Grant Final Report

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Web-Based Intervention for Alcohol Use in Women of Childbearing Potential

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Abstract

Purpose: 1) Evaluate effectiveness of adapted program in reducing risky alcohol consumption in non-pregnant women (1 month post-baseline). 2) Evaluate sustainability of reduction at 2 months post-baseline among women reporting a reduction at 1 month post-baseline.

Scope: More effective programs to accurately measure and reduce alcohol consumption among women before conception in high-risk populations are needed. eHealth may serve this purpose; however, its effectiveness within this population is not known. We worked with women whose children or dependents receive services through the WIC in San Diego County, California.

Methods: A small-scale randomized controlled trial among non-pregnant women of reproductive age who reported currently drinking at a moderate risk level was conducted. 150 participants completed a web-based assessment and were randomly assigned to either receive a personalized feedback intervention or general health information about alcohol consumption and FAS. Follow-up assessments were conducted via telephone at 1- and 2-months post-baseline.

Results: At baseline, all respondents reported consuming ≥ 3 standard drinks on ≥ 1 occasion in the previous month. The main outcome measure, reduction in number of risky drinking occasions, did not differ significantly between treatment conditions, (OR 1.200, 95% CI 0.567-2.539, p = 0.634) (N=131). However, over 70% of the participants reported a reduction in risky drinking occasions regardless of treatment condition (Control 43/63, 68%; Experimental 49/68, 72%). The results demonstrate that web-based assessment of alcohol consumption within this population is feasible and acceptable and that detailed and interactive assessments of consumption may be sufficient without personalized feedback.

Key Words: web-based, brief intervention, fetal alcohol spectrum disorders, alcohol use in women, prevention

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Purpose

The objectives of this study were two-fold. First, the primary objective was to evaluate the effectiveness of the adapted Web-based assessment and intervention program in reducing risky alcohol consumption in non-pregnant women who have children or dependents enrolled in WIC by comparing rates of reduction in alcohol consumption between women who receive the Web-based feedback intervention and women who do not at 1 month post-baseline. The rates of reduction were measured by analyzing mean drinks per occasion and number of risky-drinking occasions. Second, the secondary objective was to evaluate the sustainability of reduction in alcohol consumption (number of risky-drinking occasions) between women who receive the Web-based feedback intervention and women who do not at 2 months post-baseline among women reporting a reduction at 1 month post-baseline.

Scope

Fetal Alcohol Spectrum Disorders (FASD) represent a range of physical, developmental, cognitive and behavioral abnormalities in children exposed to alcohol in the womb, and are estimated to occur as frequently as 1 in 100 births or in approximately 1% of the general U.S. population (May and Gossage, 2001; Sampson et al., 1997). These rates likely underestimate the prevalence of FASD in low-income populations, who may have a higher frequency of risky drinking in pregnancy and additional risk factors, such as peers with drinking problems, low education levels, younger or older maternal age, and reduced access to prenatal education and healthcare (Abel, 1998).

Results from the 2005 National Survey on Drug Use and Health indicate that among pregnant women, an estimated 12.1% report current alcohol use and 3.9% report binge drinking (SAMHSA, 2006). Rates of the most risky patterns of alcohol consumption during pregnancy have not declined in recent years, and remain higher than the 2010 Healthy People objectives (SAMHSA, 2000). It is important to note that the prevalence estimates for pregnant women are based on survey respondents who knew they were pregnant. As many women do not recognize a pregnancy until the sixth week of gestation and more than 50% of pregnancies in the U.S. are unplanned; prevalence rates for women of childbearing potential probably represent more-accurate estimates of actual alcohol consumption in the first four to eight weeks of pregnancy (Floyd et al., 1999). Therefore, of most concern are sexually active women of childbearing potential who do not plan to become pregnant, but who do so and continue to consume alcohol during the early stages of pregnancy (CDC, 2002). There is a need for more effective primary prevention and intervention programs aimed to reduce preconception and, therefore, prenatal alcohol use--especially risky drinking. However, there are barriers to the applicability of existing measures in primary care and community settings due to the extensive personnel time, training, and other cost factors involved. One alternative is to develop more cost-effective,

efficient programs using health information technology (Kwankam, 2004). To fill this void, we conducted a randomized trial to test the efficacy of a brief web-based screening and intervention protocol in reducing risky drinking among low-income women who had the potential to become pregnant.

