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SAN DIEGO STATE UNIVERSITY

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

A dissertation submitted in partial satisfaction of the
requirements for the degree Doctor of Philosophy

in

Public Health (Health Behavior)

By

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2010

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The Dissertation of Katia Delrahim Howlett is approved, and it is acceptable in quality and form for publication on microfilm:

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University of California, San Diego

San Diego State University

2010

## DEDICATION

In memory of my father: Bahram Ebi Delrahim

Without whose support, I would not have made it through my many journeys in life. I wish he could be here as this chapter in my life closes and the next commences. He believed that I could accomplish anything even when I did not quite believe in myself. He gave me the courage to take risks in life, to express my creativity, and to follow my determination…wherever that may lead me.

I miss him terribly and dedicate this dissertation to his smiling face and loving heart.

An additional tribute: Mack "What's there *not* to love?" Sakni

Your 'lectures' will remain with me always.

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## ABSTRACT OF THE DISSERTATION

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

By

Katia Delrahim Howlett

Doctor of Philosophy in Public Health (Health Behavior)
University of California, San Diego, 2010
San Diego State University, 2010

Professor Christina D. Chambers, Chair
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There is a need for more effective assessment and primary prevention programs aimed at accurately measuring and reducing alcohol consumption among women before conception in underserved, high-risk populations. Health Information Technology (HIT) may serve this purpose; however, the effectiveness of such tools is not known. We conducted a small-scale randomized controlled trial to test the effectiveness of an adapted web-based alcohol assessment and intervention tool among low-income, non-pregnant women of reproductive age who were receiving WIC services in San Diego County and who reported currently drinking in a binge

pattern. A total of 150 binge-drinking 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 Fetal Alcohol Syndrome. Follow-Up assessments on reported alcohol consumption were conducted via telephone at 1- and 2-months post baseline. Participants ranged in age from 18 to 44 and were predominately Hispanic/Latina (44%). At baseline, all respondents reported consuming $\geq 3$ standard drinks on $\geq 1$ occasion in the previous month. Outcome was available for 131 participants. The main outcome measure was reduction in number of risky drinking occasions, and did not differ significantly between treatment conditions, (*OR* 1.200, 95% *CI* 0.567-2.539, $p = 0.634$). 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%). Furthermore, after controlling for confounding in a multivariate hierarchical logistic regression model, the estimate of treatment effect reached borderline significance (*OR* 2.922, 95% *CI* 0.991-8.613, $p = 0.052$). The results of the present study demonstrate that web-based assessment of alcohol consumption among low-income women of reproductive age, as represented by WIC clients, is feasible and acceptable. The findings also suggest that detailed and interactive assessments of alcohol consumption may be sufficient for the reduction of risky drinking within this population and personalized feedback may provide additional benefits for some individuals.

# INTRODUCTION

Occurring in as many as 1 in 100 children in the U.S., Fetal Alcohol Spectrum Disorders (FASDs) resulting from prenatal alcohol exposure, are among the most common developmental disabilities. Alcohol-related physical and neurodevelopmental abnormalities in the fetus are completely preventable if the mother avoids alcohol during pregnancy. Despite widespread educational efforts regarding the fetal health risks associated with prenatal alcohol use, recent estimates from the U.S. Centers for Disease Control and Prevention indicate that 10% of women, who know that they are pregnant, report alcohol use.

In research settings, selected face-to-face assessment and brief intervention strategies are effective in the reduction of alcohol use in women who have the potential of becoming pregnant; however, these labor-intensive methods are costly for use in primary care. Therefore, from a public health perspective, the use of health information technology to develop self-administered, cost-effective methods for efficiently measuring alcohol consumption and for delivering targeted interventions has broad-based appeal for integration into maternal and child primary care.

Furthermore, if such methods could be applied to low-income populations, the recognized health disparities associated with alcohol use in pregnancy can be better addressed. The setting for this project involved non-pregnant women whose children or dependents were receiving services through the Women, Infants and

Children Special Supplemental Nutritional Program (WIC) in San Diego County, California during the study period.

The present study tested an adapted web-based alcohol assessment and intervention tool in a population of low-income women. The web-based tool was adapted from the "electronic-Check Up To Go" (e-CHUG) currently used in over 400 college campuses throughout the U.S. To accomplish the objectives of this study, the existing web-based tool was tailored to appropriately address alcohol consumption in women of childbearing potential. We tested the effectiveness of the adapted program, with and without the addition of a web-based personalized feedback intervention as compared to general information about alcohol consumption during pregnancy and associated risks, in reducing risky alcohol use, as defined by the consumption of three or more alcoholic drinks in one occasion.

## Primary Aim

To evaluate the effectiveness of the adapted web-based assessment and intervention program in reducing risky alcohol consumption in a subset of risky drinking non-pregnant women who visit a WIC Program Clinic by comparing likelihood of reduction in the number of risky alcohol consumption occasions in the previous month (Reduction in Number of Risky Drinking Occasions of $\geq 3$ Drinks: Yes/No) between women who received the web-based personalized feedback intervention and women who did not, at 1-month Follow-Up.

The following hypothesis was tested (stated in the alternative for ease of interpretation): Women who complete the web-based assessment and receive the personalized feedback intervention will be considerably more likely to reduce the number of risky drinking occasions, as measured by a binary measure of Reduction in Number of Risky Drinking Occasions of $\geq 3$ Drinks at 1-month post baseline, as compared to women who complete the web-based assessment and receive general health information about prenatal alcohol consumption.

## Secondary Aim

To evaluate the effectiveness of the adapted web-based assessment and intervention program in reducing quantity of alcohol consumption in a subset of risky drinking non-pregnant women who visit a WIC Program Clinic by comparing rates of alcohol consumption (Mean Drinks Per Occasion) in the previous two weeks between women who received the web-based personalized feedback intervention and women who did not, at 1-month Follow-Up.

The following hypothesis was tested (stated in the alternative for ease of interpretation): Women who complete the web-based assessment and receive the personalized feedback intervention will have a lower rate of alcohol consumption, as measured by Mean Drinks Per Occasion at 1-month post baseline, as compared to women who complete the web-based assessment and receive general health information about prenatal alcohol consumption.

## Exploratory Aim

To evaluate the sustainability of intervention effects in the subset of participants that reported a reduction at 1-month post baseline as measured by the number of risky alcohol consumption occasions in the previous month (Reduction or Maintained Reduction in Number of Risky Drinking Occasions of ≥ 3 Drinks: Yes/No) between women who received the web-based personalized feedback intervention and women who did not, at 2-month Follow-Up as compared to reduction at 1-month Follow-Up.

The following hypothesis was tested (stated in the alternative for ease of interpretation): Looking only at the subset of the study sample that report a Reduction in Number of Risky Drinking Occasions of ≥ 3 Drinks at 1-month post baseline, women who complete the web-based assessment and receive the personalized feedback intervention will be more likely to sustain their behavior change as compared to women who complete the web-based assessment and receive general health information about prenatal alcohol consumption.

# BACKGROUND AND SIGNIFICANCE

## Epidemiological Rationale

### Alcohol Use During Pregnancy and Associated Risks

Maternal alcohol use during pregnancy is associated with a spectrum of health risks affecting the exposed offspring. The most serious consequence of prenatal alcohol use is fetal alcohol syndrome (FAS) (Jacobson & Jacobson, 2002). Characteristics of FAS consist of abnormal facial features, growth deficiencies, and central nervous system problems, including life-long deficits in cognitive and behavioral performance. FAS represents only the severe end of the spectrum of fetal alcohol effects. 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 at 1 in 100 births or in approximately 1% of the general U.S. population (May & 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 low socioeconomic status, peers with drinking problems, low education levels, younger or older maternal age, and reduced access to prenatal education and healthcare (Abel, 1998).

FASD is completely preventable if pregnant women avoid alcohol consumption. Despite general awareness of the health risks associated with alcohol

use during pregnancy, many women continue to drink through part or all of gestation (May & Gossage, 2001). A 2002 survey among pregnant women noted that approximately 10.1% of women who knew they were pregnant reported some level of alcohol use, 1.9% reported frequent drinking, and 1.9% reported binge drinking (Centers for Disease Control and Prevention (CDC), 2004; Weber, Floyd, Riley, & Snider Jr, 2002). 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 (Substance Abuse and Mental Health Services Administration (SAMHSA), 2006). Rates of the most risky patterns of alcohol consumption (i.e., risky drinking (defined as 3 or more drinks per occasion for women), binge drinking (defined as 4 or more drinks per occasion) and frequent drinking) during pregnancy have not declined in recent years, and remain higher than the 2010 Healthy People objectives (SAMHSA, 2000). In a 2006 report, Tsai et al. found risky, binge, and frequent drinking prevalence rates of 11.9%, 12.4%, and 13.0% among women of childbearing age in the years 2001 to 2003 respectively; the prevalence rate for pregnant women was 1.6%, 1.9%, and 2.1% during those same years (Tsai, Floyd, & Bertrand, 2007). A more recent study looking at data from the National Survey on Drug Use and Health Report suggested that approximately 19% of women in their first trimester of pregnancy report some alcohol use in the previous month (SAMHSA, Office of Applied Studies, 2008). 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, Decouflé, & Hungerford, 1999). Therefore, of most concern are sexually active women of childbearing potential who do not plan to become pregnant, but do so and continue to consume alcohol during the early stages of pregnancy (CDC, 2002).

These data demonstrate that there is a need for more effective primary prevention and intervention programs aimed to reduce preconception and prenatal alcohol use, especially binge and risky drinking. The maximum benefit of these types of programs can be gained when intervention occurs with women at the greatest risk for an alcohol-exposed pregnancy before they are pregnant.

## Association Between Alcohol Use in Women and Socio-Economic Status

Historically, the empirical literature has been inconclusive about the relationship between socio-economic status and alcohol consumption patterns among the general population (Van Oers, Bongers, Van de Goor, & Garretsen, 1999). However, recent studies looking at consumption rates among young Latinas of low socio-economic status demonstrate an increase in alcohol use during pregnancy as well as a steep increase in alcohol use in Latina women who are not pregnant but are of childbearing potential (Chambers, et al., 2005; Cherpitel, et al., 2007; Polednak, 1997). Studies looking specifically at risk factors of alcohol consumption and alcohol

related problems among ethnic minorities have found that among African American women, lower income and unemployment were risk factors; and among Hispanic women, unemployment was a risk factor (Caetano, Clark, & Tam, 1998). These findings suggest that low-income populations and specifically ethnic minorities in low-income populations are at risk for increased alcohol consumption and alcohol related problems, which strongly support the need for more accurate alcohol assessment and effective intervention among low-income women.

## Maternal Risk Factors for Fetal Alcohol Spectrum Disorders

The existing literature identifies a variety of maternal risk factors that are associated with FASDs. Researchers believe that these variables are differentiated as health or social factors that vary by the level of impact to the mother and/or fetus (May & Gossage, 2001). According to May and Gossage, some risk factors are associated with increased risk of heavy prenatal drinking, such as genetic polymorphisms that lead to higher tolerance for alcohol; while other risk factors alter maternal biological mechanisms leading to an increased risk of FASDs when associated with heavy drinking, such as compromised nutritional status (May & Gossage, 2001). The National Institute on Alcohol Abuse and Alcoholism (NIAAA) reports that the most common and consistent risk factors for FASDs are maternal health variables that include advanced maternal age, already having three or more children, comorbid use of alcohol and tobacco, and alcohol-related morbidity (National Institute on Alcohol Abuse and Alcoholism (NIAAA), 2000). Furthermore,

Abel states that social variables that increase the risk for having a child with FASD include low socio-economic status, low education level, familial or peer social settings with high alcohol use/misuse, and populations or cultures that are tolerant of heavy alcohol consumption (Abel, 1998). In addition, women who have already given birth to a child with FAS or women who have a history of heavy prenatal alcohol use but whose offspring do not have the characteristic facial features of FAS, have an elevated risk of having a child with FAS (Abel, 1988). The empirical literature suggests that a combination of factors, including lack of access to high-quality health care, contribute to the above high-risk associations (Naimi, Town, Mokdad, & Brewer, 2006).

## Theoretical Perspectives

We selected the most appropriate and applicable components of the Health Belief Model (HBM) and Social Norms Theory (SNT) to guide the assessment and intervention program used in the present study (Glanz, Lewis, & Rimer, 1997). The specific constructs that we incorporated from each theory were appropriate in the context of the desired health behavior as well as the specific methodology used in the present study. The selected constructs complement each other in a logical combination, a method that has been previously supported in the literature (Cummings, Becker, & Maile, 2004). We begin with a description of the selected HBM constructs, and then proceed to an explanation of the selected SNT constructs, followed by a discussion of personalized feedback, and conclude with specific applications in and examples from the present study.

## Health Belief Model

Specifically, the Health Belief Model (HBM) constructs of perceived susceptibility, perceived severity, cues to action, demographic characteristics, and behavior change helped guide the study activities and helped identify the potential mechanism of action for the desired behavior change in the present study (Becker, 1974; Glanz, Rimer, & Lewis, 2002). According to the HBM, the perceived seriousness of and susceptibility to a health risk influence an individual's perceived threat of risk. An individual's level of perceived threat is influenced by cues to action and demographic characteristics. Cues to action include both internal and external forms of communication such as a feedback intervention. Thus, a personalized feedback intervention that increases the level of perceived threat should theoretically increase the likelihood of behavior change in favor of the desired behavior (Becker, Maiman, Kirscht, Haefner, Drachman, & Taylor, 1979). Other constructs of the HBM include perceived benefits of behavior change, perceived barriers of behavior change and self-efficacy (Glanz, Rimer, & Lewis, 2002). We decided to not assess these components in the present study because the aim of the study was to evaluate the effectiveness of the personalized feedback intervention in the reduction of risky alcohol consumption as compared to general information about prenatal alcohol use. All participants received the same assessment regardless of treatment allocation. Therefore, in order to avoid the possibility for the assessment of perceived benefits of, perceived barriers to, and self-efficacy for behavior change to serve as a cue to action, these components were excluded from the conceptual model guiding the present study.

## Social Norms Theory

Social norms theory consists of two different types of norms--descriptive norms and injunctive norms--that researchers have shown to operate independently of one another (Klein & Boster, 2006). Descriptive norms refer to an individual's perception of the actual behavior his/her peers engage in, such as alcohol consumption. Conversely, injunctive norms refer to an individual's perception of his/her peers' thoughts/beliefs/approval/disapproval of a particular behavior, such as alcohol consumption. Although the behavior of interest for both types of norms may be the same, each type operates differently in its influence on behavior (Klein & Boster, 2006). We included descriptive norms--information about actual behavior rather than beliefs about others' approval or disapproval of behavior--as one of the components of the personalized feedback intervention used in the present study (Lewis & Neighbors, 2006). Specifically, participants in the Experimental group received feedback about alcohol consumption of women in the general population and specific information of how her (the participant's) alcohol consumption behavior compared to other women of her ethnicity in her age group. Research suggests that normative feedback incorporating reference groups that are socially proximal to the target population may be more relevant and have greater influence than feedback with distal reference groups such as the general population (Larimer, et al., 2009).

