Published in final edited form as:

Alcohol Clin Exp Res. 2018 June ; 42(6): 1132–1144. doi:10.1111/acer.13635.

A Pilot RCT of an Internet Intervention to Reduce the Risk of Alcohol-Exposed Pregnancy

Karen Ingersoll, Ph.D., Christina Frederick, B.S., Kirsten MacDonnell, B.S., Lee Ritterband, Ph.D., Holly Lord, Ph.D., Brogan Jones, B.A., and Lauren Truwit, B.S.Ed.

University of Virginia School of Medicine

Abstract

Background—Preventing alcohol-exposed pregnancies (AEP) could reduce the incidence of Fetal Alcohol Spectrum Disorders. Previous face-to-face interventions significantly reduced risk for AEP, but a scalable intervention is needed to reach more women at risk.

Methods—This study compared a 6 Core automated, interactive, and tailored Internet intervention, the Contraception and Alcohol Risk Reduction Internet Intervention (CARRII), to a static patient education (PE) website for its effect on alcohol-exposed pregnancy risk. Participants were recruited online to a pilot randomized clinical trial with baseline, 9 weeks post-treatment, and 6 month (6M) follow-up assessments. 71 women completed online questionnaires and telephone interviews and were randomized to CARRII (n=36) or PE (n=35). Primary outcomes were rates of risky drinking, unprotected sex episodes, and AEP risk, collected from online prospective diaries.

Results—CARRII participants showed significant reductions in rate of unprotected sex from pre-treatment (88.9%) to post-treatment (70.6%) ($p<.04$), and to 6M follow-up (51.5%), ($p<.001$); rate of risky drinking from pre-treatment (75.0%) to post-treatment (50.0%) ($p<.02$), but insignificant change from pre-treatment to 6M follow-up (57.6%) ($p<.09$); and rate of AEP risk from pre-treatment (66.7%) to post-treatment (32.4%) ($p<.001$) and to 6M follow-up (30.3%) ($p<.005$). PE participants demonstrated no significant changes on all three variables across all time points. Intent-to-treat Group by Time tests were not significant, but power was limited by missing diaries. Over 72% of CARRII participants completed all 6 Cores. Exploratory analyses suggest that higher program utilization is related to change.

Conclusions—These data show that CARRII was acceptable, feasible, promising to reduce AEP risk, and merits further testing in a fully powered RCT.

Keywords

alcohol-exposed pregnancy; eHealth; Internet; prevention; contraception; risk drinking

Corresponding author: Dr. Karen Ingersoll, kareningersoll@virginia.edu, 804-651-6929 telephone, 434-297-7720 fax, Mailing address: Center for Behavioral Health and Technology, PO Box 801075, UVA, Charlottesville, VA 22903.

DR. KAREN INGERSOLL (Orcid ID : 0000-0001-8115-2548)

Introduction

Reducing alcohol use during pregnancy is a health care objective identified by Healthy People 2020 (U.S. Department of Health and Human Services, 2013) and the Surgeon General (U.S. Department of Health and Human Services, 2005) with an aim to reduce the occurrence of fetal alcohol spectrum disorders (FASD). AEP prevention must reach women who drink alcohol prior to conception to achieve primary prevention (Floyd, Ebrahim et al., 1999; Peterson and Lowe, 1992; Weiner et al., 1989). An AEP is one in which a woman drinks any alcohol, in any amount, at any time during the pregnancy (Mengel et al., 2006). A pragmatic definition of AEP risk is a combination of risk drinking and risk for pregnancy due to ineffective contraception (Velasquez, Ingersoll, Sobell, Sobell, 2016). Fetal alcohol spectrum disorders (FASDs) can result from AEP, and include a range of effects including lowered intelligence and developmental delays (Mattson et al., 2013; Streissguth and LaDue, 1987). FASD includes neurological damage (Coles and Li, 2011) that creates lifelong challenges for the individual (Streissguth et al., 2004) and substantial costs to society (Popova et al., 2013; Amendah et al., 2011).

Current Surgeon General-issued recommendations are that women at risk for pregnancy should not drink, or should employ effective contraception to prevent alcohol exposure in unintended pregnancies (Services, U.S. Department of Health and Human, 2005). Unfortunately, nearly 30% of the pregnancies in the U.S. are not planned, most women are not aware of an unintended pregnancy until after the fourth week, and many women do not recognize pregnancy until much later (Floyd, Decoufle et al., 1999). These early weeks of pregnancy are a critical period of fetal susceptibility to the teratogenic actions of alcohol (Nykjaer et al., 2014). Women are at risk for unintended pregnancy if they are sexually active, able to become pregnant, not currently pregnant and not trying to become pregnant, but not always using contraception. The rate of unintended pregnancy in the U.S. remained stable for decades but declined significantly from 27% in 2008 to 22% in 2011 (Finer and Zolna, 2016). Those not intending pregnancy may not prevent it due to using ineffective methods of contraception such as withdrawal, forgetting to take contraception pills or obtain a hormone shot, not always using a condom, running out of contraception supplies, using birth control methods incorrectly, using no contraception, or interpersonal dynamics including partner or social/religious pressures to avoid contraception or accept pregnancy (U.S. Department of Health and Human Services, 1997). U.S. rates of unintended pregnancy are highest among women and girls who are poor and/or cohabiting (Finer and Zolna, 2016). If they are also drinking alcohol, these women are at risk for AEP (Project CHOICES Research Group, 2002). A recent study estimated that 7.3% of U.S. women are at risk for AEP in any one-month period (Green et al., 2016). Primary prevention requires assisting women at risk for pregnancy across a range of drinking habits to modify drinking or contraception habits to prevent AEPs.

Motivational Interviewing (MI, Miller and Rollnick, 2012) interventions can be efficacious in preventing AEP. Two of these interventions, the CHOICES intervention (Floyd et al., 2007) and the BALANCE intervention (Ceperich and Ingersoll, 2011), used MI to guide women to recognize and change risk behaviors for AEP by reviewing personalized feedback, identify goals for drinking and contraception, and plan change systematically. These

interventions decreased drinking, binge drinking, ineffective contraception, and AEP risk among community women (Floyd et al., 2007) and university women (Ceperich & Ingersoll, 2011). The CHOICES intervention included 4 counseling sessions and a contraception counseling visit (Velasquez et al., 2010). CHOICES sessions were highly individualized, with activities, pace, and focus of the intervention tailored to participant interest in changing one or both target behaviors. An RCT with 830 women found that those receiving the CHOICES intervention rather than a patient education control condition were more likely to make changes in both drinking and contraception behaviors, maximizing the likelihood of avoiding an AEP up to 9 months post-intervention (12 months after enrollment), and found that the proportion of women with AEP risk in the CHOICES condition declined from 100% to 36.4% at the 6M follow-up and 30.9% at the 9M follow-up (Floyd et al., 2007).

The BALANCE study, modified from CHOICES for university women, was the first to demonstrate that a lower intensity intervention targeting AEP risk behaviors could be efficacious. In an RCT of the experimental condition vs. a patient education control condition among 208 university women, those in the experimental condition reduced drinking risk and increased effective contraception use more than women in the control condition at the 4 month follow-up, and found that the rate of AEP risk declined from 100% to 20.2% at the 4M follow-up (Ceperich and Ingersoll, 2011). Since then, several lower intensity CHOICES-based interventions have shown efficacy in other studies using the CHOICES intervention framework, including a single session model (EARLY) tested in face-to-face (Ingersoll et al., 2013) and telephone formats (EARLY REMOTE) (Farrell-Carnahan et al., 2013), 2 very brief mailed interventions for college students and nonstudents (Sobell et al., 2017), a very brief intervention version tested in telephone and face-to-face formats (Wilton et al., 2013), a 2-session adaptation of CHOICES tested in sexually-transmitted infection (STI) clinics (Hutton et al., 2014), and a 2-session version of CHOICES including a focus on smoking in primary care clinics (Parrish et al., 2012). Additional culturally-tailored adaptations for several populations have been developed, including Hispanic women (Letourneau et al., 2017), an American Indian tribe (OST CHOICES) (Hanson et al., 2015; Hanson et al., 2017), Russian women (Balachova et al., 2013), and South Africans (Rendall-Mkosi et al., 2013). While all of these interventions have demonstrated efficacy, the largest decreases in the proportion of women with AEP risk were found in the CHOICES and BALANCE studies.