Methods

Design

A double blinded, two-group randomized controlled design was used. Participants were non-pregnant risky drinking women who were recruited from three separate Women Infant and Children (WIC) Special Supplemental Nutrition Clinics in San Diego County and randomized to receiving a web-based screening with or without a personalized feedback intervention. Randomization occurred at the individual level (i.e., across clinics). Follow-up consisted of telephone-based assessment of current drinking at 1 month and 2 months post-baseline assessment and intervention. The institutional review boards from the University of California, San Diego and San Diego State University approved the study.

Sample

Participants in the trial consisted of 150 non-pregnant women recruited from three WIC clinics in San Diego County who were either WIC clients themselves (breastfeeding, postpartum), or had children or dependents enrolled in the WIC program. Eligibility criteria for recruitment included:1) a minimum age of 18 years, 2) the woman being non-pregnant, 3) the woman being capable of future pregnancy, 4) being proficient in the English language, 5) being able to read, and 6) being comfortable using a computer. The third criterion of capability of a future pregnancy was defined as currently sexually active and not permanently sterilized. In addition, only women who met criteria for current risky alcohol consumption (should they inadvertently become pregnant) were included. For this study we defined "risky" alcohol consumption as ≥ 3 drinks on at least one occasion in the previous month. This cutoff was selected based on the data linking 3 or more drinks per occasion in pregnancy to adverse infant outcomes, and based on the National Institutes of Alcoholism and Alcohol Abuse estimates of quantity of alcohol resulting in binge and risky drinking blood alcohol levels among adult females (NIAAA, 2004; Saitz, 2005; May et al., 2008;). Those women who met criteria and agreed to participate were consented to participation in a "study to learn more about the effectiveness of using a computer to provide health education about the use of alcohol in women of childbearing age".

Intervention

The WIC clinics participating in the study provided a private space for a computer and printer in the clinic for participant use to access the WIC eCHECKUP website during the study period. Following informed consent, each participant accessed the WIC eCHECKUP website

and logged into her own personal account with a one-click option in the program. The participant was then assigned a unique study identification number by the computer program. Using a random number table generated by computer software, the WIC eCHECKUP program then randomized the participant to one of the two study groups. Those in the experimental group received personalized feedback in electronic format during the session, and also in printed format before they could log out of the system. Women in the control group received generic information about risks associated with alcohol use in general and during pregnancy in electronic format and in printed form before they could log out of the system. Each participant was given a study folder consisting of a reminder calendar noting the dates of her follow-up assessments; in which, they could place the summary report printout. Participants in the intervention group received feedback on their alcohol consumption, health risks associated with risky alcohol use, and social norms information. Participants in the Control group received general (non-personalized) information about alcohol consumption, the U.S. Surgeon General recommendations about alcohol use for women of childbearing potential, generic information about Fetal Alcohol Syndrome, and a listing of local alcohol and other health behavior resources.

Measures

Demographic and health behavior characteristics were assessed for all participants. Variables included age, race/ethnicity, education level, marital status, other drug use, contraceptive use and method, illicit drug use, tobacco use, family history of alcohol use disorders, age of first alcohol use, number of living children and number of pregnancies. Contraceptive Method was categorized according to WHO established levels of effectiveness (WHO, 2007). Alcohol consumption at baseline was measured for all participants in several ways. Each participant was asked to report the number of days in the past month on which they consumed ≥ 3 drinks containing alcohol. In addition, a modified version of the Timeline Follow-Back (TLFB) procedure was used to assess specific amounts and types of alcohol consumed by day over the previous two-week period. (Sobell et al., 1979; Sobell and Sobell, 1992). To aid in recall and estimation of standard drink size, participants were presented with a series of pictures depicting several options for alcohol beverage sizes and types. The participant was asked to choose the picture that best represented the type and size of beverage that she consumed. Standard drink size measures as defined by the National Institute on Alcohol Abuse and Alcoholism were used to calculate the number of standard drinks in each vessel (NIAAA, 2010). Conversion calculations for number of standard drinks were programmed into the WIC eCHECKUP tool, which automatically converted the picture chosen into the respective number of standard drinks. The T-ACE (Tolerance, Annoyed, Cut Down, Eye-Opener) screening instrument was used to assess the level of risky-drinking behavior in the past year for all participants, with T-ACE positive defined as a score of 2 points or greater (Sokol et al., 1989). Finally, a series of True/False questions were used to assess all participants' knowledge and perceptions about alcohol-associated risk to herself, risk to an unborn child, and common drinking behaviors among peers of the same age and ethnic group. Each participant also completed a satisfaction questionnaire after she completed the study activities on the computer.