Researchers consistently find social norms--explicit or implicit rules that a group uses to determine values, beliefs, attitudes and behaviors--to be one of the

strongest predictors of excessive drinking, alcohol misuse, and alcohol related problems among young adults (Clapp & McDonnell, 2000; Haines & Spear, 1996; McAlaney & McMahon, 2007; Perkins, Haines, & Rice, 2005; Perkins, Meilman, Leichliter, Cashin, & Presley, 1999). Work in this area has focused largely on normative feedback--tailored commentary of an individual's undesirable deviation from normative standards--as an effective mechanism in correcting misperceptions about alcohol use and a successful intervention in decreasing harmful drinking behavior (Agostinelli, Brown, & Miller, 1995; Cunningham, Wild, Bondy, & Lin, 2001; McShane & Cunningham, 2003).

In 1986, Perkins and Berkowitz were the first to apply the descriptive norms construct of social norms theory in a college-based study on alcohol use perception among college students (Perkins & Berkowitz, 1986). They found that if misperceptions about the frequency and the quantity of drinking among peers were corrected, there might be a direct reduction in student heavy drinking and related harm (Perkins & Berkowitz, 1986).

## Theoretical Foundations: Personalized Feedback

In 2001, DiClemente and colleagues provided a review of the taxonomy of feedback approaches and potential mechanisms of action (DiClemente, Marinilli, Singh, & Bellino, 2001). They defined *personalized feedback* as individualized feedback based on information provided by the individual through an assessment procedure, which "can provide a normative comparison to a reference group or

ipsative comparison where the information is self-referent" (pg. 219). The present study provided participants in the intervention group with personalized feedback based on the participant's responses within the assessment and relative to other women of reproductive age from the same race/ethnic group. Borrowing from DiClemente et al., the feedback in the present study was primarily self-referent but followed social norms theory to include some normative comparisons to provide a referent for participants to assess their behavior.

## Applications in the Present Study and Examples

Figure 1 provides a conceptual model illustrating the constructs adapted from the Health Belief Model and Social Norms Theory that guided this study. Within this model, the assessment used in the program directly influenced the information provided in the personalized feedback intervention, which served as a cue to action. Please see Methods Chapter for a detailed description of the assessment and intervention materials and Appendices B, C, and D for screen shots of a sample assessment and samples of the Control and Experimental interventions. As described above, the hypothesis was that the various components of the personalized feedback intervention (described in detail in the Methods Chapter) would work together to act upon the perceived susceptibility to and severity of health risks associated with alcohol consumption as well as provide key educational information and resources. Specifically, the baseline demographics and behavioral variables of the individual along with imbedded cues to action (messages to activate action--which include

educational information, correction of social norms perceptions, alcohol and other health resources, and federal recommendations and guidelines) within the intervention would influence and, theoretically, increase the perceived threat of these risks for the individual participant. The increase in perceived threat would then lead to a change in behavior as measured by alcohol consumption. Baseline levels of Perceived Threat were measured for each participant in context to: 1) health risks associated with alcohol consumption among women of childbearing potential and 2) health risks associated with alcohol consumption during pregnancy. Within this conceptual framework and the target population, the primary outcome of interest was Any Reduction in the Number of Risky Drinking Occasions (RDO).

Although there have been some criticisms of the predictive value of the HBM or SNT alone in health behavior change, this study combined specific theoretically and methodologically appropriate constructs of the HBM with techniques borrowed from social norms theory in a screening and brief intervention approach previously demonstrated to be effective to reduce hazardous levels of alcohol consumption (Armitage & Conner, 2000; Beich, Throsen, & Rollnick, 2003; Harrison, Mullen, & Green, 1992). Tailored interventions grounded on these theoretical foundations combined with the evidenced-based techniques of screening and brief intervention (described below) may be effective in specific populations at elevated risks of alcohol misuse, such as low-income women of childbearing potential and pregnant women.

## Methodological Rationale

Special Supplemental Nutritional Program for Women, Infants and Children (WIC)

Created in 1972, WIC is a national program that seeks to improve fetal development and decrease the risk of poor nutrition and health outcomes of low-income women, infants and children. To be eligible for WIC benefits, participants must be infants or children up to the age of 5 years; pregnant, breastfeeding, or postpartum women; at a nutritional risk; and have an income level below 185% of the U.S. poverty level (United States Department of Agriculture (USDA), 2006). According to a 2004 report, Hispanics make up the largest percentage of WIC participants (~39.2%), followed by Caucasians (~34.6%), African Americans (~20%), Asian or Pacific Islanders (~3.5%), and American Indian or Alaskan Natives (~1.6%) with approximately 67% at or below the poverty level (USDA, 2006). Approximately 11% (~900,000 women) of the total number of WIC participants are pregnant women. This represents approximately one-quarter of U.S. annual births. Among pregnant WIC clients, 12.1% reported substance abuse upon enrollment in WIC. In California, 82 WIC agencies serve 16.7% of the total WIC participants in the U.S.; of which, approximately 10.5% are pregnant women (USDA, 2006).

Certification requirements for WIC programs mandate an increase in participant access to information on the dangers of using alcohol, drugs, and other harmful substances during pregnancy and while breastfeeding. WIC agencies are required to screen and make referrals for counseling and treatment. The above

requirements were put into effect through the Anti-Drug Abuse Act of 1988 (P.L. 100-690), and the Child Nutrition and WIC Reauthorization Act of 1989 (P.L. 101-147). Limited local resources have lead to ill-equipped staff and limited time to conduct appropriate assessments for women participating in WIC (Hughes, et al., 2009). In addition, these requirements only extend to women who are WIC clients themselves; currently, there are no requirements to provide screening of and/or education for substance abuse among women whose children are WIC clients. Although WIC agencies collaborate with local programs for treatment and counseling, referrals to groups outside the WIC system result in limited follow-up and treatment post referral. If appropriate financial or human resources and programs were available to conduct adequate on-site assessment and immediate intervention, WIC clients would likely experience increased benefits, and the effective evaluation of such interventions would be more easily accomplished.

Given that women participating in the WIC program (either enrolled as a client or the mother/guardian of a child enrolled as a client) are low-income women of primarily low educational levels and at nutritional risk, these women may be at increased risk of alcohol use during pregnancy. In addition, they are particularly vulnerable to alcohol-related effects due to the health disparities associated with their demographic characteristics. Approximately 15-30% of women within the WIC program in Southern California report alcohol use during pregnancy, including binge drinking in the first trimester (Chambers, et al., 2005; O'Connor & Whaley, 2003).

## Prevention of Alcohol-Exposed Pregnancies

The Institute of Medicine (IOM) recommends the implementation of "selective" and "universal" interventions for the prevention of FAS and FASD (Institute of Medicine (IOM), 1996). Selective interventions target individuals at greater risk for a particular outcome (i.e. women of childbearing age who are at risk of an alcohol-exposed pregnancy) and universal interventions include public health strategies to inform and educate the public of the risks associated with a certain health behavior (i.e. pregnant and non-pregnant women, family members, and healthcare professionals).

However, current efforts to prevent alcohol-exposed pregnancies in populations at the greatest risk are labor intensive and tend to focus on secondary and tertiary prevention. According to a 2002 CDC report, approximately 8% of women between the ages of 18 and 44 who were sexually active, fertile, not using any form of contraceptive and at risk to become pregnant reported high rates of binge and frequent alcohol consumption (CDC, 2002). This level of risky health behavior suggests that additional primary prevention research is needed to evaluate interventions aimed at women of childbearing age who face an increased risk of alcohol consumption during pregnancy. Studies with findings demonstrating effective methodologies that successfully intervene on risky health behaviors prior to conception may have important implications on health practices and policies.

## Screening and Brief Intervention

Brief interventions (also referred to as SBIRT (screening, brief intervention, referral to treatment) or SBI (screening and brief intervention) programs) incorporating feedback mechanisms have been demonstrated to be the most effective treatment for alcohol abuse and misuse in the general population (Miller, et al., 1995). A brief intervention can range from 5-10 minutes of information and advice, to 2-3 sessions for high-risk drinkers. The primary aim is to convince the individual that their drinking levels may be harmful to their health and to encourage reduced consumption prior to the need of specialized substance use treatment. A review by Bien et al. found that brief alcohol interventions are significantly better than no treatment, often comparable to outcomes from more-extensive interventions, and a lower-cost method that can be applied to large populations across cultures (Bien, Miller, & Tonigan, 1993). Similarly, a recent meta-analysis found comparable effects of brief interventions compared to extended treatments (Moyer, Finney, Swearingen, & Vergun, 2002).

Recent reviews of brief interventions suggest success in reducing alcohol abuse and demonstrate that feedback interventions are effective via individual interview, the mail, or computer (Larimer, Cronce, Lee, & Kilmer, 2005; Walters & Neighbors, 2005). In 2005, Walters and Neighbors conducted a review of 13 studies on interventions using normative feedback as a major component of a prevention program aimed to reduce alcohol abuse in college students (Walters & Neighbors,

2005). Eleven of the 13 studies found a reduction in drinking as compared to a control or comparison group. Furthermore, another review conducted by Larimer et al. concluded that the empirical literature suggests that the most effective approach to prevention incorporates personalized feedback interventions about norms, expectations, and risks associated with consumption (Larimer, Cronce, Lee, & Kilmer, 2005). Findings from these studies suggest that brief interventions incorporating normative and ipsative feedback are effective in changing high-risk behavior in vulnerable populations. The brief intervention model (SBI/SBIRT) can be implemented in a variety of settings and the use of innovative technology in the delivery of such interventions substantially increases the overall population reach.

Project TrEAT (Trial for Early Alcohol Treatment), a study evaluating the efficacy of two physician-delivered brief interventions in primary care settings administered one month apart, found that adults receiving the intervention reported reduction in the number of episodes of binge drinking and frequency of excessive drinking relative to controls (Fleming, Barry, Manwell, Johnson, & London, 1997). Looking specifically at women of childbearing potential participating in this study, the investigators noted that women in the intervention group had significant sustained reduction in alcohol use in the previous week ($p = 0.0039$) and number of episodes of binge drinking ($p = 0.0021$), and that this reduction was sustained over four years of follow-up (Manwell, Fleming, Mundt, Stauffacher, & Barry, 2000). Project CHOICES was a randomized trial testing a time and labor-intensive face-to-face motivational interviewing intervention to reduce alcohol consumption and/or increase

appropriate contraceptive methods in a sample of women at increased risk of a future alcohol-exposed pregnancy. Women in the intervention group (n = 416) were approximately twice as likely to be at a reduced risk for an alcohol-exposed pregnancy at all follow-up periods as compared to the control group (n = 414) (Floyd, et al., 2007).

Chang et al. reported success with a brief intervention to reduce prenatal alcohol consumption (Chang, et al., 2005). Women reporting alcohol use during pregnancy were randomized to a brief intervention (n = 152) or to a control group (n = 152). A study nurse or the principal investigator administered a single brief intervention (25 minutes) evaluating the participant's knowledge and providing feedback, goal setting, and suggestions for behavioral modification. Participants with high baseline consumption in the brief intervention group had a significant decrease in post-intervention alcohol consumption ($p < 0.01$).

In a similar study, O'Conner and Whaley evaluated face-to-face brief intervention for alcohol in a sample of pregnant women participating in the WIC program in the Los Angeles area (O'Connor & Whaley, 2007). Participants were randomized to assessment only (n = 183) or to a brief intervention (n = 162). Women in the assessment only group were advised to avoid alcohol, while women in the brief intervention group received a workbook and personal intervention delivered by a nutritionist. The intervention consisted of education and feedback regarding alcohol use and cognitive behavioral techniques leading to goal setting and contracting,

combined with extensive training for the nutritionist. Women in the intervention group were five times more likely to report abstinence after the intervention compared with women in the control condition. Furthermore, infants born to mothers in the intervention group had higher birth weights and lengths than those born to mothers in the assessment only group.

In a variation on brief interventions, clinical social workers at Kaiser Permanente in Northern California delivered a labor-intensive prenatal substance abuse screening and treatment program, Early Start. This program involved risk assessment, education, and brief intervention integrated with routine prenatal care visits (Armstrong, et al., 2001). The intervention utilized cognitive behavioral techniques, norms clarification and direct feedback, motivational interviewing, and goal setting (Bertrand, Floyd, & Weber, 2005; Bien, Miller, & Tonigan, 1993; Fleming & Manwell, 1999). Despite the added resources needed for program implementation, Early Start was expanded to include a computer-guided delivery system and has been found to be superior to usual care (Armstrong, Gonzales-Osejo, Lieberman, Carpenter, Pantoja, & Escobar, 2003; Armstrong, et al., 2009; Witbrodt, et al., 2007).

Findings from the above studies demonstrate the effectiveness of brief intervention programs in the prevention of alcohol use in women of childbearing potential as well as pregnant women; however, there are barriers to the applicability of these measures in primary care based on the limitations posed by the extensive

personnel time, training, and other cost factors involved. Further research is needed to develop cost-effective, more efficient programs (i.e. interventions that can be delivered in brief periods of time) that incorporate the successful elements of brief interventions for this population. The findings of this study may provide pilot data to support the development and implementation of web-based brief interventions tailored specifically for low-income populations.

## Alcohol Use Measurement and Methodological Concerns

Despite epidemiological work suggesting an increase in alcohol consumption among women of childbearing potential and pregnant women, estimates of the true prevalence are difficult to obtain due to methodological limitations in assessment strategies (Rehm, 1998). A variety of methodological concerns may influence the measurement of alcohol consumption in research. According to a report by Dawson, common methodologies that may influence the accurate assessment of prevalence include: 1) the use of self-report measures of the quantity/frequency and/or graduated frequency of consumption, 2) the mode of delivery (i.e. in person, telephone, computerized, etc.), 3) the reference period—long vs. short, and 4) additional design components that affect data collection (Dawson, 2003).

Although some reviews generally suggest that most existing measures are equivalent in validity and reliability, there are conflicting viewpoints in the literature on methodologies that contribute to a more accurate assessment (Sobell & Sobell, 1995). For example, some researchers suggest that self-report is reliable, while others

question the accuracy of data collected using this methodology. Due to the ease and popularity of self-report methodology in substance use assessment, unless a "gold standard" comparison is available and feasible for use, limitations in measurement must be mitigated through alternative means. Some possible methods to decrease biases resulting from methodological limitations include increasing confidentiality within a study by using alternative modes of delivery as compared to face-to-face assessment (i.e. private computer, automated phone-in assessment, etc.), providing examples of drink size, and providing cues that help memory of consumption (Kaskutas & Graves, 2000; Sobell & Sobell, 2003). Theoretically, such methodology will increase the probability of accurate reporting by participants, decrease recall bias by reducing reference periods and therefore increase the reliability of information obtained, and reduce under-reporting or over-reporting of quantity by providing visual references for standard drink sizes while reducing inaccurate conversion of actual drink size to standard drink size. The present study incorporated many of these methodologies to increase the accuracy of the data collected.