In sum, AEP risk interventions based on the CHOICES program are efficacious, but lower intensity face to face, telephone, or mailed interventions yield smaller reductions in the rate of AEP risk than did CHOICES or BALANCE. Additionally, these interventions are not widely available, accessible, or scalable, mostly due to the need for skilled counselors and the logistical requirements (scheduling, travel, etc.) of counseling sessions. Moreover, face-to-face evidence-based AEP interventions are delivered by only a few organizations in the U.S. and Canada, and most of these required significant support from the CDC, SAMHSA, and NIAAA. Given that there are 3.3 million U.S. women at risk for AEP in any one month (Green et al., 2016), most of whom have no access to evidence-based AEP prevention services, there is an urgent need for a scalable, accessible, and efficacious intervention that results in large reductions in risk for AEP.

This gap in prevention could, in part, be addressed through the use of Internet-delivered interventions. In contrast to health websites which are mostly informational (Fox and Fallows, 2003; Ritterband and Thorndike, 2006), a growing minority of sites provide health interventions that transform behavioral treatments for Internet delivery and emulate processes from face-to-face counseling (Marks et al., 2007; Ritterband et al., 2003). Most of these are based on efficacious face-to-face interventions, and present highly structured, self-guided, interactive, information using audio, video, and animated graphics to promote depth of understanding, and are tailored to provide feedback on progress. Treatment adherence and efficacy may be enhanced by increased user satisfaction (Ritterband et al., 2008), and the financial costs of treatment may be reduced (Andrade et al., 2016; Hunter et al., 2017; Kaner et al., 2017; Rogers et al., 2017). Internet interventions are truly scalable, and can reduce barriers of traditional face-to-face treatments, such as the need for trained counselors and skillful supervision to achieve treatment fidelity, and user inconveniences such as scheduling and travel to receive specialized care. Internet interventions have strong evidence of treatment fidelity and may help achieve the public health goal of obviating racial, ethnic, and socioeconomic disparities in health (Ray et al., 2017; Jang et al., 2017) that are related to persistent economic and racial inequalities (Satcher, 2000).

There have been some studies of reducing AEP risk using Internet-delivered interventions. In a quasi-experimental study of a health website to reduce AEP risk, a static (meaning fixed, and not personalized or tailored) Internet presentation of AEP risk reduction intervention materials was compared to the same intervention delivered by mail (Tenkku et al., 2011). The web-delivered and mailed versions of this intervention significantly reduced AEP risk from 100% to 42%, indicating a less potent effect than that of CHOICES or BALANCE. A randomized trial among American Indian and Alaska Native women of childbearing potential in Southern California compared a web-based alcohol screening, brief intervention, and referral to treatment (SBIRT) intervention to assessment alone and measured the impact on drinking, binge drinking, and AEP risk (Montag et al., 2015). The web-delivered SBIRT provided individualized feedback on risk of AEP, impact of alcohol exposure on a fetus, costs of drinking, and normative feedback about drinking. Both conditions resulted in significant reductions in AEP risk from 35% at baseline to 17-20% at 6 month follow-up in control and SBIRT conditions, respectively. That trial showed promise for consciousness-raising information provision and brief intervention, but did not enroll women at risk of an AEP specifically. To address the need for an AEP risk-specific Internet-delivered intervention, the investigators developed the Contraception and Alcohol Risk Reduction Internet Intervention (CARRII), transformed from the CHOICES intervention (Ingersoll et al., 2014). The purpose of this study was to conduct a pilot randomized clinical trial investigate the impact of CARRII compared to a non-tailored patient education (PE) website on AEP risk and constituent contraception and drinking behaviors among a sample of women at risk for AEP recruited online.

Methods

Eligibility

Eligibility criteria were: women, ages 18-44 who were fertile, could legally provide informed consent, spoke and read English, had Internet and telephone access, had risky drinking, defined as more than 1 episode of drinking 4 or more standard drinks/day (considered a binge) (NIAAA, 2004) during the past 3 months, and were at risk for unintended pregnancy due to ineffective, inconsistent, or absent contraception in the past 3 months.

Recruitment Procedures

Investigators posted online advertisements to sites such as Craigslist, Facebook, Twitter, UVA Clinical Trials page, and [ClinicalTrials.gov](https://www.clinicaltrials.gov). Craigslist ads targeted locations across the US with high drinking rates, with advertisements for the study placed in the Volunteer Opportunities section. Paper flyers were posted across the Charlottesville/UVA area. Investigators notified other colleagues and students about the study by email and Facebook posts. Women read a description of the study on the CARRII study website, and completed an online Interest Screen.

Screening Procedures

Once Interest Screens were submitted, the project coordinator determined ineligibility and sent ineligible women an email thanking them for their interest. When a candidate seemed eligible, the project coordinator sent an invitation by email to arrange a telephone appointment to review and complete the verbal and online informed consent process, and to complete an interview. Interested women completed the online *Interest Screen*, a 30-item measure that included contact information and assessed for selected eligibility criteria. If the individual appeared to be an eligible candidate, the study coordinator invited her by email to participate in an *enrollment telephone call*. The *telephone call* oriented participants to the online informed consent process, and confirmed eligibility if satisfaction of any criterion was unclear from the *Interest Screen* (see Figure 1 for the flow of participants through study steps).

Measures and Assessment Procedures

Measurement time points were interest form, enrollment, pre-treatment period, post-treatment 9 weeks after the first day of intervention availability ("day 0"), and post-treatment 6-month follow-up, 6 months after day 0. See Figure 2 for a depiction of the flow of study activities. For most participants, the consent and enrollment telephone call took 45 minutes, while follow-up phone calls took 25-30 minutes. Participants were compensated for completion of the post-treatment assessment with Amazon gift cards in amounts of \$15 for the questionnaire, \$15 for online diaries, and \$20 for phone interview, and for completion of the 6-month follow-up completion with Amazon gift cards in amounts of \$30 for the questionnaire, \$30 for online diaries, and \$40 for phone interview.

Measures selected for this RCT had been utilized in the CHOICES and related AEP risk reduction studies or in prior Internet intervention trials to facilitate comparison to other

studies. During the consent and enrollment telephone call, the 90-day Timeline Follow-back (TLFB) retrospective recall procedure was completed for the 90 days before the pre-treatment assessment during the telephone call with participants, and repeated during post-treatment assessment and 6M follow-up assessment telephone calls. The version used was the adaptation of the TLFB that included alcohol, sexual intercourse, and contraception for each day that was used in previous AEP prevention studies (Project CHOICES Intervention Research Group, 2003; Floyd et al., 2007) and was used to confirm that each woman enrolled was at risk of AEP at the point of enrollment. During the enrollment telephone call, the MINI International Neuropsychiatric Interview (Sheehan et al., 1998) reviewed the domains of Major Depression, Anxiety Disorders (Panic, Generalized, OCD), and Alcohol and Drug Use Disorders.

