set a goal. Participants who chose to make a change goal were free to define it as abstinence, a reduction in use, maintenance of a previous reduction, or maintenance of abstinence. The brief intervention was highly interactive and tailored, particularly on participants' status with regard to change since becoming pregnant and goals for the remainder of their pregnancy.

This intervention was based on a prior trial (Tzilos et al., 2011) but differed in three major ways. First, a series of brief videos were added. These videos featured a physician providing gain-framed information about alcohol use in pregnancy and a mother providing a testimonial regarding her decision to avoid alcohol use during pregnancy. Multiple versions of each video were available and were tailored based on three participant characteristics: quit status, self-efficacy, and frequency of binge drinking. Second, given evidence from the initial trial that most women screening positive for alcohol risk report having quit drinking upon becoming aware of their pregnancy, we targeted this group for feedback and revised the intervention accordingly prior to beginning the trial (see Pollick et al., 2013). Third, a series of three tailored mailings was added to extend contact with the participant.

The e-SBI intervention included three primary branches, with branching taking place following the video (see Figure 2). The first branch was focused on women who reported current use with no interest in quitting, and most closely followed typical brief intervention techniques described above (e.g., decisional balance, feedback, and optional goal-setting). The second branch was tailored for women who reported active alcohol use but a desire to quit. Given evidence that motivational approaches with persons already intending to change may be contraindicated (e.g., Stotts et al., 2001), participants in this branch were provided with relatively brief feedback regarding the benefits of their decision (such as in money saved) then moved directly into the goal-setting process. Finally, in contrast to typical brief interventions which focus primarily on active use, the third major branch targeted participants who reported having quit since becoming pregnant. We included these participants because of the possibility of relapse, and because the stigma of substance use during pregnancy and/or the threat of child welfare involvement may lead to significant under-reporting (Grekin et al., 2010, Whaley and O'Connor, 2003, Ernhart et al., 1988). This path thus sought to help maintain genuine abstinence while also promoting reduction or

cessation of alcohol use among those who were in fact still drinking; it did so without in any way implying that the participant had not been forthcoming.

The e-SBI intervention used in the present study placed substantial emphasis on the common or non-specific therapy factors that have been shown to be associated with therapy outcome (e.g., Wampold, 2001). For example, the intervention used an emotive and nonjudgmental animated narrator who provides natural-language reflections, seeks participant input, and offers specific affirmations. Notably, evidence from the human-computer interaction literature suggests that people reflexively respond to computers in ways that mirror how they respond to humans (e.g., Nass and Moon, 2000). For example, research has shown that people respond positively to flattery from a computer (Fogg and Nass, 1997), are hesitant to be critical of a computer (Nass et al., 1999), and engage in more social responses to computers when they exhibit elements of personality (Nass et al., 1995). Further, participants are also more likely to persist with, like, and trust computer-based agents that exhibit social and relational skills (Bickmore et al., 2005, Bickmore and Picard, 2005). In particular, expression of empathy by a computer agent leads to higher ratings of perceived support, trust, and liking (Brave et al., 2005).

The three tailored mailings were sent at evenly spaced intervals that varied with the participant's expected due date. The first mailing was sent one month after enrollment in the study, and the next two were sent so that the second mailing was received in the middle of the remaining time left, and the third near the expected due date. All mailings were tailored based on participant age, gestational age, race, quit goal, level of social support for stopping alcohol use, frequency of binge drinking, and self-efficacy for quitting, all of which were collected via the ACASI software at baseline. Each participant's pattern of responses on tailoring variables was then entered into a form developed using the University of Michigan's *Michigan Tailoring System* (http://chcr.umich.edu/mts/), which generated single-page flyers consisting of standard text, tailored text, and tailored images.

Control condition

The control condition provided a time-matched (20 minutes) and moderately interactive intervention focused on infant nutrition, with no mention of alcohol use during pregnancy. Although developed using the same intervention authoring tool as the experimental condition, the control condition specifically avoided engaging in actions such as expressions of empathy or affirmations.

Randomization

Participants were randomized by the software using simple randomization to either e-SBI or control conditions in a 1:1 ratio. Randomization by the software maintained research assistant blinding with respect to participant allocation into study conditions at the baseline data collection/intervention session.