## Health Information Technology and eHealth

An emerging approach for reducing the burden--both cost to society and quality of life--of chronic disease involves engaging patients and consumers in health promotion activities that require sustained behavior change (i.e., healthy eating, increased physical activity, smoking cessation, etc). Research has demonstrated that prevention can play a significant role in reducing morbidity and mortality as a result of

chronic illness (Atkins & Clancy, 2004; Fine, Philogene, Gramling, Coups, & Sinha, 2004; Glade, 1999; Mcginnis & Foege, 1993). However, prevention efforts in clinical settings are often time consuming and require the extensive use of limited resources (Fiore, et al., 2000; Glasgow, Bull, Piette, & Steiner, 2004; Stange, Woolf, & Gjeltema, 2002; Whitlock, Orleans, & Allan, 2002). Health disparities present further challenges in the consistent and effective delivery of prevention interventions to traditionally underserved populations, where the probability of multiple behavioral risk factors increases and the access to care decreases (Curry, 2004; IOM, 2002).

In order to address the limited capacity of the current health care system to provide behavior change prevention interventions, the use of Health Information Technology and/or eHealth programs has been rapidly increasing (Berry, Seiders, & Wilder, 2003; Kwankam, 2004). The definition of eHealth used throughout this dissertation is the use of emerging information and communication technologies (e.g., Internet, computer kiosks, and mobile computing and communication devices) to facilitate health improvement and improve access to health care services (Eng, 2001). The different applications of eHealth include, but are not limited to, health information inquiry, health management, Internet-based support groups, online health consultations, and delivery of behavioral health interventions for health promotion and disease prevention (Christensen, Griffiths, & Jorm, 2004; Eysenbach, 2003; Fox & Rainie, 2000; Slack, 2004). eHealth technology may be able to make a significant contribution to reducing health disparities by increasing access to evidenced-based interventions that address a multitude of public health concerns.

eHealth approaches in alcohol misuse prevention adapt behavioral health interventions for a technologically focused mode of delivery. However, the most prominent benefit of eHealth is the ability to efficiently provide immediate feedback to the individual and tailor the communication to meet the needs of the individual. Many eHealth programs deliver a brief intervention derived from different behavioral strategies that focus on changing behavior and increasing intervention compliance and sustainability.

In a study conducted by Hester et al., 61 problem drinkers were randomly assigned to either immediate treatment with a computer-based brief motivational intervention or a 4-week wait-list control group (Hester, Squires, & Delaney, 2005). The authors found that compared to the wait-list control group participants who immediately received the active intervention had a significantly greater reduction in drinking at 4 weeks post intervention as measured by the Brief Drinker's Profile ($p$ = 0.005). In addition, both study groups continued to report a reduction in drinking at 12 months post baseline with an approximate 50% decline in drinking as measured by the Form 90. However, declines in drinking did not differ between groups at the 12-month follow-up. Kypri et al. evaluated the efficacy of a web-based screening and brief intervention (eSBI) to reduce university student hazardous drinking in a double-blind controlled trial (Kypri, et al., 2004). A total of 104 students were randomized to a print-only control group (n = 53) or a web-based assessment and personalized feedback group (n = 51). At 6 weeks, participants in the feedback group reported significantly lower total alcohol consumption as compared to the control group ($p$ =

0.030). These findings suggest the efficacy of web/computer-based treatment interventions to reduce drinking in vulnerable populations.

The literature suggests that brief web-based approaches, by ensuring privacy, increase the probability that individuals who drink will respond with increased honesty (Kypri, Saunders, & Gallagaher, 2003; Walters, Miller, & Chiauzzi, 2005). The Electronic-Check Up To Go (e-CHUG), developed by Drs. Doug Van Sickle and Richard Moyer (collaborators on this study) from San Diego State University, is a web-based version of the Check Up to Go (CHUG), which draws on Motivational Interviewing and Social Norms Feedback theories to motivate individuals to reduce their alcohol consumption (S. Walters, 2000). The e-CHUG program is a brief assessment and intervention tool that electronically collects standard information about drinking patterns and risk factors and provides the individual with a tailored feedback intervention (Haines & Spear, 1996; Miller & Rollnick, 2002). Participants in the e-CHUG program are given personalized feedback that includes risks associated with their drinking patterns, how they compare to others, personal risk factors, consequences, and family risk factors.

In a controlled trial, Walters et al. tested the efficacy of the "electronic Check-Up to Go" (e-CHUG) to reduce drinking among a group of at-risk college students in their first year (Walters, Vader, & Harris, 2007). Participants were randomized into an assessment only control group or a feedback intervention group after completing baseline assessment. The participants used a personalized

identification number to access the e-CHUG site and received e-mail prompts to complete assessments at various time points. As compared to the control group, participants in the feedback group had a significantly greater reduction in the number of drinks per week as assessed by validated self-report measures (43% reduction, $p = 0.008$). An earlier study by Walters et al. tested the efficacy of the e-CHUG program within a cohort of students enrolled in freshman orientation classes (Walters, Matson, & Harris, 2005). Students who reported drinking were either randomized to a control condition or to the e-CHUG program with immediate feedback. Analyses from an 8-week follow-up demonstrated that those who received the feedback showed significantly greater reductions in peak blood alcohol concentrations achieved while drinking. Results from additional controlled trials evaluating the efficacy of the e-CHUG program suggest that it is as effective as face-to-face extensive interventions aimed at reducing alcohol consumption in college student populations (Henry, Lange, & Wilson, 2004; Lane & Schmidt, 2007; Steiner, Woodall, & Yeagley, 2005; Wilson, Henry, & Lange, 2005). Currently, e-CHUG is being used as a standard assessment and intervention tool at over 400 college campuses throughout the United States.

Recent experience among WIC clients by our group and similar studies by other researchers suggest the feasibility of implementing a web-based intervention based on e-CHUG and that a computer-based delivery system would not be a barrier to success in a low-income population of women who may have lower computer literacy as compared to the general population. In an effort to evaluate an internet-based nutrition education program, Bensley et al. conducted an on-line survey and

intervention study with 39,541 WIC participants in seven states (wichealth.org) (Bensley, Brusk, Anderson, Mercer, Rivas, & Broadbent, 2006). One of the most compelling findings was that almost all participants said that the online program *was easy to use* (97%), and furthermore, that they wanted to use the Web to learn about other topics related to nutrition (84%). Nearly all of the study participants stated that they had some form of computer access with 56% reporting home access. In another study involving 41 WIC clients participating in focus groups, Birkett et al. found that websites were among the preferred methods of health education for WIC clients (Birkett, Johnson, Thompson, & Oberg, 2004). Furthermore, Carroll and colleagues reported that an interactive, multimedia software application is an effective method of delivering nutrition education for women participating in the WIC program (Carroll, Stein, Byron, & Dutram, 1996). A recent randomized controlled trial of WIC clients evaluated the effectiveness of an interactive multimedia food-safety education program as compared to pamphlet education. The researchers found that the multimedia program was well-accepted among participants (94% agreeing that they *enjoyed using the computer kiosk* and 95% agreeing with the statement that they *learned a lot from the program*) and resulted in larger improvements in self-reported food-safety practices as compared to the pamphlet education ($p = 0.005$) (Trepka, Newman, Davila, Matthew, Dixon, & Huffman, 2008). A study by Jantz et al. found that low-income Hispanic participants who received nutritional education through interactive media had significantly increased knowledge and positive attitudes

between pre and post-test than those in a comparison group (Jantz, Anderson, & Gould, 2002).

We worked with the developers of e-CHUG to build upon the established and successful basic structure of the tool to create an adapted version, termed 'WIC eCheckUp to Go' (eCheckUp), suitable for use among low-income, low education level women who are English speaking. Adaptation of this type of program for implementation in a low-income population will extend the current science in this field, enhance the conceptual framework described above, and potentially provide a cost-effective approach to prevent prenatal alcohol use.

## Pilot Study

Data from a small pilot study comparing the assessment tool from the adapted WIC eCheckUp to Go program to a paper-and-pencil version was recently collected and analyzed. The study looked at self-reported alcohol consumption quantities and frequencies in a sample of 30 women receiving WIC services. All women successfully completed both the web-based assessment and the paper-based assessment in random order. A comparison between the web-based vs. paper/pencil versions of the assessment demonstrated that there were no significant differences between the two modalities among the participants (Wilcoxin Rank Sum test, $p > 0.05$ on all comparisons). As demonstrated in Table 1, on all measures of quantity and frequency, at least 27 out of the 30 participants (90%), had identical responses on the paper assessment version and the computer assessment version.

# METHODS

## Pre-Implementation Program Evaluation

Prior to implementing the present study at the first WIC Clinic, a small evaluation of the program was conducted at an alternative WIC Clinic not selected for use in the study. Ten WIC clients were asked to participate by completing the assessment and receiving the personalized feedback. Upon completion, each participant was asked to complete a brief survey about the program and provide verbal feedback to the author. Each participant was given a $5 gift card to Target for her time and effort. Information gathered during this testing period was used to make necessary modifications prior to commencing the full study. Furthermore, in order to thoroughly test the program prior to implementation, the author and other study staff completed the final version of the assessment on multiple occasions.

## Study Design

A double blind, two-group randomized control group design, illustrated below, was used (R→Random Assignment, O→Observation/Measurement, X→Treatment). For *Measurement*, Both groups completed the same assessments at each time-point (1 and 2 or 1); however, follow-up assessments only measured selected items from the baseline assessment (1). For *Treatment*, the Experimental group received personalized feedback (1) and the Control group received general

information about FAS (2). Participants were recruited from three separate clinics. Randomization occurred at the individual level (i.e., across clinics).

| | | | | |
|---|---|---|---|---|
| R | $O_{1,2}$ | $X_1$ | $O_1$ | $O_1$ |
| R | $O_{1,2}$ | $X_2$ | $O_1$ | $O_1$ |

Figure 2 illustrates study implementation, projected recruitment and sample sizes needed to achieve power, and randomization activities. Sample sizes and power estimates were based on pilot work and previous studies in this population as described below. The institutional review boards from the University of California, San Diego and San Diego State University approved the study.

## Study Sample

### Population and Setting

Participants were 150 non-pregnant women who were WIC clients themselves (breastfeeding, postpartum, etc), or whom had children or dependents enrolled in the WIC program. Participants in the present study received WIC services from the San Diego State University WIC program (SDSU WIC). The SDSU WIC is one of the regional WIC Programs providing services for approximately 38,000 WIC clients in San Diego County. Non-pregnant women were chosen as the target population in order to effectively evaluate the program as a primary prevention approach. The race and ethnicity of study participants (44% Hispanic, 34%

Caucasian, 8% African American, 8% Multi-Racial, and 6% Other) was somewhat representative of WIC clients within the SDSU WIC Program (78% Hispanic, 10% Caucasian, 4% African American, 3% Multi-Racial, and 5% Other). Specifically, the ethnic distribution of study participants was representative of participants from the El Cajon Clinic population (54% Hispanic, 29% Caucasian, 6% African American, 5% Multi-Racial, and 6% Other), the Mira Mesa Clinic population (32% Hispanic, 20% Caucasian, 6% African American, 7% Multi-Racial, and 35% Other), and the Vista Clinic population (85% Hispanic, 8% Caucasian, 2% African American, 2% Multi-Racial, and 3% Other) (Larson, 2009). However, because participants in the present study were selected for particular inclusion/exclusion criteria, the study sample was not representative of the entire SDSU WIC population on all demographic and behavioral characteristics. Specifically, participants in the present study were non-pregnant women of childbearing potential, English speakers and English literate, reported alcohol consumption at study defined risky levels, and reported comfort using a computer. Participants ranged from 18-45 years of age.

## Inclusionary and Exclusionary Criteria

According to the Centers for Disease Control (CDC), a safe threshold of alcohol use during pregnancy has not been established (CDC, 2005). The literature suggests that an average of more than one drink (0.5 oz of absolute alcohol) per day or more than four to five drinks per occasion may potentially harm the fetus (Hankin & Sokol, 1995). Therefore, we used $\geq 3$ drinks in at least one occasion in the

previous month as the definition of risky alcohol consumption (Saitz, 2005). Potential participants were screened for risky alcohol consumption in the previous month (defined as having at least one (≥ 1) occasion in the past month when they consumed three or more (≥ 3) drinks) (Saitz, 2005). Individuals who met criteria for alcohol abuse or dependence (defined as the consumption of more than twenty (> 20) drinks in a typical drinking week in the past month) were screened out of potential participation. The following exclusion criteria were used when recruiting participants. A participant was **excluded** if she:

1) was under the age of 18 due to the requirement of parental consent for minors participating in research.
2) was not proficient in the English language.
3) was unable to read.
4) did not meet the criteria for providing Informed Consent (e.g., mentally handicapped).
5) was currently in treatment for alcohol or drug abuse, or substance abuse–related medical illness.
6) had a current physical dependence on alcohol requiring medically supervised detoxification.
7) was unable to use a computer.
8) did not meet pre-screening criteria of current alcohol use with at least one episode of consuming 3 or more drinks in at least one occasion in the previous month.

9) was post-menopausal or has undergone tubal ligation.

10) was not sexually active.

11) had completed all pregnancies.

12) was infertile.

## Sample Size and Power Calculations

We conducted an intervention trial with randomization to exposure with an equal number of participants in each of the treatment conditions (Experimental and Control). One goal of this study was to test the null hypothesis that the reduction in risky alcohol consumption occasions is identical in the Experimental and Control groups. Or, equivalently, the odds ratio is 1.0, the log odds ratio (beta) is 0.0, and the relative risk is 1.0 for treatment condition as a predictor of reduction in alcohol consumption. Similar studies evaluating the effectiveness of brief interventions in reducing problem drinking demonstrate a mean of 10% to 40% difference between control and exposure groups (Chiauzzi, Green, Lord, Thum, & Goldstein, 2005; Moore, Soderquist, & Werch, 2005). Based on this, it was estimated that 5% of the Control group and 25% of the Experimental group would have a reduction in risky drinking. Assuming an effect size of 0.20, with greater effect in the Experimental group as compared to the Control group, analysis to estimate the required sample size and power calculations was conducted with the statistical software package Power and Precision, Version 3 (BioStat Inc., Englewood, New Jersey) (Borenstein, Rothstein, & Cohen, 2001).