Participants were randomized following a random assignment list created by the PI using Research Randomizer software. Once enrolled, participants were invited by email to complete an online pre-treatment questionnaire that included demographics, ob/gyn history, and medical, psychiatric, and addiction treatment history using measures from the CHOICES study, and Internet intervention assessments such as treatment usage, Internet intervention utility, and treatment prognosis questions (Thorndike et al., 2008). Following completion of the questionnaire, participants were directed to enter up to 14 days of online diaries. These diary data were highly correlated with data from the TLFB that determined eligibility (Chow et al., 2017). This report focuses only on primary outcomes, which were collected from daily online diaries tracking drinking (number of standard drinks and drinking environment) and contraception usage during the 2 weeks immediately before they could begin their randomly assigned intervention condition. We used all available data from the 7 required and 14 days possible of diary entries to calculate rates of risky drinking, unprotected sex, and AEP risk at pre-intervention, post-intervention, and follow-ups for the primary outcomes. Once at least 7 diaries in a 14-day period were submitted, women received access to their randomly allocated intervention. Participants completed the online post-treatment questionnaire 9 weeks after completion of the baseline measures. After completing the post-treatment questionnaire, they were prompted to enter diaries, and they had continued access to the assigned online program. Participants completed the online post-treatment questionnaire one additional time 6 months after baseline completion. At each of these assessment periods, participants provided diaries of drinking, sex, and contraception use for at least 7 of 14 days.

Interventions

The CHOICES intervention provided the basis for the CARRII condition. CARRII is a fully automated Internet intervention that incorporated dynamic, interactive, and feedback elements designed to mirror the therapist-patient interaction in face-to-face interventions. Using the intervention materials from CHOICES, investigators adapted the four CHOICES sessions and associated materials to create six web-based Cores of information, videos, and interactive activities. The six Core topics and summaries (Overview, Your Risk of AEP, Contraception, Drinking, Thoughts & Decisions, and Commit to It!) are shown in Figure 2. The Cores were metered out over time, with a new Core available one week after completing the previous Core. Each Core began with review of the past weeks' diary data, first by

distinct behavior (drinking and contraception use) and then with both behaviors overlaid. Motivational Interviewing techniques of open questioning and reflection were used for summary, checking in on participant thoughts and progress, and goal setting. Change talk was elicited using open questions, with pre-populated answers to select, or that could be answered using open field text. Summaries were provided after each major activity, and affirmations were given for completing various steps of CARRII, to mirror additional MI processes of a typical CHOICES counseling session. CARRII participants completed online diaries that included graphical feedback of her progress during each week of the intervention period, mirroring a process from CHOICES in which therapists guided participants to review self-monitoring diaries in each session.

The Patient Education Intervention (PE) served as the control condition. It is a website containing the same educational content as CARRII, but the information is delivered in a static and untailored format, like a typical health website. It presents information on: Alcohol Exposed Pregnancy, Fetal Alcohol Spectrum Disorders, alcohol consumption among women, reducing risk from drinking, contraception use, contraception types and efficacy, and links to vetted health information about each of these topics. The website has a linear navigation scheme with one page per topic.

Statistical Analyses

Sample size was determined by powering the study to identify changes in AEP risk rates between pre-treatment and post-treatment in CARRII and to detect differences between changes in AEP risk from pre-treatment to post-treatment in the CARRII and the PE condition separately. Calculations were based on effect size data from the CHOICES and BALANCE studies. Powering the study at 80% to detect pre-post differences in AEP risk between groups, with $\alpha = .05$ (using G*Power 3), a total sample size of 75 participants was needed to achieve 28 participants per group (after expected attrition). Differences by treatment group in pre-treatment characteristics were analyzed with t-tests, and χ^2 or Fisher's Exact tests for categorical variables, as appropriate. Each participant's 7-14 daily diaries were averaged at each time point to determine whether they met criteria for risky drinking (yes, no), unprotected sex (pregnancy risk yes, no), and their combination (AEP risk, yes, no). The proportion of women at risk for these 3 variables was the primary outcome.

Primary outcome variables (rate of drinking risk, pregnancy risk, AEP risk) were modeled using mixed effects logistic regression. We also collected additional data on drinking and contraception variables (proportion of drinking days, drinks per drinking day, proportion of binge days, and proportion of unprotected sex days) that were modeled using mixed effects logistic regression with binomial family for proportion variables, and mixed effects linear regression for drinks per drinking day (this variable was log-transformed prior to analysis to address a positive skew). For all mixed effects models, the effects of interest were the group by time interactions. Time was treated as a categorical variable, and an independent covariance matrix was assumed. Random effects were modelled for time. To examine within-group changes over time, 2-tailed McNemar's test and Wilcoxon signed-rank test were used on binary/proportion/skewed data as appropriate. For binary outcomes, within-

group effect sizes are presented as percent change from pre-treatment to post-treatment and 6M follow-up assessment. For other outcomes, within-group effect sizes were computed as the mean difference between pre-treatment and each post assessment, divided by the full sample pre-treatment standard deviation (Cohen's *d*), indicated by *d* in Table 3. Mixed-model analyses were intent-to-treat; however, given the relatively small attrition rate and exploratory nature of this pilot study, within-group differences on primary outcomes between pretreatment to posttreatment and pretreatment to 6 month follow-up were examined using completers' data. Raw means are presented in the tables. Analyses were conducted in SAS (version 9.4) and STATA (version 14).

Results

71 women participated in the pilot RCT. Table 1 shows the pre-treatment demographic, medical, psychological, and addiction characteristics of the sample by assigned group. In brief, the mean age was 27.8 (SD = 6.2) years old and participants' racial and ethnic characteristics were similar to those in the general US population. Educational level was most commonly college (65%), followed by high school graduation or less (35%). Sixty-nine percent of participants had never been pregnant, while 11 in CARRII and 12 in PE had been pregnant, and 5 in the CARRII and 8 in the PE condition had given birth. Condoms (32%) and withdrawal (38%) were the most commonly reported primary methods of contraception. The rate of unprotected sex was significantly higher for women in the CARRII condition. About 42% of participants ever smoked 100 cigarettes, and most reported substance use consistent with no problems (35%) or low-moderate problems (59%). In contrast, women drank alcohol regularly, reporting a mean of 11.14 drinks per week on the TLFB and reporting over 34 drinking days in 90, with more than 15 binge days. Additionally, 45% of women reported binge drinking weekly or daily. Alcohol Dependence was the most common positive screen on the MINI, with 33% of women reporting symptoms consistent with this disorder. Anxiety and depressive disorders were more common in the CARRII group, but only the higher rate of anxiety disorders was significantly different from PE. Most participants were comfortable with the Internet and used email and the Internet daily.

Of the 71 participants who were randomized, only 6 were lost to follow-up at the post-treatment assessment, and only 1 additional was lost to follow-up at the 6-month assessment (see Figure 1), resulting in 64 who completed at least part of the 6-month assessment. Two women became pregnant. One failed to complete the next assessment after she became pregnant and the other completed both post-treatment assessments after becoming pregnant; available data for participants who became pregnant were included in analyses. Calculating attrition as those who completed neither the post-questionnaire nor 6M diaries, the attrition rate for the study was 7.04% (5 out of 71). While a high rate of women were retained throughout the study, some did not complete enough online diaries at the 6-month assessment for these data to be included in the analysis of primary outcomes, even if they completed other components of the 6M follow-up. Table 2 shows the numbers of women with primary outcomes at each time point by condition. Fisher's exact test showed no association between group and attrition at post-treatment ($p=0.429$) or 6M follow-up ($p=0.710$).