Data analysis

All participants were analyzed according to their randomly assigned condition. This study's primary aim was to evaluate feasibility and acceptability, and to obtain an effect size

estimate by comparing the e-SBI against the control condition as reflected by 90-day period-prevalence abstinence at the postpartum follow-up. Differences in response distributions between conditions were assessed using Logistic Regression, controlling for baseline drinking, with the odds ratio as the effect size. Analysis of secondary outcomes was similar for healthy pregnancy outcome, a categorical variable that was treated as positive if the pregnancy ended in a live birth ≥ 2500g with no admission to a Neonatal Intensive Care Unit (NICU); Poisson regression was used for the secondary outcome of number of drinking days in the past 90. Both completer and intent-to-treat analyses were conducted, with the latter using a multiple imputation approach for participants lost to follow-up; variables used for multiple imputation were experimental condition, number of drinks per month, whether or not the infant was viable or spent time in the NICU, the number of drinking days within the past 90 days, the number of days with 3 or more drinks in the past 90 days, infant weight, and 90-day alcohol abstinence. Sensitivity analysis using these imputed values confirmed findings from analyses using only participants who completed follow-up. Therefore only observed data are presented here.

Results

Sample characteristics and success of randomization

Participant flow is depicted in Figure 1. A total of 524 pregnant women were assessed for eligibility; 476 (90.8%) were excluded, with most of these (455, or 95.6%) being excluded for not meeting inclusion criteria, primarily regarding alcohol-related risk. Within the final sample of 48 participants, half were assigned to the e-SBI condition and half to the control condition. As seen in Table 1, participants were primarily African-American, most of whom had received some form of public assistance in the past year. Although all participants were positive on the T-ACE alcohol risk screen, most did not meet criteria for an alcohol use disorder in the 12 months prior to becoming pregnant (per the alcohol subtest of the MINI), and only two (4.2%) had received any prior treatment for alcohol use. A total of 39 participants completed the in-hospital follow-up evaluation (81.3%), with most loss to follow-up being due to miscarriage or delivering at another hospital. Birth outcome data, however, were available for 44 participants (91.7%). We did not find evidence that any participants experienced harm or unintended effects from participation in this study. As seen in Table 1, there were no baseline differences between the e-SBI and control groups on any of the characteristics measured.

Feasibility and acceptability

Clinic staff had no difficulty recruiting participants to the study, and all participants were able to complete the brief intervention. The e-SBI was also well-received: using a 1 – 5 scale reflecting level of agreement (where 1 = “not at all” and 5 = “very much”), mean scores on satisfaction items ranged from 4.7 to 5.0 for ease of use, helpfulness, respectfulness, and whether it might help other moms like them. The item “Did participating get you thinking about your alcohol use?” received a mean rating of 4.2, and 75% of e-SBI participants said that they were more likely to change their alcohol use/successfully maintain a pre-existing quit goal because of the intervention.

Intervention flow

As noted above, participants all received an introduction and viewed a tailored video prior to being asked a key question regarding their interest in being abstinent from alcohol use during pregnancy. As seen in Figure 2, all participants either chose to make a quit goal or reported that they had already done so.

Intervention efficacy

Table 2 shows all dichotomous alcohol-related outcomes for control and intervention conditions. The group receiving the e-SBI plus tailored mailings showed a non-significant advantage of moderate magnitude in terms of the primary outcome of 90-day period prevalence abstinence, with an increase in rate of abstinence of 16.1%. Results were similar for secondary outcomes, all of which showed non-significant effect sizes of small- to medium-magnitude in favor of the intervention condition. Similarly, the continuous outcome —number of drinking days in the past 90 days—also suggested small but non-significant effects in favor of the intervention condition (.7 fewer days, $p = .25$). Finally, in terms of treatment-seeking for alcohol use, only one participant (part of the e-SBI condition) reported at follow-up that she had received any substance abuse services in the past five months.

Discussion

A prior pilot trial of a computer-delivered brief intervention for alcohol use in pregnancy (Tzilos et al., 2011) showed promising results in terms of birth outcomes but was unclear with respect to alcohol use outcomes. The present study tested an augmented intervention and included in-depth, in-person follow-up assessment. Results for alcohol use and birth outcomes were of moderate size and consistently favored the intervention. These encouraging findings mirror those of the earlier pilot, and suggest that a fully-powered trial of this approach is merited. Although these effects did not reach significance, significance was not expected given the sample size and the more preliminary goals of this Stage I pilot trial (Rounsaville et al., 2001).