Power was computed to reject the null hypothesis testing for a small effect size (difference between groups) of 0.20. The criterion for significance (alpha) was set at 0.05 with a two-tailed test. A minimum of 49 Experimental participants and 49 Control participants were required to produce an estimated power of 0.80 (calculations based on Initial F/U Assessment—Follow-Up Assessment I). However, to account for attrition based on our previous studies with this population (about 3-5%) the sample size was increased to a very conservative total N of 150 (75 per group), assigned as follows: 50% in the Control group, 50% in the Experimental group. For this distribution in participants, effect size (event rates of 0.05, 0.25) sample size (150), and alpha (0.05, 2-tailed), power is 0.88.

Based on conservative estimates from previous experience, it was projected that 50% of eligible participants would enroll, and therefore the sample size necessary to screen in order to yield 150 women who would be available to be randomized was determined (Please see Figure 2). Including eligibility in the equation, we estimated that 10% of screened participants would be eligible and agree to enroll. Approximately 1500 women needed to be screened to identify 20% (300) of women who met criteria for enrollment, of which 50% would agree to participate. The primary goal was to demonstrate any reduction in the number of risky drinking occasions in individuals that are drinking at risky levels at baseline assessment (at least one occasion of $\geq 3$ drinks in the previous month).

With 5% attrition between baseline and the Follow-Up Assessment I, we projected that 71 participants in each group would be available for analysis. Of these, it was projected that 5% would have reduced alcohol on the basis of web-based assessment alone (Control) and that 25% of the intervention group (Experimental) would have reduced alcohol consumption by the 1-month post-intervention assessment (15% in total). Based on estimates of alcohol reduction alone from the Fleming and Manwell brief intervention study, and previous results among Latinas, which targeted alcohol use and contraceptive practices, the above effect sizes are clinically feasible (Fleming & Manwell, 1999).

In addition, although the preliminary pilot study suggested that this population of low income women could successfully self-navigate through a carefully designed computer-delivered assessment and educational program, if supervision was a requirement to complete the program, individuals needing such assistance were noted and evaluated as a subsample for analysis. Based on a previous study looking at alcohol consumption among low-income Latinas participating in WIC, once recruited, a low lost-to-follow-up rate (< 4%) was expected. However, slightly higher attrition estimates (as identified above) were used to be conservative. To address any potential bias, the baseline data of those who were lost-to-follow-up were compared to study completers.

## Recruitment and Retention

Participants were recruited through referral from The El Cajon WIC Office located at 321 Van Houten, El Cajon, CA 92020; the Mira Mesa WIC Office located at 10737 Camino Ruiz, San Diego, CA 92126; and The Vista WIC Office located at 1031 South Santa Fe Avenue, Vista, CA 92083. A letter of support indicating willingness to collaborate from the SDSU Foundation WIC Director was obtained prior to study initiation. The WIC clinics participating in the study provided a space for the author to set up a computer and printer in the clinic for participant use to access the eCheckUp website during the study period. The computers were modified to allow access only to the study website to reduce the possibility of unauthorized personal use. Non-pregnant women entering the WIC clinic were approached by study staff for initial pre-screening. A brief explanation of the study was provided to each potential participant and screening was completed if appropriate (i.e. participant did not refuse). Study staff were trained to screen potential participants based on the inclusionary and exclusionary criteria, to administer informed consent, and to dispense baseline incentives. The author or a trained research assistant was on-site at the clinic during the highest traffic periods in order to achieve the required sample size and to assist with orienting participants to the study computer. The author was responsible for contacting participants to be re-assessed at the appropriate post-test time points, conducting all follow-up assessments, and dispensing the follow-up study incentives.

## Compensation for Participation

Once a study participant provided the initial intake interview information and met the inclusionary criteria for participation, agreed to participate, signed the informed consent document, and completed the baseline eCheckUp assessment, the participant received a $5 gift card to Target, a discount retail store chain with locations across the United States. Subsequent study incentives of additional $5 gift cards were provided for each activity requiring time and effort (Follow-Up Assessment I and II). Total incentives for each participant did not exceed $15.

## Pre-Screening and Randomization Activities

Each woman who agreed to initial screening completed a brief pre-screen questionnaire asking about general health behaviors and risky alcohol consumption. Study staff confirmed eligibility and established the minimum literacy level of each woman completing the pre-screening based on responses to the questionnaire. Once a woman 1) met study criteria, 2) agreed to participate in the study, 3) signed an informed consent document, and 4) began the web-based assessment; she accessed the eCheckUp website at a dedicated computer at the WIC clinic site and logged into her own personal account with a one-click option in the program. She was then assigned a unique study identification number by the computer program. The study identification number was based on the participant's personal responses to general questions including the first two letters of her first name, her day and month of birth and the last four digits of her telephone number; this procedure helped maintain confidentiality

throughout the study and allowed for the linking of follow-up and baseline data. Study staff emphasized the importance of not sharing study ID numbers with other participants, and baseline data were compared against follow-up data to check for inconsistencies in general demographic data responses. Using a random number table generated by computer software, the eCheckUp program then randomized the participant to one of two study groups as illustrated in Figure 2. WIC and study staff were blinded to all randomization activities and group allocation to prevent research outcomes from being influenced by observer bias. As described in the Results Chapter and illustrated in Tables 6 and 7, randomization was successful and the baseline characteristics of participants in the Experimental group were similar to those of the Control group ($p > 0.05$). Furthermore, although the ability to use a computer was a criterion prior to randomization, study staff observed system navigation and did not note any women who failed to navigate through the system independently after orientation. Participants, irrespective of study condition, continued to receive standard WIC care for their children or dependents.

In order to log out of the eCheckUp system, each participant was required to print out a three to four page summary report (Control participants received generic information about risks associated with alcohol use, information about FAS, and local alcohol and other health behavior resources and services and Experimental participants received a detailed personalized feedback summary of their alcohol consumption and individual risk). 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. The specific steps for each group at each level of randomization are illustrated in Figure 2.

## Study Assessment Measures

Building on established and validated screening methods, the author worked with the developers of the original web-based program to adapt and modify the assessment tool for appropriateness among women who are at a sixth grade level of education. In addition, qualitative data from the completed pilot study was used to make necessary modifications to the assessment questions and measures to ensure appropriateness for the target population. Previously validated and reliable methods and measures were used to assess the quantity and frequency of alcohol use, evidence of risky drinking behavior, knowledge about alcohol related risk to self and an unborn child should pregnancy occur, and perceptions of social norms in relation to alcohol use. Please see Appendix B for a sample assessment from the program used in the present study.

### E-Chug Adaptation and Rationale

As discussed in the Background and Significance section, the rationale and theoretical foundation for the intervention stems from extensive literature demonstrating the efficacy of brief interventions (SBIRT programs) incorporating personalized feedback in reducing alcohol use in high-risk populations (Babor & Higgins-Biddle, 2000; S. Walters, 2000). Although much of this work has focused on

binge drinking in the general population, the theoretical underpinnings extend to special populations, and the adaptation incorporates established and validated methods of assessing and intervening for alcohol use in women of childbearing potential. The original version of the e-CHUG combines a brief assessment with motivational feedback tailored to college students (Van Sickle & Sokolow, 2006). Use of the original program includes on-line administrative reports, specialized data reports, and raw data for every individual completing the program. For the present study, we only requested that raw data be provided. Building on an established product, the substantial investment in the development of the original e-CHUG adds to the cost-efficiency of this study. Relevant changes to the measurement components of the program were made and the feedback was tailored to include either general information about fetal alcohol syndrome OR personalized information about the participant's alcohol use, associated health risks, and health risks associated with alcohol use during pregnancy. The adapted eCheckUp version of the e-CHUG was tailored to an appropriate reading and comprehension level for WIC clients and the visual graphics were modified to appeal to women in this population. The program used multiple levels of communication (i.e. video clips, visual graphics, and text) to keep participants engaged in the program activities. The e-CHUG website provides details illustrating both the rationale and literature supporting the development of the original program (e-CHUG website, 2006). Table 2 provides a brief summary of this information with cross-references to how the program was modified for the present project.

Measurement of Demographic Information and Other Health Behaviors

Demographic characteristics and variables were assessed using general pull-tab questions. Variables included Age (continuous), Race/Ethnicity (categories defined by National Institutes of Health), Education Level (continuous total years of education starting from first grade), Marital Status (categorical), Common Health Behaviors {i.e. Other Drug Use (binary, Yes/No), Contraceptive Use (binary, Yes/No) and Method (specific type of contraceptive used), and Tobacco Use (continuous number of cigarettes if current smoker)}, Family History of Alcohol Use Disorders (continuous number of immediate family members with problems), Age of First Alcohol Use (continuous), Number of Living Children (continuous), and Number of Lifetime Pregnancies (continuous).

The following continuous variables were categorized for data analysis: Age, Education Level, Tobacco Use, Family History of Alcohol Use Disorders, Age of First Alcohol Use, and Number of Living Children. In addition, Contraceptive Method was categorized according to WHO established levels of effectiveness (World Health Organization/Department of Reproductive Health and Research (WHO/RHR) & Johns Hopkins Bloomberg School of Public Health/Center for Communication Programs (CCP), 2007). For both the Experimental group and the Control group, the adapted eCheckUp assessment was used to measure the above demographic variables.

## Measurement of Quantity and Frequency of Alcohol Use

Measurement of alcohol use in the present study followed recommendations put forth by the NIAAA Task Force on Recommended Alcohol Questions (NIAAA, 2003). Risky alcohol use in the prior month before study participation was assessed at baseline. An assessment of previous drinking behavior allows for a more precise assessment of current drinking behaviors, which provides a more accurate evaluation of individual risk levels (Russell, et al., 1994; Zammit, Skouteris, Wertheim, Paxton, & Milgrom, 2008). Each participant was asked to report the number of days in the past month on which they consumed 3 or more ($\geq 3$) drinks containing alcohol.

To capture a more detailed measurement of the quantity and frequency of alcohol use, a modified version of the Timeline Follow-Back (TLFB) procedure currently in the e-CHUG program was used (Sobell, Maisto, Sobell, & Cooper, 1979), (Sobell & Sobell, 1992). The TLFB technique involves asking participants to reconstruct their drinking behavior over a specified interval. For the purposes of the present study, the previous 2-week interval was used at baseline, 1-month and 2-months post baseline. At all assessment points, details of behavior for all alcohol use were sought, irrespective of specific use at baseline. Several studies have demonstrated the reliability and validity of the TLFB in the assessment of drinking history for multiple time-periods (Pearson Correlations of 0.7 to 1.0) (Jacobson, Chiodo, Sokol, & Jacobson, 2002; Sobell & Sobell, 2003; Sobell, Sobell, Leo, & Cancilla, 1988).

In addition, 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 typically consumes. This helped establish a more accurate measurement of standard drink size consumption in the two-week period assessed by the TLFB. Graphical drink pictures were captured via digital photography by the author. Common alcoholic beverages and corresponding drinking vessels were selected. 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 and multiple levels of standard drinks were depicted by each picture selection (NIAAA, 2010). Conversion calculations for number of standard drinks were programmed into the eCheckUp tool, which automatically converted the picture chosen into the respective number of standard drinks. The conversion calculations are provided in Table 3.

Data on multiple time periods in the previous month were captured or calculated for alcohol consumption using the previous month question, TLFB method and the standard drink size pictures: 1) Number of Days the participant had any alcoholic drinks in the previous 2-weeks, 2) Mean Drinks per Occasion in the previous 2-weeks, 3) Number of Risky Drinking Episodes in the previous 2-weeks, 4) Most Number of Drinks per occasion in the previous 2-weeks, 5) Number of Standard Drinks (i.e., 12 oz. beer, 5 oz. wine, or 1.5 oz. liquor) consumed in a typical drinking month and week, and 6) Number of Risky Drinking Episodes (3 or more drinks) in the previous month. For both the Experimental group and the Control group, the adapted

eCheckUp assessment was used to measure the above alcohol use quantity and frequency variables.

When examining the validity and reliability of self-report of alcohol use, some studies have found that in certain circumstances participants may over-report their alcohol use (Midanik, 1982). However, in most cases, studies looking at self-report of alcohol use in the general population and studies looking specifically at the WIC population suggest that participants often under-report their alcohol use (Chambers, et al., 2005; Hughes, et al., 2009; Midanik, 1988). Furthermore, studies that have compared different modalities of assessment (i.e. face-to-face, computer, paper-and-pencil, etc) suggest that modalities which provide a perception of anonymity (i.e. computer) yield more accurate measures of alcohol consumption (Duffy & Waterton, 1984). Given the perceived anonymous nature of responding to questions through a web-based program and the more extensive nature of the queries within the eCheckUp tool as compared to standard WIC assessment, the level of alcohol consumption provided to the eCheckUp program by participating women should exceed that reported through standard WIC assessments, which are conducted face-to-face. Although, a comparison to standard assessment was not available in the present study, previous studies with WIC clients conducted by our research team and others have verified this hypothesis (Chambers, et al., 2005; Hughes, et al., 2009).

## Measurement of Individual Risk for Alcohol Problems

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. The T-ACE instrument was designed for use in obstetric settings to identify at-risk (alcohol consumption of 1 ounce or more per day) drinkers, with T-ACE positive defined as a score of 2 points or greater (Sokol, Martier, & Ager, 1989). The T-ACE contains four questions, which take less than 1 minute to administer, 1) *Tolerance:* How many drinks does it take to make you feel high? 2) *Annoyed:* Have people annoyed you by criticizing your drinking? 3) *Cut down:* Have you ever felt you ought to cut down on your drinking? *4) Eye-opener:* Have you ever had a drink first thing in the morning to steady your nerves or get rid of a hangover? Numerous reports have demonstrated the reliability of the T-ACE as an alcohol screening instrument for pregnant and non-pregnant women (Sensitivity: 83-91%, Specificity: 70-75%, Area Under the Receiver Operating Characteristic curve (AUROC): 0.84-0.89) (Bradley, Boyd-Wickizer, Powell, & Burman, 1998; Chang, 2001; Chang, 2004; Chang, Goetz, Wilkins-Haug, & Berman, 1999; Chang, Wilkins-Haug, Berman, Goetz, Behr, & Hiley, 1998). This instrument helped provide an accurate assessment of individual risk as reported by the participant and was used as a component within the personalized feedback for the Experimental group. For both the Experimental group and the Control group, the adapted eCheckUp assessment was used to capture the T-ACE instrument items.