Primary outcomes from the online diary data are shown in Table 2. Intent-to-treat group by time tests were not significant. Each follow-up value was compared to the pre-treatment value by condition in within-group analyses. CARRII participants demonstrated significant reductions in unprotected sex across time, improving 17.65% ($p<.04$) from pre-treatment to post-treatment, and 39.39% from pre-treatment to 6M follow-up ($p<.001$). In contrast, PE participants did not change in unprotected sex from pre-treatment to post-treatment (0.00%) and improved 16.13% from pre-treatment to 6M follow-up (not significant). CARRII participants had significant reductions in risky drinking from pre-treatment to post-treatment (23.53%) ($p<.02$), but the change from pre-treatment to 6M follow-up (18.18%) ($p<.09$) was not significant. In contrast, PE participants did not improve significantly from pre-treatment to post-treatment (16.13%) ($p<.10$) nor to 6M follow-up (19.36%) ($p<.09$). Analysis of within-group differences in AEP risk across time for the CARRII condition showed significant reductions from pre-treatment to post-treatment of 32.36% ($p<.001$) and from pre-treatment to 6M follow-up of 36.37% ($p<.01$). In contrast, PE participants did not demonstrate significant improvements in AEP risk from pre-treatment to post-treatment (3.23%) and to 6M follow-up (16.13%).

Secondary outcomes, including the proportion of drinking days, drinks per drinking day, the proportion of binge episodes, and rate of unprotected sex are shown in Table 3. In a mixed-model analysis of group by time interactions, only the change in rate of unprotected sex was significantly different between groups, with CARRII participants achieving a medium improvement at post-treatment ($d=0.51$) and a large improvement by 6M follow-up ($d=0.90$). In contrast, PE participants showed a very small improvement at post-treatment ($d=0.08$) and a small improvement at 6M follow-up ($d=.36$) (mixed-model group-by-time $p=.05$). Those in the CARRII condition had a higher rate of unprotected sex at pre-treatment, and their improvements lead to similar levels of unprotected sex at follow-ups as observed in the PE condition. Both groups improved similarly in risky drinking behaviors, with a moderate effect sizes on most secondary measures of drinking.

We examined the rate of program usage by login and diaries submitted by women in each condition, and found that the CARRII group had higher average logins and diaries submitted than the PE group, which was expected due to the design of the interventions (see Table 4). Additionally, over 72% of CARRII participants completed all 6 Cores, consistent with feasibility and acceptability of the intervention to the participants.

Table 5 presents an exploratory analysis of the change in risk behaviors by login group among CARRII participants (login group determined by falling above or below the median of 10 logins). These analyses show that for those with greater than 10 logins, there is a 28% change in unprotected sex at post-treatment from pre-treatment, compared to a 6% change among those with fewer logins, and that at the 6M follow-up, those with greater than 10 logins show a 59% change in unprotected sex from pre-treatment, compared to only a 19% change seen in those with fewer logins. For risky drinking, both login groups' risky drinking rates were similar by 6M even though those who logged in less reduced more in absolute terms. While there was no significant association between logins and change in AEP risk at post-treatment, those with more than 10 logins had nearly double the percent change in AEP risk (47%) by the 6M follow-up compared to those with fewer logins (25%).

Discussion

This pilot RCT compared a fully automated, interactive, tailored Internet intervention for AEP risk, CARRII, to an online patient education intervention, PE. CARRII usage was high, with most participants completing all Cores. This high rate of intervention completion indicates that it is feasible to implement an automated AEP risk intervention, and that the sample found it acceptable. Additionally, pilot outcomes data from this study indicates that CARRII show promise to reduce AEP risk, while the comparison intervention, PE, does not. Specifically, participants in the CARRII condition showed significant reductions in the proportion with unprotected sex (reducing risk of unintended pregnancy) from pre-treatment to post-treatment and 6-month follow-up, reductions in the proportion with risky drinking from pre-treatment to post-treatment (that was not significant at 6 month follow-up), and large reductions in the proportion at risk for AEP from pre-treatment to post-treatment that remained significant at the 6 month follow-up. The overall reduction of AEP risk to 32.4% at post-treatment and to 30.3% at 6-month follow-up are similar to the changes seen in the most potent face to face interventions, CHOICES and BALANCE, suggesting that CARRII may have similar effects. In contrast, those assigned to the PE condition showed some changes, but none were statistically significant from pre-treatment to post-treatment, or to 6-month follow-up. On most measures, the randomized groups did not differ from one another at pre-treatment, lending confidence that the interventions were responsible for different outcomes. Moreover, usage data suggest that more logins, which may be a marker of engagement, may be related to change in AEP risk. In summary, these data suggest that the CARRII intervention is feasible and acceptable, and has a sustained impact on the proportion with pregnancy risk and AEP risk, with a short-term impact on the proportion with risky drinking. The PE control condition showed no significant impacts on AEP risk, contraception, or drinking.

Most studies of AEP risk reduction interventions that focus on both drinking and contraception behaviors demonstrate a medium to large effect on reducing AEP risk, and this effect is usually related to a large reduction in pregnancy risk due to uptake of effective contraception, with a smaller change in risky drinking. In the present study, women in both conditions reduced risky drinking by 18-19% at 6M, but this was not statistically significant. This pattern has also been seen across populations at risk including general samples of adult women, college women, and Native American women. One study of Native American women that tested a brief alcohol intervention found that the reduction in drinking came by reducing frequency of drinking rather than reducing drinks per drinking day (Montag et al., 2015). This consistent finding means that there is a need to improve the impact of AEP interventions on risky drinking, which may involve modifying social norms and drinking contexts, in addition to consistently increasing contraception.

Several limitations of this study must be discussed to put these results into context. As with most pilot studies, this one had a small sample size of self-selected volunteers. Additionally, a majority of participants reported a college educational level, which represents only a subset of women at risk for AEP. Another limitation is the lower than optimal completion of diaries from which we calculated primary outcomes, which was disappointing given the overall low study attrition. Online diaries of target behaviors are commonly used in Internet

intervention studies, and while data reporting on diaries was adequate to calculate effect sizes for each condition, it was not adequate to support the power needed for intent-to-treat group by time interaction analyses with dichotomous outcomes. Despite attrition, the within-group analyses were robust, and those data show a distinct pattern of benefit for participants in the CARRII condition, which did not occur for those in the PE condition. Another limitation is that there were a few differences in the groups that were not equated by randomization. The CARRII participants were significantly more anxious and had higher rates of unprotected sex at pre-treatment. While the current paper focuses on primary outcomes and the acceptability/feasibility of CARRII, we plan to examine these secondary variables and explore the potential influence of participant pre-treatment characteristics on outcomes. A potential limitation is the lack of biomarkers of alcohol levels, causing reliance on self-report data. Biomarker collection was not feasible in this pilot study and is particularly challenging for studies of Internet interventions that solicit participants from dispersed locations. However, given that measures used similar self-report measures from a series of previous studies of interventions based on CHOICES, there is no reason to expect they performed differently here than in earlier studies.

Taken as a whole, these data suggest that the CARRII program shows feasibility, acceptability, and promise to reduce AEP risk. We conclude that CARRII merits further testing in a fully-powered study. As the first study of an automated, highly interactive, tailored Internet intervention based on the successful CHOICES paradigm for reducing AEP risk, this project is a significant extension of the growing literature on Internet interventions to reduce problem drinking (Bertholet et al., 2011; Kypri et al., 2009; Murphy et al., 2010). The current project extended the focus to a new population (women recruited mostly online) and on a new goal (AEP prevention) by targeting both risky drinking AND ineffective contraception that confers risk for unintended pregnancy.