The at-risk women in this study who received the intervention were asked to indicate whether they were unwilling to quit, willing to quit, or had already quit drinking when they discovered they were pregnant. All study participants either made a quit goal or indicated that they had already quit. In contrast, traditional motivational interventions are designed to initiate a change goal and may be most effective with those who are not currently ready to set such a goal (Stotts et al., 2001). This raises questions as to the applicability of typical motivational approaches in this context.

It is important to consider the present findings in the context of the larger literature regarding brief interventions for alcohol use. Meta-analyses have suggested that screening and brief intervention for alcohol use in primary care leads to small to moderate reductions in alcohol consumption (Kaner et al., 2009, Jonas et al., 2012); a recent systematic review of 23 studies of computer-delivered approaches (Donoghue et al., 2014), although including a broad range of intervention types (not all brief), reaches a similar conclusion. The magnitude of effects in the current study is consistent with this literature, as well as with e-SBI trials

using the same software platform to address smoking in pregnancy (Ondersma et al., 2012) and postpartum drug use (Ondersma et al., 2014).

Future research should recognize important differences between computer- and person-delivered interventions. First, technology-delivered brief interventions—as with person-delivered interventions—can vary in duration, theoretical basis, and verbal content. But technology-based interventions are more likely to also include elements such as videos or other multimedia, location awareness, user input, and tailoring. This means that technology-delivered interventions may be at least as heterogeneous as person-delivered approaches, and that the success or failure of one approach may not reflect on that of another. Second, the various elements of computer-delivered approaches can be more easily dismantled and combined than in person-delivered interventions. This relative advantage should be leveraged in studies seeking to optimize e-SBI interventions. Third, technology-delivered approaches are likely to prove easier to implement than approaches that require significant training and time commitment from providers. Because of this, comparisons between person- and technology-delivered brief interventions should include consideration not just of relative efficacy and cost-effectiveness, but also of ease of implementation. Finally, three-group designs—including a screen-only or other minimal contact control—may be needed to help isolate brief intervention effects from assessment effects (Donovan et al., 2012).

Limitations

As a pilot, this study was not powered as a confirmatory trial. In addition, the study sample of low-income African-American women limits generalizability to other populations. The two-arm trial design used in this study also does not allow evaluation of the separate contributions of the e-SBI vs. the subsequent tailored mailings.

Conclusion

This pilot trial demonstrated that the combined e-SBI and tailored mailing intervention was feasible and highly acceptable to participants. Additionally, intervention effect sizes on alcohol use as well as birth outcomes were promising for such a brief intervention and thus clearly merit confirmation in a fully-powered trial. At present, e-SBI strategies are showing continued promise and may be important targets for research given growing recognition of challenges associated with person-delivered SBI.