## Measurement of Alcohol Use Knowledge and Perceived Threat

A series of True/False questions were used to assess the participant's knowledge and perception about alcohol-associated risk to self, risk to an unborn child, and common drinking behaviors among peers of the same age and ethnic group. The pertinent constructs of the Health Belief Model and Social Norms Theory that were selected for the present study were incorporated within these questions and collected responses were used in the personalized feedback intervention for the Experimental group as described below. Baseline knowledge and perception of threat may have influenced the participant's alcohol consumption behavior. Providing feedback that discussed the participant's responses to these questions and corrected any misperceptions may have served as a cue to action within the conceptual model of the present study. Questions selected for the present study and corresponding HBM and SNT constructs and their application in the behavior change conceptual model are presented in Table 4. For both the Experimental group and the Control group, the adapted eCheckUp assessment was used to capture the alcohol knowledge and perceived threat questions described above.

## Measurement of Participant Satisfaction

Each participant also completed a satisfaction questionnaire after she completed the study activities on the computer. Please see Appendix E for a snap shot of the questionnaire used.

## Follow-Up Assessments

Participants, irrespective of study condition, had follow-up measures collected via telephone. Each participant received a call from the author approximately one week before her scheduled follow-up assessment (1-month and 2-months post baseline) to remind them of the upcoming follow-up assessment. During each follow-up assessment, the participant was asked to provide answers to the general questions used to determine unique study identifier at baseline. As depicted in the study design notation above, Follow-Up assessments only consisted of selected measures that were assessed at baseline. After the participant identifier was verified, the participant was asked 1) her Current Marital Status (categorical), 2) whether she had become Pregnant since the last assessment (binary), 3) whether she was currently using some form of Contraceptive (binary), 4) if applicable-the Contraceptive Method, and 5) alcohol consumption quantity and frequency since the last assessment using the same baseline measures described above. All follow-up assessments were completed between 28-33 days post previous assessment.

Although it would have been ideal to conduct the follow-up assessment via the web-based program, it was not be feasible for the current study. In addition, various studies have demonstrated the validity of telephone follow-up assessments as compared to other follow-up methodologies in various health disciplines (Fournier & Kovess, 1993; Hepner & Hayes, 2005; Midanik & Greenfield, 2003; Sobell, Brown, Leo, & Sobell, 1996; Sturges & Hanrahan, 2004). Furthermore, a study by Cohen and

Vinson evaluating the reliability of a follow-up assessment using the Timeline Follow-Back via telephone as compared to face-to-face found that the follow-up assessment was as reliable when conducted via telephone as when done with a face-to-face interview (Cohen & Vinson, 1995).

## Study Intervention Procedures and Content

The personalized feedback intervention used in the present study for the Experimental group was designed for appropriateness for women of childbearing potential with low education levels and meeting socio-economic requirements for the WIC program. The personalized feedback was further tailored to each individual Experimental group participant's responses to the assessment measures. The general information provided for the Control group was also specifically designed for women of childbearing potential with low educational levels and low-income status. However, as described below all participants in the Control group received the same general information about alcohol-associated risks and Fetal Alcohol Syndrome (not personalized). As described above, we adapted the existing e-CHUG program that has already been successfully studied and implemented in various populations and settings and modified program components to ensure appropriateness for the target population. We conducted multiple pilot and pre-implementation tests to evaluate the feasibility, acceptability, and content appropriateness of the adapted program within the WIC population. In addition, any media used in the program was specifically tailored to the target population.

## Description and Content of Experimental Group Feedback Intervention

Participants in the intervention group received feedback on their alcohol consumption, health risks associated with risky alcohol use, and social norms information. The personalized feedback consisted of four main sections: 1) feedback on the level of alcohol consumption and drinking pattern, 2) social norms information, 3) alcohol associated health risks before and during pregnancy including perceived susceptibility and severity and individual and familial risk, and 4) general information about alcohol consumption and the U.S. Surgeon General recommendations for women of childbearing potential and a listing of local resources. Snap shots of a sample personalized feedback intervention used for the Experimental group are provided in Appendix C.

### Feedback on Level of Consumption and Drinking Patterns

Participants were presented with statements indicating the number of alcohol units (number of drinks reported) they consumed in the previous two-weeks, and the associated financial cost. In addition, statements highlighting the number of risky use occasions per week and the number of standard alcoholic drinks per occasion (number calculated from NIAAA definition of standard drink size and participant's picture depiction of typical drink) were provided along with equivalent caloric intake. Example feedback: *On average, you reported drinking 3 drinks per week in the last two weeks. This equals an average of 12 standard drinks per week in the last two*

*weeks based on the picture you chose…You reported that you spend $520.00 on alcohol every year…In the last two weeks you drank about 2760 calories*.

### Social Norms Feedback

Personalized statements that indicate the percentage of women in the general population reporting drinking less than the amount reported by her were presented to each participant. The percentages were standardized according to the race/ethnicity of the participant and were calculated from the Behavioral Risk Factor Surveillance System (BRFSS) database. Example feedback: *Did you know…only 48.1% of women in the U.S. drink alcohol. Of these women who drink, only one out of ten (1/10) averages two or more drinks a day. 98.1% of women in the U.S. who are about your age and of the same ethnic background drink less than you*.

### Health Risk, Perceived Threat and Knowledge Feedback

Statements summarizing the participant's responses to True/False questions assessing knowledge about alcohol-associated risks, their perception of common drinking behaviors among the general population, and their perceived susceptibility to associated health risks and the severity of the consequences of risky alcohol consumption were presented. In addition, actual susceptibility and severity was provided through individual and family risk levels. Example feedback: *Even in small amounts, alcohol affects women differently than men. In some ways, heavy drinking is much more risky for women than it is for men. A woman's brain and other organs are*

*exposed to more of the toxic byproducts from alcohol. No amount of alcohol can be considered safe during pregnancy. Alcohol can damage a baby at any time during pregnancy…Your individual risk score is 2 out of 5. Based on your Score, you have an 11.7 likelihood of risk-drinking. Your family risk level is 4. Based on your family risk level, your risk for developing future alcohol dependence or related problems is high*.

### General Information Feedback

The general health risks and negative consequences of alcohol use for women of childbearing potential and during pregnancy were presented. Tips for sensible drinking and contact information for local support services were provided. Example feedback: *Space your drinks over time. Set a drinking limit of less than 2 drinks before you start. Spend more time with friends who don't drink*.

#### Description of General Intervention Provided for Control Group

Participants in the Control group received general information about alcohol consumption, the U.S. Surgeon General recommendations for women of childbearing potential, generic information about Fetal Alcohol Syndrome, and a listing of local alcohol and other health behavior resources. Snap shots of a Control group feedback intervention sample are provided in Appendix D.

### Referral for Treatment

All participants were presented with information for available local treatment and information resources in the community by the eCheckUp program such as the Pregnancy Risk Information Line of the California Teratogen Information Service (CTIS) in the Department of Pediatrics at the University of California, San Diego and other local resources.

## Statistical Analysis Plan

The primary objective of this study was to evaluate the effectiveness of the eCheckUp web-based assessment and intervention program in reducing the number of risky (defined as ≥ 3 drinks) drinking occasions (RDO) in the sample of non-pregnant women participating in the present study, by comparing the women who received a personalized feedback intervention (Experimental) to the group who received general non-personalized information (Control). The secondary objective was to evaluate the effectiveness of the web-based eCheckUp program in reducing mean drinks per occasion (MDPO) in the group receiving the personalized feedback intervention (Experimental) as compared to the group only receiving general information (Control). An exploratory objective was to evaluate the sustainability of change in the subset of participants that reported reduction in the number of risky drinking occasions at 1-month post baseline, comparing the feedback group (Experimental) to the general information group (Control). The statistical analysis plan for the present study will be presented in multiple sections. We begin with the evaluation of possible nesting within

data due to recruitment from three geographically separate WIC clinics, then proceed to the explanation of the analyses used for assessment of the effectiveness of randomization, followed by the analyses used for each study objective as relevant to their respective hypothesis, and concluding with a discussion of supplemental analyses. Statistical analyses were conducted with the Statistical Package for the Social Sciences (SPSS) for Windows Version 16.0 (SPSS for Windows, 2007).

## Evaluation of Potential Nesting Within Data

The statistical models used in the present study assumed that between participant observations were independent. Because we expanded the study setting to three geographically separate WIC Clinics, the possibility of non- independent observations was introduced. The existence of three Clinics, therefore, could produce nested observations–participants nested within clinics (Hedeker & Gibbons, 1994). Various analytical methods (described below) were used to test for independence of observations within clinics in the present study (Hedeker, McMahon, Jason, & Salina, 1994). To test for independence at baseline, we first conducted analyses using baseline variables related to the primary and secondary outcomes (DeCoster, 2002; J. Clapp, personal communication, January 21, 2010). For these analyses, a generalized linear mixed model was used with Treatment Condition as a fixed factor, Clinic as a random effect, with Baseline Number of Risky Drinking Occasions (RDO) as the dependent variable for the Primary Aim and Baseline Mean Drinks Per Occasion (MDPO) as the dependent variable for the Secondary Aim (both continuous). We also

conducted analyses using the outcome variables for the Primary (Reduction in RDO-binary) and Secondary (MDPO at Follow-Up-continuous) Aims to test for independence of observations of the overall study (Tabachnick & Fidell, 2007; R. Xu, personal communication, January 19, 2010). For the Primary Aim, we conducted a Chi-Square test of independence with Clinic as the independent variable and Reduction in RDO as the dependent variable. For the Secondary Aim, we conducted a one-way analysis of variance (ANOVA) with Clinic (3-groups) as the independent variable and MDPO at Follow-Up as the dependent variable. In all analyses, we failed to reject the null hypotheses that observations were independent ($p > 0.05$). Therefore, we concluded that there was no evidence of nesting within clinic and that the planned analyses were appropriate. Specific findings are presented in the Results Section.

## Effectiveness of Randomization at Baseline

Baseline characteristics of the two groups were summarized using demographic data collected from the eCheckUp assessment questions. The effectiveness of randomization was assessed by comparing characteristics of the Experimental group to the Control group. *T*-tests (for continuous variables), Chi-Square tests (for dichotomous variables), Fisher's Exact tests (for dichotomous variables of small cell size), or nonparametric analyses (for non-normal distributions) were used to test for equivalence between groups. Analyses revealed no significant differences in baseline characteristics between the Experimental and Control groups ($p > 0.05$). Specific findings are presented in the Results Section.

## Statistical Methods-Primary Aim

Aim: To evaluate the effectiveness (at 1-month post baseline) of the adapted web-based assessment and intervention program in reducing risky alcohol consumption in a subset of risky drinking non-pregnant women who visit a WIC Program Clinic by comparing evidence of any reduction in the number of Risky Drinking Occasions of $\geq 3$ Drinks (RDO) between women who received the web-based feedback intervention (Experimental) and women who did not (Control).

Hypothesis (stated in the alternative for ease of interpretation): Women who complete the web-based assessment and receive the personalized feedback intervention will be considerably more likely to reduce the number of risky drinking occasions, as measured by a binary measure of Reduction in Number of Risky Drinking Occasions of $\geq 3$ Drinks at 1-month post baseline, as compared to women who complete the web-based assessment and receive general health information about prenatal alcohol consumption.

Analysis: Logistic regression was used to test the hypothesis that the intervention was effective at reducing the number of risky drinking occasions from baseline to the 1-month assessment using. Odds ratios (OR) and 95% confidence intervals (CIs) are presented for the effect of the intervention on risky alcohol consumption. Where the dependent variable (DV) is reduction in number of RDO ($y = 1$ indicates Yes/Reduction; $y = 0$ indicates No Reduction) and the parameter of interest ($\beta 1$) is treatment group:

*Log odds* (y = 1) = β0 + β1 (Treatment Group)

*Primary Outcome (y)* → *Any Reduction in Number of RDOs in Previous Month*

Statistical Methods- Secondary Aim

Aim: To evaluate the effectiveness (at 1-month post baseline) of the adapted web-based assessment and intervention program in reducing quantity of alcohol consumption in a subset of risky drinking non-pregnant women who visit a WIC Program Clinic by comparing rates of Mean Drinks per Occasion (MDPO) in the previous two weeks between women who received the web-based personalized feedback intervention (Experimental) and women who did not (Control).

Hypothesis (stated in the alternative for ease of interpretation): Women who complete the web-based assessment and receive the personalized feedback intervention will have a lower rate of alcohol consumption, as measured by Mean Drinks per Occasion (DPO) at 1-month post baseline, as compared to women who complete the web-based assessment and receive general health information about prenatal alcohol consumption.

Analysis: A one-way analysis of covariance (ANCOVA) was used to test the hypothesis that the intervention was effective by comparing groups on Mean DPO at the 1-month assessment (Vickers & Altman, 2001). Where the dependent variable (DV) is Mean DPO at Follow-Up I and the parameter of interest (β2) is treatment group, controlling for Mean DPO at Baseline:

Mean DPO (Follow-Up I) = $\beta 0 + \beta 1$ (Mean DPO at Baseline) + $\beta 2$ (Treatment Group)

*Secondary Outcome (y) → Reduction in MDPO in Previous Two-Weeks*

Statistical Methods-Exploratory Aim

Aim: To evaluate the sustainability of intervention effects (at 2-months post baseline) in the subset of participants that reported a reduction in number of risky drinking occasions at 1-month post baseline by comparing maintenance of reduction or further reduction in Number of Risky Drinking Occasions of $\geq 3$ Drinks between women who received the web-based personalized feedback intervention (Experimental) and women who did not (Control).

Hypothesis (stated in the alternative for ease of interpretation): Looking only at the subset of the study sample that report a Reduction in Number of Risky Drinking Occasions at 1-month post baseline; women who complete the web-based assessment and receive the personalized feedback intervention will be more likely to sustain their behavior change, as compared to women who complete the web-based assessment and receive general health information about prenatal alcohol consumption.

Analysis: In the subgroup of women who showed a reduction in RDOs at 1-mont post baseline, Chi-Square was conducted to evaluate differences in the sustainability of study effects between participants in the Experimental and Control groups at 2-months post baseline. Where the Sustained Reduction was coded as (y = 1 indicates Yes/Sustained or Further Decreased; y = 0 indicates No/Increased).

## Supplemental Analyses

### Theoretical Variables

Multivariate analyses incorporating variables related to the conceptual model guiding the present study were conducted to test whether baseline perceived threat had an impact on the treatment effect for the Primary and Secondary Aims. We included the variables for overall level of perceived threat (determined by score received on True/False questions), general health/alcohol perceived threat, and pregnancy/alcohol perceived threat in a logistic regression model for the Primary Aim; ANCOVA was used to test for the Secondary Aim. Level of Perceived Threat was categorized as low or high depending on the number of True/False questions the participant answered correctly (convergent with the direction of the conceptual model).