This project resulted in a novel Internet version of an AEP risk reduction intervention that was delivered to women who would not otherwise receive it. The sample was relatively diverse, reaching those who sometimes show lower participation rates in eHealth studies (Latulippe et al., 2017), such as those with only high school education, a range of racial group members, and smokers. It is likely that an Internet intervention could prove less costly than trained counselors in resource-limited settings, but may also appeal to women due to perceptions of confidentiality, and convenience of self-treatment when and where they choose. Scalable interventions like CARRII could serve women who are at risk for AEP, but who are not part of a specific patient or service sector group, and thus may be overlooked for prevention. An epidemiological survey indicated that women with specific risk factors such as recent drug use, ever smoked more than 100 cigarettes, had a history of inpatient treatment for drugs, alcohol or mental health, had multiple sex partners, or experienced recent physical abuse had increased risk for AEP (Project CHOICES Research Group, 2002). CARRII could be deployed from a variety of settings that already serve women with one or more of these risks, potentially reaching a broader population of women at risk for AEP.

Based on these data, we conclude that the Contraception and Alcohol Risk Reduction Internet Intervention (CARRII) is acceptable, feasible, and promising. These data show it

may have a similar impact as the most efficacious face to face interventions. This novel Internet intervention should be tested in a fully-powered RCT. If efficacious in a larger trial, CARRII would lower the number of women at risk for AEP and thus could reduce new incident FASDs. As an intervention targeting 2 behaviors, it will contribute to the further development of a model of how behavior change occurs in people using Internet interventions. It has potential to be disseminated broadly following a subsequent trial. Because CARRII is scalable, its dissemination could reduce the public health impact of AEP and could supplement universal and targeted prevention efforts that reach only a small proportion of the 3.3 million women at risk.

Acknowledgments

Sources of Support: Funding for this study was provided by a grant from the National Institute of Alcoholism and Alcohol Abuse of the National Institutes of Health, R34 AA020853. We thank Angela Chang for referencing assistance.

References

- Amendah DD, Grosse SD, Bertrand J. Medical expenditures of children in the United States with fetal alcohol syndrome. *Neurotoxicol Teratol.* 2011; 33:322–324. [PubMed: 21073947]
- Andrade AL, de Lacerda RB, Gomide HP, Ronzani TM, Sartes LM, Martins LF, Bedendo A, Souza-Formigoni ML, WHO e-health project on Alcohol and Health Investigators Group. Web-based self-help intervention reduces alcohol consumption in both heavy-drinking and dependent alcohol users: A pilot study. *Addict Behav.* 2016; 63:63–71. [PubMed: 27424165]
- Balachova T, Bonner BL, Chaffin M, Isurina G, Shapkaitz V, Tsvetkova L, Volkova E, Grandilevskaya I, Skitnevskaya L, Knowlton N. Brief FASD prevention intervention: physicians' skills demonstrated in a clinical trial in Russia. *Addict Sci Clin Pract.* 2013; 8 1-0640-8-1.
- Bertholet N, Walther MR, Burnand B, Daeppen JB. Web-based screening and brief intervention for unhealthy alcohol use: www.alcoquiz.ch. *Rev Med Suisse.* 2011; 7:1466–1470. [PubMed: 21838013]
- Ceperich SD, Ingersoll KS. Motivational interviewing + feedback intervention to reduce alcohol-exposed pregnancy risk among college binge drinkers: determinants and patterns of response. *J Behav Med.* 2011; 34:381–395. [PubMed: 21318412]
- Chow PI, Lord HR, MacDonnell K, Ritterband LM, Ingersoll KS. Convergence of online daily diaries and timeline followback among women at risk for alcohol exposed pregnancy. *Journal of Substance Abuse Treatment.* 2017; 82:7–11. [PubMed: 29021118]
- Coles CD, Li Z. Functional neuroimaging in the examination of effects of prenatal alcohol exposure. *Neuropsychol Rev.* 2011; 21:119–132. [PubMed: 21484401]
- Farrell-Carnahan L, Hettema J, Jackson J, Kamalanathan S, Ritterband LM, Ingersoll KS. Feasibility and promise of a remote-delivered preconception motivational interviewing intervention to reduce risk for alcohol-exposed pregnancy. *Telemed J E Health.* 2013; 19:597–604. [PubMed: 23763608]
- Finer LB, Zolna MR. Declines in Unintended Pregnancy in the United States, 2008-2011. *N Engl J Med.* 2016; 374:843–852. [PubMed: 26962904]
- Floyd RL, Decoufle P, Hungerford DW. Alcohol use prior to pregnancy recognition. *Am J Prev Med.* 1999; 17:101–107. [PubMed: 10490051]
- Floyd RL, Ebrahim SH, Boyle CA, Gould DW. Observations from the CDC. Preventing alcohol-exposed pregnancies among women of childbearing age: the necessity of a preconceptional approach. *J Womens Health Gend Based Med.* 1999; 8:733–736. [PubMed: 10495253]
- Floyd RL, Sobell M, Velasquez MM, Ingersoll K, Nettleman M, Sobell L, Mullen PD, Ceperich S, von Sternberg K, Bolton B, Johnson K, Skarpness B, Nagaraja J, Project CHOICES Efficacy Study Group. Preventing alcohol-exposed pregnancies: a randomized controlled trial. *Am J Prev Med.* 2007; 32:1–10. [PubMed: 17218187]

- Fox, S., Fallows, D. Internet Health Resources (the Pew Research Trust). 2003. Accessed at <https://ssrn.com/abstract=2054071>
- Green PP, McKnight-Eily LR, Tan CH, Mejia R, Denny CH. Vital Signs: Alcohol-Exposed Pregnancies—United States, 2011–2013. *MMWR Morb Mortal Wkly Rep*. 2016; 65:91–97. [PubMed: 26845520]
- Hanson JD, Ingersoll K, Pourier S. Development and Implementation of CHOICES Group to Reduce Drinking, Improve Contraception, and Prevent Alcohol-Exposed Pregnancies in American Indian Women. *J Subst Abuse Treat*. 2015; 59:45–51. [PubMed: 26265591]
- Hanson JD, Nelson ME, Jensen JL, Willman A, Jacobs-Knight J, Ingersoll K. Impact of the CHOICES Intervention in Preventing Alcohol-Exposed Pregnancies in American Indian Women. *Alcohol Clin Exp Res*. 2017; 41:828–835. [PubMed: 28173632]
- Hunter R, Wallace P, Struzzo P, Vedova RD, Scafuri F, Tersar C, Lygidakis C, McGregor R, Scafato E, Freemantle N. Randomised controlled non-inferiority trial of primary care-based facilitated access to an alcohol reduction website: cost-effectiveness analysis. *BMJ Open*. 2017; 7:e014577-2016-014577.
- Hutton HE, Chander G, Green PP, Hutsell CA, Weingarten K, Peterson KL. A novel integration effort to reduce the risk for alcohol-exposed pregnancy among women attending urban STD clinics. *Public Health Rep*. 2014; 129(Suppl 1):56–62. [PubMed: 24385650]
- Ingersoll KS, Ceperich SD, Hettema JE, Farrell-Carnahan L, Penberthy JK. Preconceptional motivational interviewing interventions to reduce alcohol-exposed pregnancy risk. *J Subst Abuse Treat*. 2013; 44:407–416. [PubMed: 23192220]
- Ingersoll, KS., Ritterband, L., Frederick, C., Hilgart, M., Heath, G., Johnson, S. Paper presented to the 7th International Society of Research on Internet Interventions. Valencia Spain: 2014 Oct. Development and Initial Usability Testing of an Internet Intervention to Reduce Alcohol-exposed Pregnancy Risk.
- Jang M, Johnson CM, D'Eramo-Melkus G, Vorderstrasse AA. Participation of Racial and Ethnic Minorities in Technology-Based Interventions to Self-Manage Type 2 Diabetes: A Scoping Review. *J Transcult Nurs*. 2017 1043659617723074.
- Kaner EF, Beyer FR, Garnett C, Crane D, Brown J, Muirhead C, Redmore J, O'Donnell A, Newham JJ, de Vocht F, Hickman M, Brown H, Maniatopoulos G, Michie S. Personalised digital interventions for reducing hazardous and harmful alcohol consumption in community-dwelling populations. *Cochrane Database Syst Rev*. 2017; 9:CD011479. [PubMed: 28944453]
- Kypri K, Hallett J, Howat P, McManus A, Maycock B, Bowe S, Horton NJ. Randomized controlled trial of proactive web-based alcohol screening and brief intervention for university students. *Arch Int Med*. 2009; 169:1508–1514. [PubMed: 19752409]
- Latulippe K, Hamel C, Giroux D. Social Health Inequalities and eHealth: A Literature Review With Qualitative Synthesis of Theoretical and Empirical Studies. *Journal Medical Internet Research [serial online]*. 2017; 19:e136.
- Letourneau B, Sobell LC, Sobell MB, Johnson K, Heinecke N, Robinson SM. Preventing alcohol-exposed pregnancies among Hispanic women. *J Ethn Subst Abuse*. 2017; 16:109–121. [PubMed: 26727077]
- Marks, IM., Cavanagh, K., Gega, L. Hands-on Help: Computer-aided Psychotherapy. Psychology Press; Hove, England and New York: 2007.
- Mattson SN, Roesch SC, Glass L, Deweese BN, Coles CD, Kable JA, May PA, Kalberg WO, Sowell ER, Adnams CM, Jones KL, Riley EP, CIFASD. Further development of a neurobehavioral profile of fetal alcohol spectrum disorders. *Alcohol Clin Exp Res*. 2013; 37:517–528. [PubMed: 22974253]
- Mengel MB, Searight HR, Cook K. Preventing alcohol-exposed pregnancies. *J Am Board Fam Med*. 2006; 19:494–505. [PubMed: 16951299]
- Miller, WR., Rollnick, S. Motivational Interviewing: Helping People Change. 3rd. Guilford Press; New York: 2012.
- Montag AC, Brodine SK, Alcaraz JE, Clapp JD, Allison MA, Calac DJ, Hull AD, Gorman JR, Jones KL, Chambers CD. Preventing alcohol-exposed pregnancy among an American Indian/Alaska