Due to inconsistencies in access to the web-based tool at the standard post-intervention assessment time points, all follow-up measures were collected via telephone interview. Each participant at each follow-up assessment was asked about her current marital status, whether she had become pregnant since the last assessment, current contraceptive method, and about her

alcohol consumption quantity and frequency since the last assessment using the same measures as described for the baseline measures. All follow-up assessments were completed between 28-33 days post previous assessment. The 1 month and 2 month follow-up time points were chosen in order to allow for assessment of change in risky drinking behavior over a comparable time period as assessed in the screening and initial assessment, and to measure persistence of change.

Limitations

The process of being asked about alcohol in a detailed and comprehensive manner both via screening and the web-based assessment increased the woman's awareness of actual levels of consumption and functioned to possibly modify her behavior on that basis alone. Future studies might address the question of assessment itself as an intervention. A study that includes a comparison group for which alcohol consumption data is available without a comprehensive study-driven assessment component and a study that compares multiple levels of intensity of assessment alone would help address this important issue. It is possible that the general information on health risks of alcohol and on recommendations about drinking in pregnancy provided for participants randomized to the Control condition served as an intervention as well, resulting in convergence of the two treatment groups with respect to outcome. It is also possible that in this population, a brief web-based intervention would have been differentially more effective among women who were much heavier drinkers and who were not included in our sample. Nevertheless, the sample that was recruited may represent the larger number of more moderate drinking women in the general population who are potentially at risk of an adverse outcome should they become pregnant and continue drinking in current patterns. Finally, since we relied on subjective reporting of alcohol use, and in particular because the follow-up interviews were by telephone, it is possible that the women reported reduction in risky drinking due to social desirability or fear of consequences related to WIC benefits for their children, and not due to a true change in behavior. To help address this possibility, we assured participants of the confidentiality of the information they provided to the research staff and, as part of the consent process, women were advised that participation would have no impact on their ability to receive benefits through WIC. Future studies might also seek to validate maternal report of consumption through use of one or more biomarkers of exposure.

Results

A total of 1,502 English speaking, non-pregnant women were approached to be screened for the study; 1,488 women (99%) were interested and agreed to be screened. Of the total number of women screened, 159 (11%) met inclusion criteria for study participation; however, nine women (6%) refused to participate after being informed about the study requirements. Thus 150 women met eligibility criteria, were enrolled, and completed baseline study activities, with 75 allocated to the Experimental group and 75 to Control group. Fifteen participants were lost to follow-up at Follow-Up I (Control n = 8, Experimental n = 7).

Selected baseline characteristics of the sample follow for the 150 women enrolled in the study from three WIC Clinics in San Diego County (Clinic 1, n = 52; Clinic 2, n = 44; Clinic 3, n

= 54) between June 2009 and October 2009. A comparison of baseline characteristics between the two treatment groups yielded no significant differences across socio-demographic characteristics or alcohol consumption patterns. Study participants were predominantly Latina (44%) with a mean age of 26.33 years (*SD* 5.30, Range 18-44). Nearly half of the participants reported education beyond the high school level (48%). Most were not current smokers (61%), with 50% having more than one living child at home. Approximately 67% reported using some type of contraceptive at the time of baseline assessment with 57% using either an effective or a very effective method. More than half (65%) scored positive on the T-ACE. All of the participants reported that they were comfortable using the program and found the program easy to use, while nearly all (96%) of the participants reported that the program was both useful and interesting. In addition, none of the participants failed to navigate through the web-based program.

Analysis of treatment effect at Follow-Up I revealed no significant differences between the experimental and the control condition on any of the alcohol measures at 1-month post-intervention. However, a reduction in all measures of quantity and frequency of risky alcohol use (approximately a two-fold decrease) was noted in both the Control and Experimental groups. Regardless of treatment condition, the majority of participants reported a reduction in Number of RDO at Follow-Up I (Total 92/131, 70%; Control 43/63, 68%; Experimental 49/68, 72%). However, treatment condition did not significantly predict reduction in number of RDOs, (*OR* 1.200, 95% *CI* 0.567-2.539, $p = 0.634$). Similarly, after controlling for baseline mean drinks per occasion, there was no significant effect of treatment on mean drinks per occasion at Follow-Up I ($p = 0.403$). Of the 131 participants that completed Follow-Up I, 92 participants reported a reduction in the number of risky drinking occasions in the previous month at Follow-Up I and, of these, 64 completed Follow-Up II and were included in the analysis of sustained reduction between Follow-Up I and Follow-Up II (Control n = 28 and Experimental n = 36). Consistent with the findings regarding reduction of RDO at Follow-Up I, the majority of individuals at Follow-Up II reported a sustained reduction 49 (77%). However, there was no significant difference by treatment group ($X^2 = 0.068$, $DF = 1$, $p = 0.795$).