### Identification of Predictors of Reduction And Possible Confounding

We conducted multivariate and univariate analyses to identify predictors of reduction in the study sample and any potential confounding that was not entirely addressed by randomization (i.e. age (continuous) and age group (categorical), contraceptive use (binary), ethnic distribution (categorical), education level (categorical), age first started drinking (categorical), baseline alcohol consumption (categorical), clinic (categorical), marital status (categorical), tobacco use (binary), number of lifetime pregnancies (continuous), family risk (binary), number of knowledge questions answered correctly (continuous), level of baseline perceived

threat (binary), T-ACE score (continuous) and score of 2 or above (binary), maximum number of drinks on any occasion in the previous two-weeks (continuous), number of standard drinks of alcohol per week in the previous two-weeks (continuous), etc.). Analyses on interactions of race/ethnicity, tobacco use, other illicit drug use, treatment group and level of alcohol use at baseline were included if appropriate. Using results from these multivariate and univariate analyses, we identified relevant predictors of Reduction in Number of Risky Drinking Occasions and confounders that influenced treatment effect to include in a multivariate model.

From the above analyses, thirteen baseline variables (ethnic distribution, age group, education level, marital status, contraceptive use, level of effectiveness of contraceptive used, number of lifetime pregnancies, age first started drinking, baseline alcohol consumption (MDPO), T-ACE status, family member with history of drinking problem, number of knowledge questions answered correctly, and treatment group) were further explored in a multivariate logistic model. These variables were selected for inclusion using three different criteria: 1) univariate analyses yielded a $p$-value $\leq$ 0.30 (although a cutoff $p$-value of 0.20 is typically used, we chose to go with a slightly more lenient cutoff of 0.30 in order to avoid under-evaluation of any potential predictors); or 2) the author believed that there was empirical evidence of potential relation to the outcome variable or predictor of interest (i.e. previously identified in the extant literature as a potential protective or risk factor); or 3) multivariate analyses revealed that inclusion of the covariate changed the effect of treatment condition by 10% or more when treatment condition was included as the predictor of interest in the

model. The combined effect of these factors was investigated using hierarchical logistic regression (Cloitre, Tardiff, Marzuk, Leon, & Portera, 1996; Tabachnick & Fidell, 2007). The thirteen possible predictors were categorized into explanatory blocks based on order of proximity to the participant (close proximity items are those inherent to the participant, such as age; while distant items are those that may be introduced by or manipulated with study participation, such as treatment group) for a logistic regression. The socio-demographic variables were entered as the first hierarchical block, theoretical/knowledge variables were entered as the second block, health behavior variables made up the third block, and treatment condition composed the final block. The independent variables were ordered in this way to determine the strength of the relationship between treatment condition (independent variable of interest) and reduction of risky drinking (Reduction in Number of RDO) after controlling for the influence of socio-demographic, theoretical/knowledge, and health behavior variables. When evaluating the combined effect of additional covariate variables on the number of mean drinks per occasion at Follow-Up I, the analyses did not reveal any predictors of significance that would suggest further evaluation of covariates would contribute to the study findings.

## Identification of Potential Subgroups

The existing literature evaluating the effectiveness of brief interventions in the reduction of alcohol consumption suggests that screening and brief intervention programs may be more effective for moderate drinkers (Bien, Miller, & Tonigan,

1993). For the present study, a moderate drinker was identified using the definition provided jointly by the U.S. Department of Agriculture and the U.S. Department of Health and Human Services of no more than one standard drink per day or seven standard drinks per week for women (United States Department of Agriculture (USDA); United States Department of Health and Human Services (USDHHS), 1990). We used the calculated variable of Number of Standard Drinks per Week to categorize participants into moderate or heavy drinkers. Participants meeting the seven drinks or fewer criterion for this variable at baseline were categorized as moderate drinkers. To test the impact of drinking level on treatment effect for the Primary Aim we used a logistic regression with Treatment Condition, Drinking Category, and the interaction between these two variables as independent variables and Reduction in Number of RDO as the dependent variable. In addition, to test the impact of drinking level on treatment effect for the Secondary Aim we used an ANCOVA with Treatment Condition, Drinking Category, and the interaction between these two variables as independent variables (controlling for Baseline MDPO) and Mean Drinks per Occasion at Follow-Up I as the dependent variable.

## Data Management

### Data Maintenance and Confidentiality

Data management was continued throughout the study period. Checklists were used to track data compilation from both study cohorts. The eCheckUp program collected data electronically from participants who completed the assessment and/or

intervention and maintained data in an established database. All data files were locked when not in use. All identifying information from participants was kept in a locked file cabinet separate from participant data. This information was only used for tracking purposes. Names and other identifying information were not used on any data files; rather, individuals participating in the study were assigned unique identification numbers. A master list of identification numbers and names was kept separate from all database files. Personally identifiable information was not used in reports, presentations or manuscripts. Data stored on the computer were archived on a backup server. Data was checked to verify variable coding and identify cases that were not consistent with other observations. Data analysis was performed on secured computers and all analyses were carried out using standard statistical software (SPSS) already available to the author.

## Treatment of Missing Values, Skewed Data and Outliers

The number of missing observations (n = 15 for Primary Aim Main Outcome, n = 18 for Secondary Aim Main Outcome) were compared between treatment arms for the Primary and Secondary Aims of the study. Logistic regression models were used to determine if the 'missingness' violated the assumption of missing completely at random (MCAR) (Ridout, 1991). Multiple models yielded a Little's test range of $\chi^2$= 0.245, $DF$ = 2, $p$ = 0.885 to $\chi^2$= 8.793, $DF$ = 4, $p$ = 0.066. Furthermore, analyses looking at the 15 participants that were lost to follow-up and the additional three that had incomplete data yielded no significant differences between treatment arms or

baseline characteristics for these subgroups as compared to the 135/132 participants that completed Follow-Up I and/or had complete data. Therefore, there was no evidence that the missing data threatened the validity of the study, MCAR was not rejected, imputation was not needed, and cases with missing main outcomes were dropped from the final analyses.

Frequencies were examined for evidence of sparseness for categorical variables. Plots and examination of skewness and kurtosis were used to identify evidence of non-normality for continuous variables. Where sparseness existed in categorical variables (i.e. race, marital status, and age group), data categories were collapsed to produce sufficient cell sizes. Although non-normal distributions are a typical characteristic of this type of data, the dataset was considered robust enough to follow all assumptions necessary for all analyses conducted (Draper & Smith, 1981; R. Xu, personal communication, December 16, 2010). Therefore, the final analyses were conducted using the original (raw scores) data.

Multivariate analyses revealed a total of four multivariate outliers (Probability Mahalanobis $D^2 < 0.001$). The outliers did not significantly impact the analyses; therefore, final outcome analyses were conducted with and presented for data from study completers (completed both baseline and Follow-Up I activities); the four identified outliers were excluded from analysis (Tabachnick & Fidell, 2007).

## Study Management and Quality Control

The author met weekly with faculty mentors in the initial phase of study implementation and continued periodic meetings for the remainder of the study period. Meetings provided information necessary for changes in recruitment efforts and study progress. The author also had periodic meetings with the participating WIC director and clinic managers to assess recruitment and study implementation feasibility. Since recruitment trends in the initial study clinic suggested that the goals would not be met within a timely period, the author extend the recruitment period and increased the number of clinics in order to ensure the timely completion of study activities.

# RESULTS

## Study flow

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 activities. Of the women screened, 150 women (10%) met eligibility criteria and completed baseline study activities. Once each woman logged into the web-based program, the program randomized the participant to one of two treatment arms using a computer generated randomization table, with 75 allocated to the Experimental group and 75 to Control group. Fifteen participants were lost to follow-up at Follow-Up Assessment I (Control n = 8, Experimental n = 7). None of the participants failed to navigate the program or reported not understanding or having difficulty understanding the assessment questions. Figure 3 illustrates the CONSORT diagram, which provides a summary of study flow.

## Analyses to Test for Nested Data

Multiple analyses were conducted to confirm independence of observations and rule out the possibility that data were nested within clinic. First, a generalized linear mixed model analysis of variance confirmed independence of baseline observations for both the Primary and Secondary Aims. Both variables of interest--

baseline Number of RDO and MDPO--did not significantly differ across the three clinics (Number of RDO: $F$ (2, 146) = 0.935, $p$ = 0.395; MDPO: $F$ (2, 143) = 0.063, $p$ = 0.939). Second, a Chi-Square test of independence evaluating the Primary Aim binary outcome variable of Reduction in RDO also confirmed independence of observations ($\chi^2$ = 2.818, $DF$ = 2, $p$ = 0.244). Third, a one-way ANOVA testing for differences in the Secondary Aim continuous outcome variable of Follow-Up I MDPO among the three clinics (controlling for Baseline MDPO) did not demonstrate significant differences across the three clinics ($F$ (2, 132) = 1.397, $p$ = 0.251). These findings suggest that the data for the present study were not nested within clinic and, therefore, there was no need to conduct further analyses (such as hierarchical linear modeling) beyond the planned analyses for the study aims.

## Effectiveness of Randomization

The effectiveness of the randomization was assessed and confirmed by comparing the experimental group to the control group. The analyses did not yield any inequalities between groups at baseline ($p > 0.05$). Results of these analyses are demonstrated in Tables 6 and 7. However, in order to account for any limitation in the sensitivity of the test for randomization success due to the small sample size, covariates related to an outcome at a significance level of $p \leq 0.30$ (conservative criterion used in this study) were included in multivariate models for supplemental analyses.

## Baseline Analyses and Participant Characteristics

Baseline characteristics of groups were generated using demographic data collected from the eCheckUp Assessment questions. Information summarized includes current age, marital status, ethnic distribution, education level, number of living children, tobacco use, contraceptive use, alcohol consumption values, and T-ACE composite scores. A total of 150 qualified and consenting non-pregnant women entering one of three WIC Clinics in San Diego County (El Cajon, n = 52; Mira Mesa, n = 44; Vista, n = 54) from June 2009 to October 2009 were enrolled in the study. Participants were randomly assigned to complete a web-based assessment and receive either a personalized feedback intervention (Experimental, n = 75) or general information about Fetal Alcohol Syndrome (Control, n = 75) during a single routine visit at each respective WIC clinic. When looking at the entire sample, study participants were predominantly Latina (44%) with a mean age of 26.33 years (*SD* 5.30, Range 18-44) with the majority between the age of 21 and 30 (73%). Nearly half of the participants reported education beyond the high school level (48%) with an average of 12.85 years of education (*SD* 2.02, Range 7-20). Most were either Single/Not Living with a Partner (29%) or Married (28%), 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. All respondents (100%) were current drinkers and most reported alcohol consumption prior to the age of 21 (83%). All respondents reported at least one occasion of risky drinking (defined as ≥ 3 Alcohol

Drinks in One Occasion) in the previous month (*Mean* 4.51, *SD* 4.17, Range 1-26), and 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*. Detailed participant satisfaction ratings are provided in Table 5. In addition, none of the participants failed to navigate through the web-based program, all of these low-income women reported being comfortable using computers, and the majority reported other advanced mobile device use (92%) such as cellular phone use with SMS (short message service) Messaging.

A comparison of baseline characteristics between the two treatment groups yielded no significant differences across socio-demographic characteristics or alcohol consumption patterns. Slight but not significant differences included marital status and age, where the Experimental group included slightly more married (35% vs. 21%) and older [Experimental *Mean* 26.91 (*SD* 5.34), Control *Mean* 25.75 (*SD* 5.23)] participants as compared to the Control group ($p = 0.259$ and 0.181, respectively). In addition, when evaluating baseline alcohol consumption patterns and other health behaviors, there were slight but not significant differences in some measures. For example, the Control group had slightly higher Mean Drinks per Occasion [Control *Mean* 3.27 (*SD* 1.89), Experimental *Mean* 2.87 (*SD* 1.33); $p = 0.134$ (95% *CI* -0.126 – 0.938)] and Most Number of Drinks [Control *Mean* 4.44 (*SD* 2.54), Experimental *Mean* 3.96 (*SD* 2.02); $p = 0.207$ (95% *CI* -0.268 – 1.226)], and answered slightly more knowledge questions correctly [Control *Mean* 5.41 (*SD* 0.74), Experimental *Mean*

5.20 (*SD* 1.05); $p = 0.153$ (95% *CI* -0.507 – 0.080)] as compared to the Experimental group. Descriptive statistics of participant baseline characteristics, stratified by treatment group assignment, are provided in Tables 6 and 7.

## Alcohol Knowledge and Theoretical Construct Characteristics

Each participant answered a series of seven true/false questions focusing on alcohol consumption and related general health effects and potential harm to an unborn child. The specific questions are identified in Table 4. In an effort to equalize perception of risk to actual risk, participants in the experimental group were given personalized feedback based on their answers to these questions. In addition, specific information on individual risk based on T-ACE assessment and family risk were also provided for this group. A comparison of composite knowledge question scores, T-ACE scores, T-ACE ranking (positive--T-ACE score of 2 or above--vs. negative--T-ACE score below 2), and family risk (report that ≥ one family member has had a problem with alcohol) yielded no significant differences between the Control and Experimental groups. However, the Control group did have a slightly, but not significantly, higher number of correct answers to knowledge questions [Control *Mean* 5.41 (*SD* 0.74), Experimental *Mean* 5.21 (*SD* 1.04); $p = 0.177$ (95% *CI* -0.092 – 0.492)] (Table 7). In addition, when categorizing the questions to a level of perceived threat at baseline for both general health/alcohol consumption and pregnancy/alcohol consumption, there were no significant differences between the Control and

Experimental groups (General Health/Alcohol Consumption: $\chi^2 = 2.655$, $DF = 2$, $p = 0.265$; Pregnancy/Alcohol Consumption: $\chi^2 = 3.138$, $DF = 3$, $p = 0.371$).

## Follow-Up Analyses and Changes in Participant Characteristics

Four participants became pregnant prior to the one-month follow up session, two in each treatment group (included in final outcome analyses). Measures of health behaviors such as contraceptive use and other measures of quantity and frequency of alcohol consumption were evaluated for both Baseline and Follow-Up I assessments. Findings from these evaluations revealed reduction in all measures of quantity and frequency (approximately a two-fold decrease) in both Control and Experimental groups and some variation in contraceptive use (greater reduction in overall use in Control group as compared to Experimental group). Despite the trend of reduction within both groups, analyses looking at differences between groups revealed no significant differences in participant characteristics at Follow-Up I as illustrated in Table 8.

## Findings for Study Aims Main Effects

Primary and Secondary outcome variables of interest included Reduction in the Number of Risky Drinking Occasions in the last month from Baseline to Follow-Up I and Mean Drinks per Occasion in the Past 2 Weeks at Follow-Up I. These variables were measured via a modified TLFB procedure assessing use in the previous two-weeks and a single question assessing risky use in the previous month. In

addition to these two main outcomes, the exploratory outcome of Sustained Reduction was calculated from responses to the TLFB at 2-months post baseline.