- Native population: effect of a screening, brief intervention, and referral to treatment intervention. *Alcohol Clin Exp Res*. 2015; 39:126–135. [PubMed: 25623412]
- Murphy JG, Dennhardt AA, Skidmore JR, Martens MP, McDevitt-Murphy ME. Computerized versus motivational interviewing alcohol interventions: impact on discrepancy, motivation, and drinking. *Psychol Addict Behav*. 2010; 24:628–639. [PubMed: 21198224]
- U.S. Department of Health and Human Services. NIAAA Council Approves Definition of Binge Drinking. 2009; 2004:2009. Accessed at: http://pubs.niaaa.nih.gov/publications/Newsletter/winter2004/Newsletter_Number3.pdf.
- Nykjaer C, Alwan NA, Greenwood DC, Simpson NA, Hay AW, White KL, Cade JE. Maternal alcohol intake prior to and during pregnancy and risk of adverse birth outcomes: evidence from a British cohort. *J Epidemiol Community Health*. 2014; 68:542–549. [PubMed: 24616351]
- Parrish DE, von Sternberg K, Velasquez MM, Cochran J, Sampson M, Mullen PD. Characteristics and factors associated with the risk of a nicotine exposed pregnancy: expanding the CHOICES preconception counseling model to tobacco. *Matern Child Health J*. 2012; 16:1224–1231. [PubMed: 21735139]
- Peterson PL, Lowe JB. Preventing fetal alcohol exposure: a cognitive behavioral approach. *Int J Addict*. 1992; 27:613–626. [PubMed: 1601539]
- Popova S, Lange S, Burd L, Chudley AE, Clarren SK, Rehm J. Cost of fetal alcohol spectrum disorder diagnosis in Canada. *PLoS One*. 2013; 8:e60434. [PubMed: 23593216]
- Project CHOICES Intervention Research Group. Reducing the risk of alcohol-exposed pregnancies: a study of a motivational intervention in community settings. *Pediatrics*. 2003; 111:1131–1135. [PubMed: 12728125]
- Project CHOICES Research Group. Alcohol-exposed pregnancy: characteristics associated with risk. *Am J Prev Med*. 2002; 23:166–173. [PubMed: 12350448]
- Ray R, Sewell AA, Gilbert KL, Roberts JD. Missed Opportunity? Leveraging Mobile Technology to Reduce Racial Health Disparities. *J Health Polit Policy Law*. 2017; 42:901–924. [PubMed: 28663182]
- Rendall-Mkosi K, Morojele N, London L, Moodley S, Singh C, Girdler-Brown B. A randomized controlled trial of motivational interviewing to prevent risk for an alcohol-exposed pregnancy in the Western Cape, South Africa. *Addiction*. 2013; 108:725–732. [PubMed: 23216868]
- Ritterband LM, Ardan K, Thorndike FP, Magee JC, Saylor DK, Cox DJ, Sutphen JL, Borowitz SM. Real world use of an Internet intervention for pediatric encephalitis. *J Med Internet Res*. 2008; 10:e16. [PubMed: 18653440]
- Ritterband LM, Gonder-Frederick LA, Cox DJ, Clifton AD, West RW, Borowitz SM. Internet interventions: In review, in use, and into the future. *Professional Psychology Research and Practice*. 2003; 34:527–534.
- Rogers MA, Lemmen K, Kramer R, Mann J, Chopra V. Internet-Delivered Health Interventions That Work: Systematic Review of Meta-Analyses and Evaluation of Website Availability. *J Med Internet Res*. 2017; 19:e90. [PubMed: 28341617]
- Satcher D. Eliminating Racial and Ethnic Disparities in Health: The Role of the Ten Leading Health Indicators. *J Natl Med Assoc*. 2000; 92:315–318. [PubMed: 10946526]
- Sheehan DV, Lecrubier Y, Sheehan KH, Amorim P, Janavs J, Weiller E, Hergueta T, Baker R, Dunbar GC. The Mini-International Neuropsychiatric Interview (M.I.N.I.): the development and validation of a structured diagnostic psychiatric interview for DSM-IV and ICD-10. *J Clin Psychiatry*. 1998; 59(Suppl 20):22–33. quiz 34–57.
- Sobell LC, Sobell MB, Johnson K, Heinecke N, Agrawal S, Bolton B. Preventing alcohol-exposed pregnancies: a randomized controlled trial of a self-administered version of Project CHOICES with college students and nonstudents. *Alcohol Clin Exp Res*. 2017; 41:1182–1190. [PubMed: 28387007]
- Streissguth AP, Bookstein FL, Barr HM, Sampson PD, O'Malley K, Young JK. Risk factors for adverse life outcomes in fetal alcohol syndrome and fetal alcohol effects. *J Dev Behav Pediatr*. 2004; 25:228–238. [PubMed: 15308923]
- Streissguth AP, LaDue RA. Fetal alcohol. Teratogenic causes of developmental disabilities. *Monogr Am Assoc Ment Defic*. 1987; (8):1–32.