In summary, we found no significant effect of treatment on any outcome measure. However, women in both treatment conditions reported similar and substantial reductions in the number of risky alcohol consumption occasions in the previous month as well as mean drinks per occasion in the previous two-weeks. In addition, those who reported reduction in RDO's at Follow-Up I were likely to sustain that reduction at Follow-Up II regardless of treatment condition. These findings suggest a possible effect of the web-based assessment alone that was not significantly improved by the personalized feedback.

From a public health and translational research perspective, the use of health information technology to develop self-administered, cost-effective (low-cost and feasible for implementation with limited resources) methods for efficiently conducting alcohol assessments and for delivering targeted interventions has broad-based appeal for integration into a variety of health service settings including maternal and child primary care. This study applied this methodology to a low-income population specifically at risk for an alcohol exposed pregnancy and having children with alcohol related birth defects. The methodology used in this study may provide valuable information to better address the recognized health disparities associated with alcohol use in pregnancy. Participant satisfaction ratings indicate that the web-based assessment is both feasible and acceptable in this population; with consistently positive responses on the seven domains assessed (comfort, ease of use, usefulness, interest, quality, length, and repeated

use). These findings suggest that health information technology may be a valuable tool in the development, evaluation and translation of assessment and prevention efforts for alcohol consumption among women of childbearing potential.

In addition to cost savings, SBI approaches using health information technology have multiple advantages over traditional approaches to assessment and brief intervention. There are substantial limitations in the accurate assessment of alcohol consumption quantity and frequency. Technology can help researchers and health providers mitigate this limitation. Through increased anonymity and more interactive methodology such as the drink size photos used in combination with the Time Line Follow-Back procedure in this study, the quantity and frequency of alcohol consumption may be measured more accurately. Furthermore, as evident from the empirical research, misinformation about alcohol use during pregnancy, both on the part of healthcare consumers and providers, persists (Morse and Hutchins, 2000). Health information technology can be used to deliver a consistent and standard message to healthcare consumers. Improved assessment and intervention approaches using technology may help increase the primary prevention of prenatal alcohol use and therefore have a broad public health impact.

Although the participants in this study were predominantly Latina and Caucasian women of low-income status, if the findings of this study can be replicated and in other populations, the use of this program is likely to be generalizable with culturally specific modifications to other groups. This study provides a starting point for additional studies testing the effectiveness of web-based assessments/interventions to appropriately capture and modify alcohol consumption in women at risk of an alcohol-exposed pregnancy. Primary prevention in risky drinking women prior to conception is the optimum intervention for FASD. The many benefits of eHealth technology may make this possible for the substantial proportion of the population who binge drink and are likely to experience an unplanned pregnancy.

List of Publications and Products

Delrahim-Howlett K, Chambers CD, Clapp JD, Van Sickle D, Moyer R, Larson S. "Pilot Project to Test Feasibility of Web-Based Screening for Alcohol Use Among Pregnant or Potentially Pregnant Women" Poster presented at the 32nd Annual Scientific Meeting of the Research Society on Alcoholism (RSA), San Diego, California, June 2009.

Delrahim-Howlett K, Chambers CD, Clapp JD, Xu R, Van Sickle D, Moyer R, Larson S. "Web-Based Intervention for Alcohol Use in Women of Childbearing Potential: A preliminary Report of Participant Demographics and Satisfaction" Poster presented at the 2009 Pediatric Translational Research Symposium, San Diego, California, November 2009.

Delrahim-Howlett K, Chambers CD, Clapp JD. "Web-Based Intervention for Alcohol Use in Women of Childbearing Potential" Poster presented at the 2010 United States Public Health Service (USPHS) Scientific and Training Symposium, San Diego, California, May 2010 and at the Agency for Healthcare Research and Quality (AHRQ) Health IT Grantee and Contractor Meeting, Washington, DC, June 2010 and at the 50th Teratology Society Annual Meeting, Louisville, Kentucky, June 2010.

Delrahim-Howlett K, Chambers CD, Clapp JD, Xu R, Duke K, Moyer III RJ, Van Sickle D: "Web-Based Assessment and Brief Intervention for Alcohol Use in Women of Childbearing Potential: A Report of the Primary Findings" *Alcoholism: Clinical and Experimental Research*, (Accepted, December 2010).