## Findings for Primary Aim

The binary dependent variable, REDUCTION, measured whether there was a reduction in the number of risky drinking occasions (RDOs) in the previous month at Follow-Up I. REDUCTION was equal to 1 if the number of RDOs at Follow-Up I was lower than the number at Baseline and 0 otherwise. The effect of treatment condition alone on reporting a reduction in the number of risky drinking occasions (RDO) in the previous month at Follow-Up I was investigated using a bivariate logistic regression. Overall, regardless of treatment condition, the majority of participants reported a reduction in Number of RDO at Follow-Up I (92/131, 70%; Control 43/63, 68%; Experimental 49/68, 72%). However, when treatment condition was considered as the only predictor, the results of the logistic regression were insignificant (*OR* 1.200, 95% *CI* 0.567-2.539, $p = 0.634$). These findings, which suggest no significant effect of treatment on reduction in Number of RDO, are presented in Table 9.

## Findings for Secondary Aim

The continuous dependent variable, MEAN DRINKS PER OCCASION (MDPO), measured the average number of drinks in a drinking occasion in the previous two-weeks at Follow-Up I as calculated by dividing the number of drinking

days into the reported total number of drink from the TLFB assessment. Analysis of covariance (ANCOVA) was used to assess whether participants in the Experimental group had lower mean drinks per occasion at Follow-Up I than participants in the Control group after controlling for baseline mean drinks per occasion. Results indicated that after controlling for baseline mean drinks per occasion, there was not a significant difference between treatment conditions on mean drinks per occasion at Follow-Up I ($F$ (l,125) = 0.703, $p$ = 0.403). Although the Experimental group (*Mean* 1.96, *SD* 1.64) had slightly lower MDPO at Follow-Up I as compared to the Control group (*Mean* 2.28, *SD* 1.90) (Table 8), as evident in the ANCOVA tests presented in Table 10, this slight difference is not statistically significant after controlling for mean drinks per occasion at baseline.

## Findings for Exploratory Aim

For the primary aim, 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, regardless of treatment condition allocation. We investigated whether there was a difference in sustaining that reduction between the treatment conditions using Chi-Square analysis among the 92 participants that reported a reduction at Follow-Up I. A total of 64 participants (of the 92 reporting a reduction) completed Follow-Up II, Control n = 28 and Experimental n = 36. SUSTAINED REDUCTION, measured whether the reported reduction in the Number of Risky Drinking Occasions (RDO) in the previous month at Follow-Up I was

maintained at Follow-Up II. SUSTAINED REDUCTION was equal to '1' if RDO at Follow-Up II was lower than RDO at baseline AND lower than or equal to RDO at Follow-Up I and '0' otherwise. When looking across treatment conditions, the majority of individuals reported a sustained reduction 49 (77%). However, the findings of the Chi-Square analysis presented in Table 11 revealed no significant difference in sustaining the reduction between treatment conditions ($\chi^2 = 0.068$, $DF = 1$, $p = 0.795$).

## Findings for Supplemental Analyses

### Evaluation of Impact of Theoretical Constructs

Multivariate logistic regression and ANCOVA models were used to evaluate the impact of overall level of perceived threat associated with alcohol consumption, perceived threat associated with general health and alcohol consumption, and perceived threat associated with pregnancy and alcohol consumption at baseline on the outcome variables for the Primary and Secondary Aims. Findings from these analyses did not reveal any significant impact of baseline perceived level of threat on treatment effect for either outcome variable (*p*-values for logistic regression ranged from 0.616 to 0.832 and for ANCOVA ranged from 0.337 to 0.938) (Tables 12 and 13). These results suggest that a participant's level of perceived threat (overall, general health/alcohol consumption, and pregnancy/alcohol consumption) did not influence whether they reported a reduction in risky alcohol consumption or mean drinks per occasion at Follow-Up I.

Evaluation of Predictors of Reduction and Possible Confounding

In order to explore the possibility that certain covariates served as predictors of reduction and investigate any evidence of confounding, we conducted a hierarchical logistic regression analysis where groups of covariates were entered into the model by blocks according to their theoretical proximity to participants. Four blocks of thirteen explanatory variables were entered hierarchically into the logistic regression with socio-demographic variables entered in the first step ($-2LL = 137.726$, $\chi^2 = 14.364$; $p = 0.278$). In the second step, we added baseline alcohol knowledge, but this addition did not enhance the predictive level of the model ($-2LL = 137.561$, $\chi^2 = 14.529$; $p = 0.338$). In the third step the addition of health behavior variables somewhat improved the prediction of reduction, but not significantly ($-2LL = 121.204$, $\chi^2 = 30.887$; $p = 0.126$). In the final step, the addition of treatment condition enhanced the level of prediction of reduction in Number of Risky Drinking Occasions to a level approaching significance ($-2LL = 117.147$, $\chi^2 = 34.944$; $p = 0.069$).

Looking at the final model, among the first block of socio-demographic variables, being African American ($p = 0.003$) or Multi Racial ($p = 0.035$) was significantly ($p \leq 0.05$) associated with a decreased likelihood for reporting a reduction in risky drinking (number of RDO) as compared to being White/Caucasian. In addition, having an education level of completing High School ($p = 0.099$) or Above High School ($p = 0.085$) was marginally ($p \leq 0.10$) associated with an increased likelihood for reporting a reduction in risky drinking (number of RDO) as

compared to an education level Below High School. The second block, comprised of the knowledge questions variable, revealed no specific association of an increased or decreased likelihood for reporting a reduction in risky drinking (number of RDO). Among the third block of health behavior variables, having a higher number of Lifetime Pregnancies ($p = 0.011$) and either Not Using ($p = 0.036$) or using an Effective ($p = 0.011$) Contraceptive Method was significantly ($p \leq 0.05$) associated with an increased likelihood for reporting a reduction in risky drinking (number of RDO) as compared to those using a Very Effective Contraceptive Method. In addition, having started drinking at a younger age (≤ 16 Years) ($p = 0.101$) was marginally ($p \leq 0.10$) associated with a decreased likelihood for reporting a reduction in risky drinking (number of RDO) as compared to those that started drinking at 21 years of age or older. In the final block, after controlling for other relevant covariates, the adjusted estimate for allocation to the Experimental group was of borderline significance; with approximately a threefold increased likelihood for reporting a reduction in risky drinking (*OR* = 2.922, 95% *CI* 0.991-8.613, $p = 0.052$). In the multivariate analysis, eight cases were not included in the analysis due to missing values—four cases from each treatment condition. The above findings are presented in Table 14.

## Evaluation of Subgroup Analyses

The impact of baseline drinking level (defined as moderate or high) on treatment effect for reporting a reduction in the number of risky drinking occasions

(RDO) in the previous month at Follow-Up 1 was investigated using a multivariate logistic regression. The results of the logistic regression were not significant, suggesting that baseline drinking level did not impact treatment effect in the present study. The findings are presented in Table 15. An analysis of covariance was used to assess whether baseline drinking level (defined as moderate or high) affected treatment effect on Mean Drinks per Occasion (MDPO) at Follow-Up I. Results indicate that treatment condition and baseline drinking level do not interact and after controlling for Baseline Mean Drinks per Occasion and Baseline Drinking Level. There is not a significant difference between Experimental and Control groups in MDPO at Follow-Up I ($F$ (l, 123) = 0.825, $p$ = 0.366). The findings are presented in Table 16.

# DISCUSSION

The present study evaluated the preliminary efficacy of a web-based assessment and primary intervention in reducing risky alcohol consumption in women of childbearing potential. Specifically, the study randomly assigned and assessed 150 women who were current alcohol consumers, drinking at risky levels in the previous month, and of childbearing potential to either an assessment plus general alcohol associated health information condition or assessment plus personalized feedback intervention condition. The web-based program began with a confidential and interactive assessment of general demographics, alcohol consumption, and alcohol consequences knowledge and then either presented general information about Fetal Alcohol Syndrome or a personalized non-threatening feedback intervention to women based on their responses to the assessment.

The study aimed to assess two main outcomes and an exploratory outcome. The primary and secondary outcomes of interest were to evaluate the effect of treatment group on two levels of alcohol consumption at Follow-Up I (one-month post baseline):

1) number of risky drinking occasions in the previous month
2) mean drinks per occasion in the previous two weeks

Subsequently, the exploratory aim was to evaluate the effect of treatment group on sustaining a reduction in the number of risky drinking occasions in the previous month

at Follow-Up II (two-months post baseline) among the subset of participants that had a reduction in this level of alcohol consumption at Follow-Up I.

## Impact on Alcohol Consumption

Our results from our primary and secondary analyses indicating that 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 at Follow Up I were similar to findings from other studies (Chang, Goetz, Wilkins-Haug, & Berman, 2000). Previous research has suggested that simply assessing a behavior may result in a change in that behavior (Clifford & Maisto, 2000). Recently, Kypri and colleagues brought attention to the historic *Hawthorne Effect* by conducting a study to evaluate the effects of assessment on the reduction of hazardous drinking (Kypri, Langley, Saunders, & Cashell-Smith, 2007). Similar to Mayo's findings, for which Landsberger coined the term *Hawthorne Effect*, Kypri et al. found that individuals seem to change their behavior as a result of external interest in that behavior (Landsberger, 1958; Mayo, 1933). In the present study, after completing baseline study activities, participants often commented on how the assessment of alcohol was "an eye-opener", the process was "very interesting", and she "never thought I [*sic*] drank that much". In addition, during follow-up assessments a common anecdotal feedback that participants provided when asked about their alcohol consumption was "I knew you would be calling so I watched what/how much I drank". Although these examples are subjective in nature, when

they are combined with other study findings on the impact of assessment on behavior change (assessment reactivity/subject reactivity), they may provide insight on the high rate of overall reduction and the lack of significant treatment effect in this study. In addition, because the follow-up assessments were conducted via telephone rather than computer, an element of social desirability bias may have resulted in underreporting of alcohol use and therefore over reporting of reduction across all conditions (Davis, Thake, & Vilhena, 2009).

Furthermore, as demonstrated by our supplemental analyses looking at potential covariates and confounders, when investigating the effects of treatment on reduction of the Number of Risky Drinking Occasions after adjusting for relevant covariates, treatment condition had borderline significance in predicting reduction. Specifically, allocation to the experimental group resulted in an approximate three-fold increase in the likelihood of reduction when controlling for relevant covariates. These analyses also suggested that participants who had experienced more lifetime pregnancies and were either not using a contraceptive method or currently using an *effective* contraceptive method were more likely to report a reduction. There is strong evidence to support the combined use of brief intervention and screening as a simple and cost-effective approach to identify problematic substance use and initiate more extensive treatment (Bien, Miller, & Tonigan, 1993). The primary goal of a brief intervention for alcohol consumption is to convince the individual that their drinking levels may be harmful to their health and help encourage them to reduce consumption in order to reduce the risk of future health problems. Therefore, our findings from the

supplemental analyses may suggest that when you control for certain confounders the feedback intervention--incorporating constructs from the Health Belief Model and Social Norms Theory--may be more beneficial for some individuals whom are better able to identify and correct their perceived threat.

However, specific analyses controlling for the impact of baseline levels of perceived threat on treatment outcomes did not yield significant associations between the level of perceived threat and reporting a reduction in alcohol consumption. Many factors may help explain this non-significant finding. First, we selected certain constructs from two theories previously demonstrated to predict behavior change. Therefore, we did not have a pure theoretical model to guide the assessment and intervention. In addition, we did not measure a change in perceived threat at the Follow-Up assessments. This limitation did not allow analyses to evaluate if change in perceived threat influenced behavior change. Furthermore, when looking at the overall perceived threat and perceived threat associated with alcohol and pregnancy, the majority of the participants had a high level of perceived threat at baseline assessment (97% and 96%, respectively) regardless of treatment allocation. Therefore, there was not much room for the intervention to influence baseline perceived threat from a lower level to higher level on these variables. However, a specific evaluation of perceived threat associated with general health and alcohol use, revealed that the majority of the sample had low levels of perceived threat at baseline assessment for this variable (91%). Therefore, it may be beneficial to focus on the

latter measure of perceived threat or a more refined measure of perceived threat in both assessment and intervention for future studies.

Subsequent analyses looking at the impact of baseline drinking levels on treatment effects were not significant. Our findings for these analyses are inconsistent with previous research looking at the impact of screening and brief intervention (SBI) on alcohol consumption, which suggest that SBI may be more effective for moderate drinkers (Bien, Miller, & Tonigan, 1993). This inconsistency may be contributed to a number of factors including the size of our sample and the alcohol consumption characteristics of our sample. Specifically, participants in the present study were screened for report of risky drinking (defined as having at least one occasion in the previous month when they consumed at least three drinks). Therefore, our sample may have consisted of individuals drinking a higher quantity and lower frequency as compared to samples not selecting for risky drinking, which may consist of individuals drinking at lower quantity and higher frequency. Consequently, when categorizing participants into moderate or high drinking levels, using the same definition can yield subsets with very different alcohol consumption patterns. Further research is warranted to evaluate whether the assessment and brief intervention used in this study may have varying effects depending on baseline level of drinking and level of perceived threat. An early review by Bien et al. found that brief interventions aimed to reduce alcohol use and misuse produce outcomes that are significantly better than no treatment and often comparable to outcomes from more extensive treatment interventions (Bien, Miller, & Tonigan, 1993). They concluded that brief

interventions are lower-cost interventions that can be applied to large populations with consistent results across cultures. A more recent meta-analytic review by Moyer et al. concurred with the findings from Bien et al. and found comparable effects of brief intervention as compared to extended treatments, which suggests that brief interventions are successful in particular settings with selected individuals (Moyer, Finney, Swearingen, & Vergun, 2002). Furthermore, a recent report by Floyd et al. recommended that SBI programs can be effective in preventing the negative consequences of prenatal alcohol exposure by providing standardized and routine screening and brief intervention for women of childbearing potential (Floyd, O'Connor, Bertrand, & Sokol, 2006).

When investigating the effect of treatment condition on mean drinks per occasion at Follow-Up I after controlling for baseline mean drinks per occasion, there was no significant difference between treatment conditions. This finding was consistent with the findings for our Primary Aim. However, we are limited in further comparability of these findings because of a limitation in measurement. The measure for our Primary Aim focused on the entire month post intervention (prior to follow-up assessment) and consisted of one simple question of count. The measure for our Secondary Aim was the TLFB and was more specific, but focused only on the latter two weeks post intervention and may not have been as sensitive due to recall bias. Unfortunately, due to this limitation in measurement, we are not fully able to compare the findings from the two aims. However, further analyses that look at these two outcomes from the TLFB procedure can be conducted in future exploration of the

data; but this would be conducted with a limited sample since criteria for participation in the study was dependent on consumption in the previous month, not two-weeks. Future studies evaluating the effect of treatment on two measures of alcohol consumption should measure consumption using equivalent time-periods.