- Tenkku LE, Mengel MB, Nicholson RA, Hile MG, Morris DS, Salas J. A web-based intervention to reduce alcohol-exposed pregnancies in the community. *Health Educ Behav.* 2011; 38:563–573. [PubMed: 21471438]
- Thorndike FP, Saylor DK, Bailey ET, Gonder-Frederick L, Morin CM, Ritterband LM. Development and Perceived Utility and Impact of an Internet Intervention for Insomnia. *E J Appl Psychol.* 2008; 4:32–42. [PubMed: 20953264]
- U.S. Department of Health and Human Services. Fertility, family planning and women's health: new data from the 1995 National Survey of Family Growth. 1997; 51:63.
- U.S. Department of Health and Human Services. US Surgeon General releases advisory on alcohol use in pregnancy. 2005. Accessed at: <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5409a6.htm>
- U.S. Department of Health and Human Services 2014. Healthy People 2020: Topics and Objectives: Family Planning. 2013. Available at: <http://www.healthypeople.gov/2020/topicsobjectives2020/objectiveslist.aspx?topicId=13>
- Velasquez, MM., Ingersoll, KS., Sobell, MB., Sobell, LC. Women and Drinking: Preventing Alcohol-Exposed Pregnancies. Hogrefe Press; Boston, MA: 2016.
- Velasquez MM, Ingersoll KS, Sobell MB, Floyd RL, Sobell LC, von Sternberg K. A Dual-Focus Motivational Intervention to Reduce the Risk of Alcohol-Exposed Pregnancy. *Cogn Behav Pract.* 2010; 17:203–212. [PubMed: 20473352]
- Weiner L, Morse BA, Garrido P. FAS/FAE: focusing prevention on women at risk. *Int J Addict.* 1989; 24:385–395. [PubMed: 2676873]
- Wilton G, Moberg DP, Van Stelle KR, Dold LL, Obmascher K, Goodrich J. A randomized trial comparing telephone versus in-person brief intervention to reduce the risk of an alcohol-exposed pregnancy. *J Subst Abuse Treat.* 2013; 45:389–394. [PubMed: 23891460]

Figure 1.
CARRII Pilot RCT Consort Chart

Figure 2.
Flowchart of Study Activities

Figure 3.
CARRII Core Content

Table 1

Pretreatment Characteristics of the Sample by Assigned Condition

Characteristic	CARRI n=36	PE n=35	Total n=71	Test of difference
n (%)				
Race				
White	26 (72.22)	19 (54.29)	45 (63.38)	$X^2_{(2df)}=4.08, p=0.130$
Black	7 (19.44)	7 (20)	14 (19.72)	
Other	3 (8.33)	9 (25.71)	12 (16.9)	
Ethnicity				
Hispanic	6 (16.67)	6 (17.14)	12 (16.9)	FET ⁺ p=1.000
Highest Degree				
> High School	24 (66.67)	22 (62.86)	46 (64.79)	FET p= 0.806
<=High school	12 (33.33)	13 (37.14)	25 (35.21)	
Email Use				
daily	33 (91.67)	33 (94.29)	66 (92.96)	FET p=1.000
less than daily	3 (8.33)	2 (5.71)	5 (7.04)	
Internet Comfort				
somewhat/very comfortable	30 (83.33)	33 (94.29)	63 (88.73)	FET p=0.260
some/very uncomfortable	6 (16.67)	2 (5.71)	8 (11.27)	
Internet Use				
daily	36 (100)	33 (94.29)	69 (97.18)	FET p=0.239
less than daily	0 (0)	2 (5.71)	2 (2.82)	
Pap smear Ever				
Yes	30 (83.33)	31 (88.57)	61 (85.92)	FET p= 0.735
Primary Contraception				
Withdrawal	13 (36.11)	14 (40)	27 (38.03)	FET p= 0.081
Condoms	9 (25)	14 (40)	23 (32.39)	
Pill	3 (8.33)	6 (17.14)	9 (12.68)	
none	6 (16.67)	1 (2.86)	7 (9.86)	
Vasectomy	2 (5.56)	0 (0)	2 (2.82)	
Rhythm/Fertility Awareness	2 (5.56)	0 (0)	2 (2.82)	
Depo-provera	1 (2.78)	0 (0)	1 (1.41)	
Problem if Pregnant				
very big problem	21 (58.33)	24 (68.57)	45 (63.38)	$X^2_{(2df)}=0.96, p=0.620$
somewhat problem	7 (19.44)	6 (17.14)	13 (18.31)	
no or small problem	8 (22.22)	5 (14.29)	13 (18.31)	
Smoked 100 cigarettes				
Yes	16 (44.44)	14 (40)	30 (42.25)	FET p=0.811
Frequency Binges				
monthly or less	20 (55.56)	19 (54.29)	39 (54.93)	FET p=1.000
weekly to daily	16 (44.44)	16 (45.71)	32 (45.07)	
DAST Category				

Characteristic	CARRI n=36	PE n=35	Total n=71	Test of difference
none	12 (33.33)	13 (37.14)	25 (35.21)	FET p=0.736
low/mod	21 (58.33)	21 (60)	42 (59.15)	
substantial/severe	3 (8.33)	1 (2.86)	4 (5.63)	
MINI ^a				
alcohol dependence	12 (33.33)	11 (32.35)	23 (32.86)	FET p=1.000
anxiety(any)	12 (33.33)	3 (8.82)	15 (21.43)	FET p=0.019 *
major depression	8 (22.22)	2 (5.88)	10 (14.29)	FET p=0.085
alcohol abuse	4 (11.11)	5 (14.71)	9 (12.86)	FET p=0.731
drug dependence	4 (11.11)	3 (8.82)	7 (10)	FET p=1.000
drug abuse	5 (13.89)	2 (5.88)	7 (10)	FET p=0.430
MINI any	25 (69.44)	20 (58.82)	45 (64.29)	FET p=0.456
Mean (SD)/Median Range				
Age	27.8 (6.2)	27.6 (6.0)	28.0 (6.3)	
Years Education	15.28 (2.33)	15.03 (2.38)	15.15 (2.34)	t ₍₆₈₎ =-.40, p=.69
	10-23	8-20	8-23	
Pregnancy Risk Variables				
Age First Contraception	17.56 (4.47)	16.43 (2.34)	17.00 (3.60)	t=-1.33 p=0.189
	14-40	11-22	11-40	
Number Sexual Partners	1	1	1	z=-0.29 p=0.769
	1-10	1-17	1-17	
Intercourse Days in 90 ^b	26.08 (16.42)	27.29 (16.35)	26.68 (16.28)	t=0.31 p=0.758
	5-70	4-90	4-90	
Unprotected Sex Rate ^b	0.76 (0.29)	0.59 (0.33)	0.68 (0.32)	t=-2.21 p=0.030 *
	0.11-1.00	0.08-1.00	0.08-1.00	
Alcohol Risk Variables				
Age First Drink	15.94 (2.77)	15.77 (2.86)	15.86 (2.79)	t=-0.26 p=0.796
	10-21	11-21	10-21	
Drinks Per Week (questionnaire)	11.78 (13.13)	11.63 (11.48)	11.70 (12.26)	t=-0.05 p= 0.960
	0-70	1-55	0-70	
Drinks Per Week ^b	10.74 (12.30)	11.54 (10.15)	11.14 (11.22)	t=0.30 p=0.767
	2.02-76.77	2.41-54.44	2.02-76.77	
Drinking Days ^b	31.53 (16.93)	37.40 (23.93)	34.42 (20.74)	t=1.20 p=0.236
	9-87	8-90	8-90	
Drinks per Drinking Day ^b	4.14 (2.33)	3.91 (1.60)	4.03 (1.99)	t=-0.47 p=0.642
	1.61-11.34	1.77-8.04	1.61-11.34	
Number Binges ^{b,c}	14.08 (15.07)	17.31 (17.83)	15.68 (16.45)	t=0.83 p=0.412
	2-87	3-90	2-90	
AUDIT Score	10.86 (7.98)	9.91 (5.12)	10.39 (6.70)	t=-0.59 p=0.555
	2-34	4-21	2-34	

Note. Tests of Difference are Chi square (χ^2), Fisher's Exact Test (FET), t-test (t) or Wilcoxon rank-sum test (z).

⁺For values on FET, no test statistic is necessary because this is not an estimation.

^aOn the MINI, data is missing for one person in the control group.

^b90 day Timeline Followback telephone interview including standard drinks per day, sexual intercourse per day, and effective/ineffective/no contraception per day; numbers indicate days in 90.