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Participant Flow

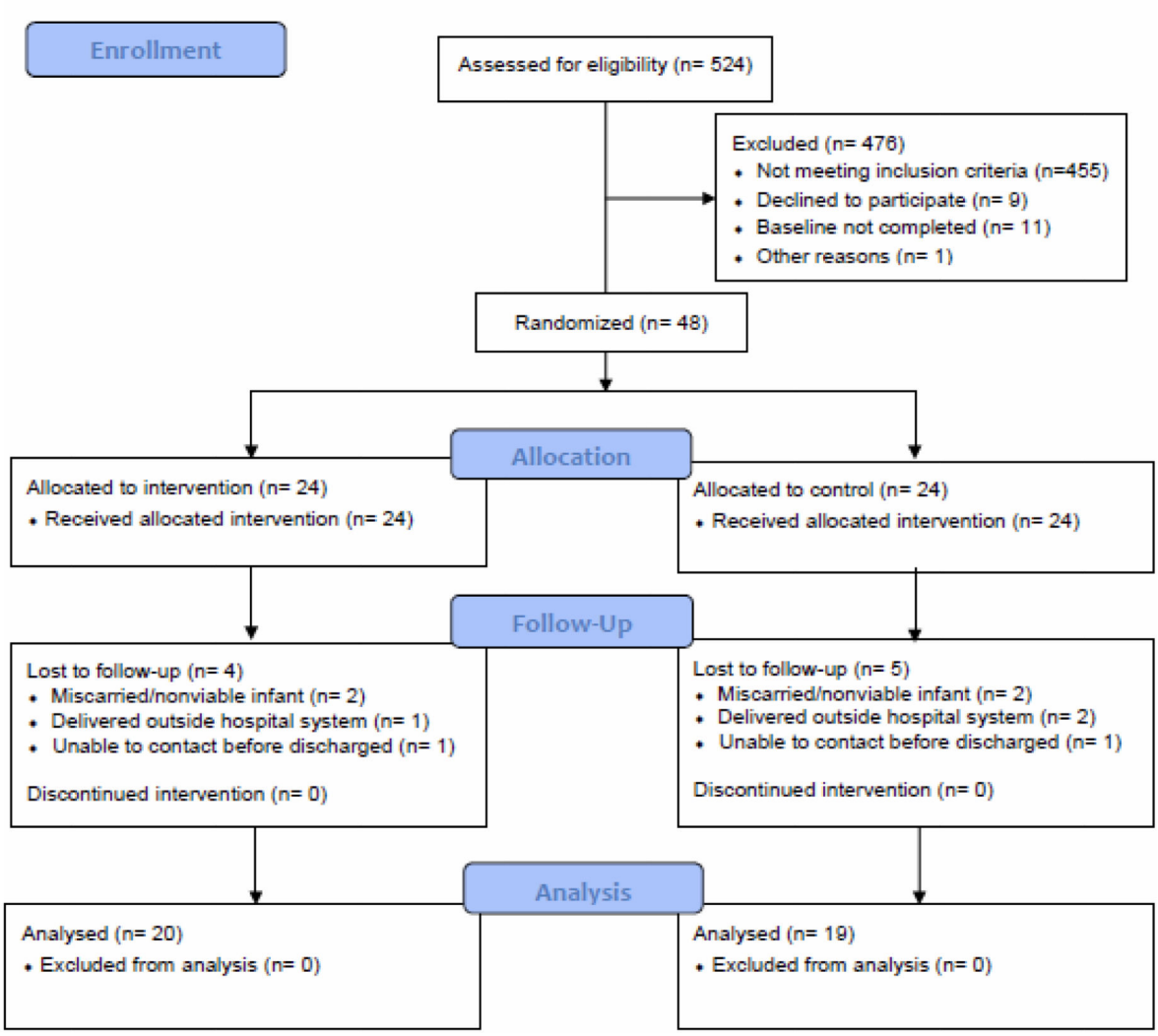

Figure 1.
Participant Flow

Intervention Flow, with Self-Selection into Major Branches

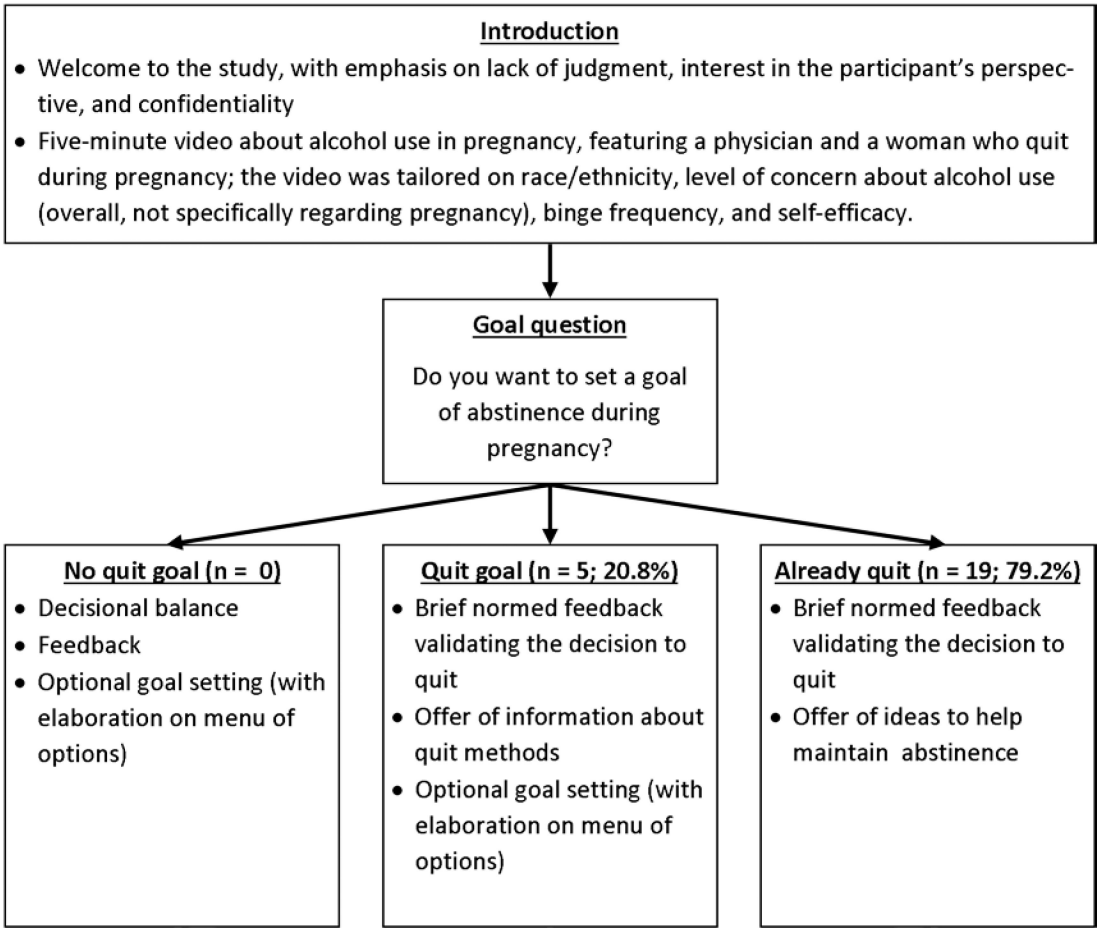

Figure 2.
Intervention Flow, with Self-Selection into Major Branches

Table 1

Baseline sample characteristics (N = 48)

Categorical variables (*N*, %)	**Total sample (*N* = 48)**	**Control (*n* = 24)**	**Intervention (*n* = 24)**	***p***
High school graduate or higher	32 (66.7%)	14 (58.3%)	18 (75.0%)	.71
Currently married	10 (20.8%)	5 (20.8%)	5 (20.8%)	.64
African-American	39 (81.3%)	21 (87.5%)	18 (75.0%)	.31
Any public assistance (WIC, etc.)	39 (81.3%)	20 (83.3%)	19 (79.2%)	.71
Binge drinking ≥ once/wk when not pregnant	28 (58.3%)	12 (50.0%)	16 (66.7%)	.24
Alcohol abuse or dependence	12 (25.0%)	5 (20.8%)	7 (29.2%)	.61
Prior treatment for alcohol use	2 (4.2%)	0	2 (8.3%)	.15
Age				.53
18-25	26 (54.2%)	14 (58.3%)	12 (50.0%)	
26-33	16 (33.3%)	8 (33.3%)	8 (33.3%)	
34-37	6 (12.5%)	2 (8.3%)	4 (16.7%)	
Continuous variables (*N*, SD)				
CESD-10 depression scale	8.7 (5.4)	8.4 (5.4)	9.0 (5.6)	.70