^cBinge was defined as consumption of 4 or more standard drinks per occasion or day.

*
p value <.05

Author Manuscript

Author Manuscript

Author Manuscript

Author Manuscript

Table 2

Percent of Women with Daily Online Diary-Based Primary Outcomes Risk at Each Time point by Group

Behavior	CARRII			PE			Within-group McNemar test/p*	effect size	Within-group McNemar test/p*	Group × Time p
	n	%	effect size	n	%	effect size				
Unprotected Sex										
Pre-treatment	32	88.89		26	74.29					
Post-treatment	24	70.59	17.65	24	77.42	0.00	$X^2_{(1)}=4.5, p=.034$	$X^2_{(1)}=0, p=1.00$		.152
6 Months	17	51.52	39.39	19	61.29	16.13	$X^2_{(1)}=11.27, p=.001$	$X^2_{(1)}=1.92, p=0.166$		
Risky Drinking										
Pre-treatment	27	75.00		29	82.86					
Post-treatment	17	50.00	23.53	20	64.52	16.13	$X^2_{(1)}=6.4, p=.011$	$X^2_{(1)}=2.78, p=.096$		.802
6 Months	19	57.58	18.18	19	61.29	19.36	$X^2_{(1)}=3.0, p=.083$	$X^2_{(1)}=3.0, p=.083$		
AEP Risk										
Pre-treatment	24	66.67		21	60.00					
Post-treatment	11	32.35	32.36	18	58.06	3.23	$X^2_{(1)}=33.34, p=.001$	$X^2_{(1)}=.08, p=.782$		.096
6 Months	10	30.30	36.37	14	45.16	16.13	$X^2_{(1)}=8.0, p=.005$	$X^2_{(1)}=1.67, p=.197$		

Notes: 100% of women who were enrolled reported unprotected sex, risk drinking, and AEP risk on the screening TLFB interview conducted prior to the pre-treatment questionnaire and 2 weeks of daily diaries. Pre-treatment diaries may have been completed up to 3 weeks after consent and TLFB and captures a smaller window of behavior, resulting in less than 100% risk at pre-treatment.

Total n's in CARRII condition at each time point are: pre-treatment n=36, post-treatment n=34, 6M follow-up=33.

Total n's in PE condition at each time point are: pre-treatment n=35, post-treatment n=31, 6M follow-up n=31. *% effect size=% change from pre-treatment

Group × Time test includes all subjects (intent to treat).

Table 3
Proportion of Women with Drinking and Contraception Risk Behaviors by Group and Time

Group	Variable Time n	Mean (SD)	95% Conf. Interval	Within group test and effect size	Mixed Model Group × Time Test (intent to treat)
Proportion Drink Days					
$\chi^2_{(0)} = 1.61$ $p = .44$					
Pretreatment					
CARRI	n=36	47.28 (24.03)	39.15-55.41		
PE	n=35	52.55 (27.46)	43.12-61.98		
Posttreatment					
CARRI	n=34	29.69 (23.13)	21.62-37.77	$z = 3.45$, $p = .0006$ $d = .68$	
PE	n=31	39.25 (25.58)	29.87-48.63	$z = 2.01$, $p = .04$ $d = .52$	
6 Month Follow-up					
CARRI	n=33	27.54 (21.42)	19.94-35.14	$z = 3.47$, $p = .0006$ $d = .77$	
PE	n=31	31.41 (23.82)	22.68-40.15	$z = 3.42$, $p = .0005$ $d = .82$	
Drinks/Drinking Day					
$\chi^2_{(0)} = .59$ $p = .75$					
Pretreatment					
CARRI	n=36	3.53 (1.86)	2.90-4.16		
PE	n=35	3.56 (1.62)	3.00-4.12		
Posttreatment					
CARRI	n=34	2.81 (2.10)	2.08-3.54	$z = -1.86$, $p = .062$ $d = .41$	
PE	n=31	2.79 (1.49)	2.25-3.34	$z = 2.42$, $p = .016$ $d = .44$	
6 Month Follow-up					
CARRI	n=33	2.78 (2.30)	1.96-3.59	$z = -1.89$, $p = .058$ $d = .43$	
PE	n=31	3.27 (3.07)	2.15-4.40	$z = -1.49$, $p = .136$ $d = .17$	

Group	Variable Time n	Mean (SD)	95% Conf. Interval	Within group test and effect size	Mixed Model Group $\times$ Time Test (intent to treat)
Proportion Binge Days					
$X^2_{(1)}=.54$ $p=.76$					
Pretreatment					
CARRII	n=36	19.86 (20.96)	12.77-26.95		
PE	n=35	22.51 (21.60)	15.09-29.93		
Posttreatment					
CARRII	n=34	11.76 (19.82)	4.85-18.68	$z=-1.64$, $p=.10$ $d=.36$	
PE	n=31	14.80 (17.85)	8.25-21.34	$z=-1.49$, $p=.016^*$ $d=.38$	
6 Month Follow-up					
CARRII	n=33	10.30 (12.94)	5.71-14.89	$z=-2.16$, $p=.03^*$ $d=.45$	
PE	n=31	11.64 (13.99)	6.51-16.77	$z=-2.95$, $p=.003^*$ $d=.51$	
Proportion Unprotected Sex					
$X^2_{(1)}=5.94$ $p=.051$					
Pretreatment					
CARRII	n=36	83.56 (34.07)	72.04-95.09		
PE	n=35	61.85 (42.95)	47.10-76.61		
Posttreatment					
CARRII	n=34	63.24 (46.02)	47.18-79.29	$z=-2.41$, $p=.016^*$ $d=.51$	
PE	n=31	58.54 (43.25)	42.67-74.40	$z=-.60$, $p=.54$ $d=.08$	
6 Month Follow-up					
CARRII	n=33	47.58 (49.44)	30.05-65.11	$z=-3.29$, $p=.001^*$ $d=.90$	
PE	n=31	47.55 (45.24)	30.95-64.15	$z=-1.61$, $p=.11$ $d=.36$	

* Indicates significant difference from pre-treatment

Table 4

Participant Usage of Interventions

Median Logins at each time point				
PE	median	min	Max	n
Pre-Post	3	0	29	35
Post-treatment to 6M FU	1	0	27	31
After 6M FU	0	0	3	31
CARRII				
Pre-Post	10	0	67	36
Post-treatment to 6M FU	5	0	78	34
After 6M FU	1	0	25	33
Intervention Diaries (Pre-Post)				
	median	min	Max	n
PE	4	0	59	35
CARRII	52	0	62	36
Highest Core Completed				
	Core	Freq	%	
CARRII	Intro	1	2.78	
	1	1	2.78	
	2	3	8.33	
	3	1	2.78	
	4	2	5.56	
	5	2	5.56	
	6	26	72.22	
Total		36	100	

Table 5

Improvements in Proportion of Risky Behavior among CARRII participants by number of logins

PRE-POST Improvement				
Unprotected Sex	n	pre	post	improvement
<=10 logins	16	0.81	0.75	0.06
>10 logins	18	0.94	0.67	0.28
Risky Drinking				
<=10 logins	16	0.75	0.38	0.38
>10 logins	18	0.72	0.61	0.11
AEP Risk				
<=10 logins	16	0.63	0.31	0.31
>10 logins	18	0.67	0.33	0.33
PRE-6M FU Improvement				
Unprotected Sex	n	pre	6M FU	improvement
<=10 logins	16	0.88	0.69	0.19
>10 logins	17	0.94	0.35	0.59
Risky Drinking				
<=10 logins	16	0.81	0.63	0.19
>10 logins	17	0.71	0.53	0.18
AEP Risk				
<=10 logins	16	0.69	0.44	0.25
>10 logins	17	0.65	0.18	0.47