Gestation (weeks)	12.2 (5.4)	12.0 (5.3)	12.5 (5.6)	.77

Note. All participants were positive on the T-ACE alcohol screener. Alcohol use disorder evaluated using the MINI International Neuropsychiatric Interview, Version 5.0.

Table 2

Intervention Effects on Categorical Alcohol-Related Outcomes

	Control (n = 24)	Intervention (n = 24)			
	N (%)	*N* (%)	OR (95% CI)	ORa (95% CI)	*p*
90-day period prevalence abstinence	14/19 (73.7%)	18/20 (90.0%)	3.2 (0.5-19.1)	3.4 (0.5-21.0)	.19
Healthy pregnancy	14/23 (60.9%)	19/23 (82.6%)	3.1 (0.8-12.0)	3.3 (0.8-13.8)	.09
Treatment-seeking	0/19	1/20 (5.0%)	---	---	---

Note. The intervention was a 20-minute, brief intervention delivered via a Tablet and completed following a prenatal care appointment, plus three subsequent tailored mailings. Period prevalence abstinence over the past 90 days was measured at delivery. Healthy pregnancy was defined as a live birth of ≥ 2500 grams with no admission to Neonatal Intensive Care Unit. ORa values are adjusted for baseline alcohol use, and treatment-seeking was defined as any services of any kind for alcohol use, including 12-step groups. All *p* values are for adjusted OR (ORa).