An exploratory aim was to evaluate any difference in the sustainability of reduction in the number of risky drinking occasions between treatment conditions at Follow-Up II as compared to Follow-Up I. This analysis only looked at the subset of participants that reported reduction at Follow-Up I. Although a large number of individuals maintain their reduction 49 (77%) across treatment conditions, there was no significant difference between treatment conditions. A number of factors can explain these findings. First, the simple school of thought that those who were more likely to reduce at Follow-Up I were more likely to maintain that reduction at Follow-Up II, regardless of the treatment condition. Second, as previously discussed, participating in the study or completing the assessment at baseline may have acted as an intervention in and of itself.

It is documented in the literature that a small percentage of individuals with alcohol disorders experience spontaneous remission (SR) or natural recovery (NR) (Bischof, Rumpf, Hapke, Meyer, & John, 2002). However, the rates of SR have varied from one study to another due to non-standardized definitions of SR/NR, the use of widely divergent follow-up periods and other limitations in methodology (Carballo, Fernández-Hermida, Secades-Villa, Sobell, Dum, & García-Rodríguez,

2007). In a quantitative review of substance abuse literature looking at SR from alcohol, tobacco, and other drugs, Walters reported that a narrow definition of SR revealed an 18% rate of remission while a broad definition revealed 26% (G. Walters, 2000). A study by Goodwin, Crane, and Guze found that with an eight-year follow-up, no treatment resulted in about 18% remission for at least two years among incarcerated individuals (Goodwin, Crane, & Guze, 1971). In another study, Kendall and Staton reported 15% abstinence in untreated alcoholics after a seven-year follow-up (Kendell & Staton, 1966). In yet another study, Kissin, Platz, and Su reported a 4% one-year improvement rate in untreated alcoholics (Kissin, Platz, & Su, 1970). These studies suggest that, accounting for variation in study methodology, the spontaneous remission rate for alcohol use disorders is about 4-18%. Although, the intent of our study was not to result in abstinence from alcohol, but rather a reduction in risky alcohol consumption, supplemental analyses evaluating the report of no alcohol use at Follow-Up I as measured by TLFB method for the previous two-weeks revealed that 33 (25%) of the 131 participants completing follow-up assessment reported no alcohol use for this time-period. This is a clinically significant percentage as compared to estimates of spontaneous remission and suggests that detailed and interactive assessments of alcohol consumption may not only be sufficient for the reduction of risky drinking within our study population but also warrants further evaluation for the impact it may have on alcohol abstinence in this population.

## Public Health Impact

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. The current 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 targeted methodology used in this study may provide valuable information to better address the recognized health disparities associated with alcohol use in pregnancy (Havens, Simmons, Shannon, & Hansen, 2009). Preliminary findings of participant satisfaction indicated that the web-based assessment was both feasible and acceptable in this population; with consistently high ratings of program satisfaction across 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. As previously discussed, there are substantial limitations in the

accurate assessment of alcohol consumption quantity and frequency (Dawson, 2003). Technology can help researchers and health providers mitigate this limitation. Through increased anonymity and more interactive methodology, the quantity and frequency of alcohol consumption can be measured more accurately. In the present study, in an attempt to capture more accurate levels of alcohol consumption, we used an interactive program representing many different standard drink size pictures for participants to use in combination with the Time-Line-Follow-Back procedure. Furthermore, as evident from the empirical research and anecdotal feedback from participants in this study, there seems to be misinformation about alcohol use during pregnancy, both on the part of healthcare consumers and providers (Morse & Hutchins, 2000). Comments from participants in this study ranged from, "my doctor told me to drink two beers a day during my pregnancy to help my morning sickness" to "my doctor said that a glass of wine a day was good for the heart, so it can't be that bad for you" and "I heard that it was okay to have a drink or two once you were in your last trimester". Health information technology can be used to deliver a consistent and standard message to healthcare consumers, and provide training that is more accurate for healthcare providers. 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.

## Limitations, Strengths, and Future Directions

The present study has inherent limitations including the reliance on self-report, the lack of a biological measure to confirm self-report, the possibility that findings may not be generalizable to women who are not low-income, the lack of a Spanish translated version of the assessment and intervention program, the use of a different modality to collect follow-up assessments, the lack of a time measure to assess the level of exposure or dose for participants in the Experimental group, and the use of selected theoretical constructs from two separate theories to guide the assessment and intervention. However, as noted above, the mode of delivery should improve biases related to self-report. In addition, although the current sample was predominantly Latina and Caucasian women of low-income status, if the findings of this study can be replicated and continue to be efficacious in similar populations, the use of this program is likely to be generalizable with culturally specific modifications to other groups. Although it would have been desirable to provide a Spanish-language version of the program for Spanish-language dominant individuals, to conduct follow-up assessments using the web-based program used at baseline, to have a biological measure to confirm self-report of consumption, and include a measure for exposure or dose for the Experimental group; limitations in funding and timing restricted the feasibility of these potential benefits for the present study. In addition, although we did not use a single theoretical model to guide the present study, the technique of combining constructs from complementary theories has been supported in the literature (Cummings, Becker, & Maile, 2004).

It should be noted that the present study also had multiple strengths that contributed to the quality of the study design and methodology:

1) As discussed above, the delivery of the assessment and intervention through a web-based platform was one of the major strengths of the study methodology. The anonymity allowed through this mode of assessment and intervention minimizes self-report bias and other biases due to the nature of the population and the sensitive information collected. Further, the adapted program is based on an already established and validated program that was developed based on sound theoretical perspectives. In addition, the study used valid and reliable tools for assessing alcohol consumption that have been previously adapted for computer use.

2) Assessment of alcohol consumption in non-pregnant women within the WIC population who are otherwise not screened for this type of risky health behavior is an additional strength of the study. Primary prevention is most effective for the reduction of FASD as consumption of alcohol during the early stages of pregnancy may cause the most harm to the fetus.

3) An additional strength is the collection of information on multiple potential confounding factors over time during the course of the study. Multiple assessments during the study period of associated health behaviors allowed the author to capture information on any

modifications in behavior that may contribute to any change in alcohol consumption such as effectiveness level of contraceptive use.

4) The participation of women who already meet criteria for risky drinking is a strength that contributed to a more accurate assessment of the effectiveness of the program in high-risk populations.

5) The reliability of the web-based assessment as compared to paper-and-pencil assessment had been previously demonstrated in a pilot study conducted by the author.

The present study followed the principles of screening, brief intervention, and referral to treatment (SBIRT) programs, which have consistently been shown to be effective in the reduction of alcohol use with clients in clinical settings (Babor & Higgins-Biddle, 2000; Barry, Blow, Willenbring, McCormick, Brockmann, & Visnic, 2004; Bien, Miller, & Tonigan, 1993). The SBIRT model targets individuals with nondependent substance use by providing effective strategies for intervention prior to the need for extensive or specialized treatment. Furthermore, it incorporates mechanisms to refer individuals with elevated risks of addiction to specialized treatment. The overarching hypothesis of SBIRT is that education and knowledge about the risks of excessive consumption and clarifications about social norms associated with substance use will be beneficial for individuals at multiple substance use risk levels--ranging from low to severe risk (Beich, Throsen, & Rollnick, 2003). SBIRT programs typically follow the emerging approach for reducing the burden of chronic substance abuse problems by engaging patients and consumers in health

promotion activities at *teachable moments* within clinical settings to promote sustained behavior change and prevent future engagement in risky behaviors (Hungerford & Pollack, 2001). Our study differed from most SBIRT programs in that it was solely web-based and computer delivered, it took no more than 15 minutes for a participant to complete the assessment and thoroughly read the feedback intervention, and it was conducted in a WIC setting without the umbrella of a *teachable moment*. However, the study itself could have created a *teachable moment* for participants and the methodology used was innovative and the findings are promising.

The results of our analyses provide a strong starting point for additional studies that will contribute to our understanding of the effectiveness of web-based assessments and personalized feedback interventions to appropriately capture alcohol consumption in low-income women and reduce risk within this population. Specifically, it may be valuable to further evaluate the data captured in this study to more accurately identify subsets of populations that may benefit more from the personalized feedback intervention. For example, a recent study assessing a range of lifetime risk factors associated with prenatal alcohol use found that family history of use and illicit substance use may increase the likelihood of prenatal alcohol use (Flynn & Chermack, 2008). Evaluation of subsets of participants from the current study targeted for these risk factors may help better understand the effectiveness of the intervention. Other studies have reported that if a woman's life partner is a heavy drinker her risk of prenatal alcohol consumption increases (Abel, 1998; Smith, Lancaster, Moss-Wells, Coles, & Falek, 1987). Such findings combined with our

results from the present study may help identify and reach populations at greatest risk and, therefore, have the largest impact on the incidence and prevalence of alcohol related birth defects.

Future efforts may also focus on the benefits of amending current WIC alcohol and drug screening and education requirements to include women whose children are WIC clients, but not considered clients themselves. In addition, the findings of this study may have broad policy implications as they could lead to expanded services of the current WIC program in order to more effectively prevent risky drinking behavior in women who are not yet pregnant but likely to become so and ultimately prevent FASD in children born to women who are currently pregnant. In addition, future studies should include formally testing the cost-effectiveness of this approach to intervention delivery against alternative methodology by performing a cost-benefit analysis. Moreover, future research to extend the findings from this study should test the program in pregnant women – a time when reduction of risky drinking behavior could prevent excessive prenatal exposure to alcohol. It will also be valuable to: 1) include biological measures to improve accurate assessment of use, 2) test single theoretical models in predicting behavior change when using the assessment and intervention program evaluated in the present study, and 3) include additional measures of exposure to intervention and change in perceived threat post intervention.

Basic and epidemiologic research has demonstrated that prevention can play a significant role in reducing morbidity and mortality as a result of substance abuse

illness, and specifically alcohol related birth defects (Johnston, O'Malley, & Bachman, 2000). However, limited resources in clinical settings make the use of time consuming prevention approaches difficult (Glasgow, Bull, Piette, & Steiner, 2004; Whitlock, Orleans, & Allan, 2002). In addition, the reality of health disparities presents further challenges in the consistent and effective delivery of prevention interventions to traditionally underserved populations where the probability of multiple behavioral risk factors increases and the access to health care decreases (IOM, 2002).

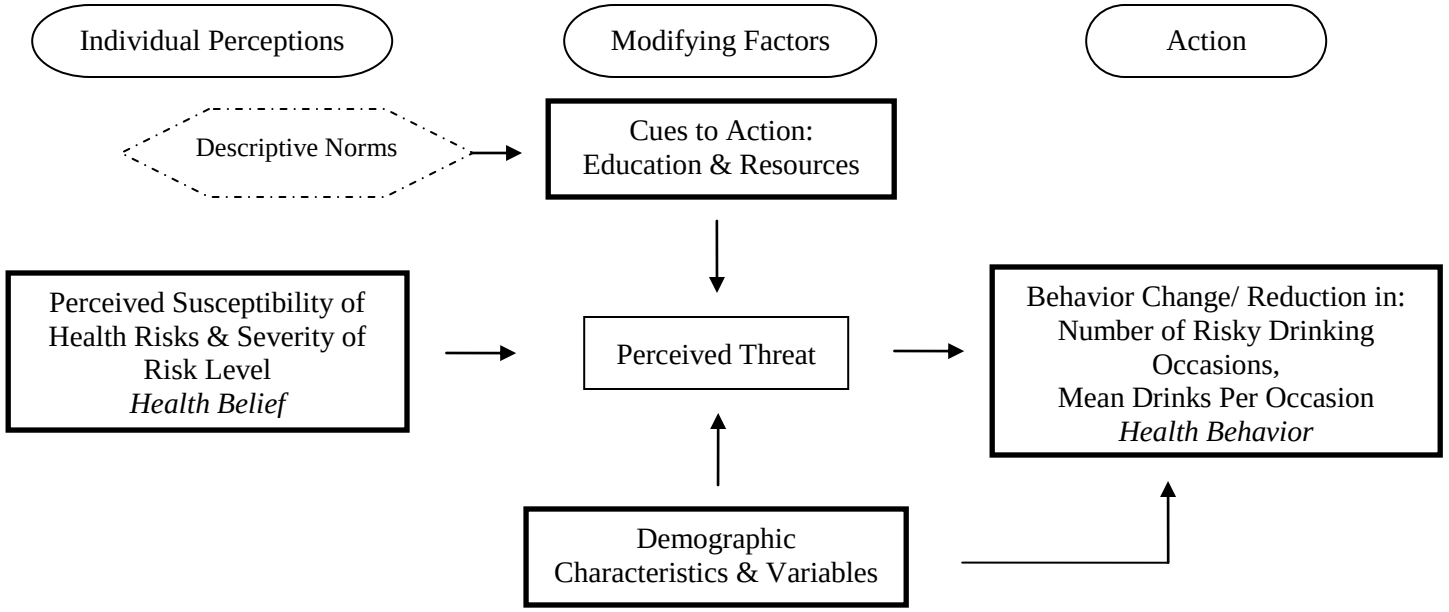
The findings from this study may help other researchers: 1) develop potentially cost-saving targeted prevention and intervention strategies that can address health disparities in preconception and prenatal education and healthcare, 2) further validate the effectiveness of web-based approaches to assessment and brief intervention that may have wide-ranging applicability in maternal and child health settings, and 3) further extend the theoretical frameworks of the Health Belief Model and Social Norms Theory using innovative intervention delivery mediums to further advance the science of eHealth.

While the utilization of traditional screening and brief intervention programs has been rapidly increasing to meet the needs of the current healthcare system, the use of health information technology has become more and more important in keeping up with the needs of society. As a recent meta-analysis concluded, "single-session personalized-feedback interventions without therapeutic guidance [may] be a viable and cost-effective option for reducing problem drinking in general populations"

(Riper, Straten, Keuken, Smit, Schippers, & Cuijpers, 2009, p. 247). Furthermore, the authors conclude that health information technology and the use of the Internet can help deliver personalized feedback interventions on a broad scale, increasing reach and mitigating health disparities (Riper, Straten, Keuken, Smit, Schippers, & Cuijpers, 2009). Our study is a first step in addressing the limited capacity of the current WIC system to provide adequate behavior change prevention interventions for non-pregnant women with the additional benefit of health information technology.

## APPENDIX A – Figures and Tables

This Appendix consists of all Figures and Tables that appear in the dissertation text. Each is numbered consecutively as it is mentioned in the text for ease of reference. The Figures are illustrated first and the Tables follow the last Figure.




**Omitting Constructs of Perceived Benefits/Barriers to Behavior Change and Self-Efficacy
Not Assessing Intention to OR Likelihood of Change
**Bold** Lines Depict HBM Constructs and Dashed Lines Depict SNT Constructs

**Figure 1: Conceptual Model Based on Health Belief Model Incorporating Social Norms Theory****

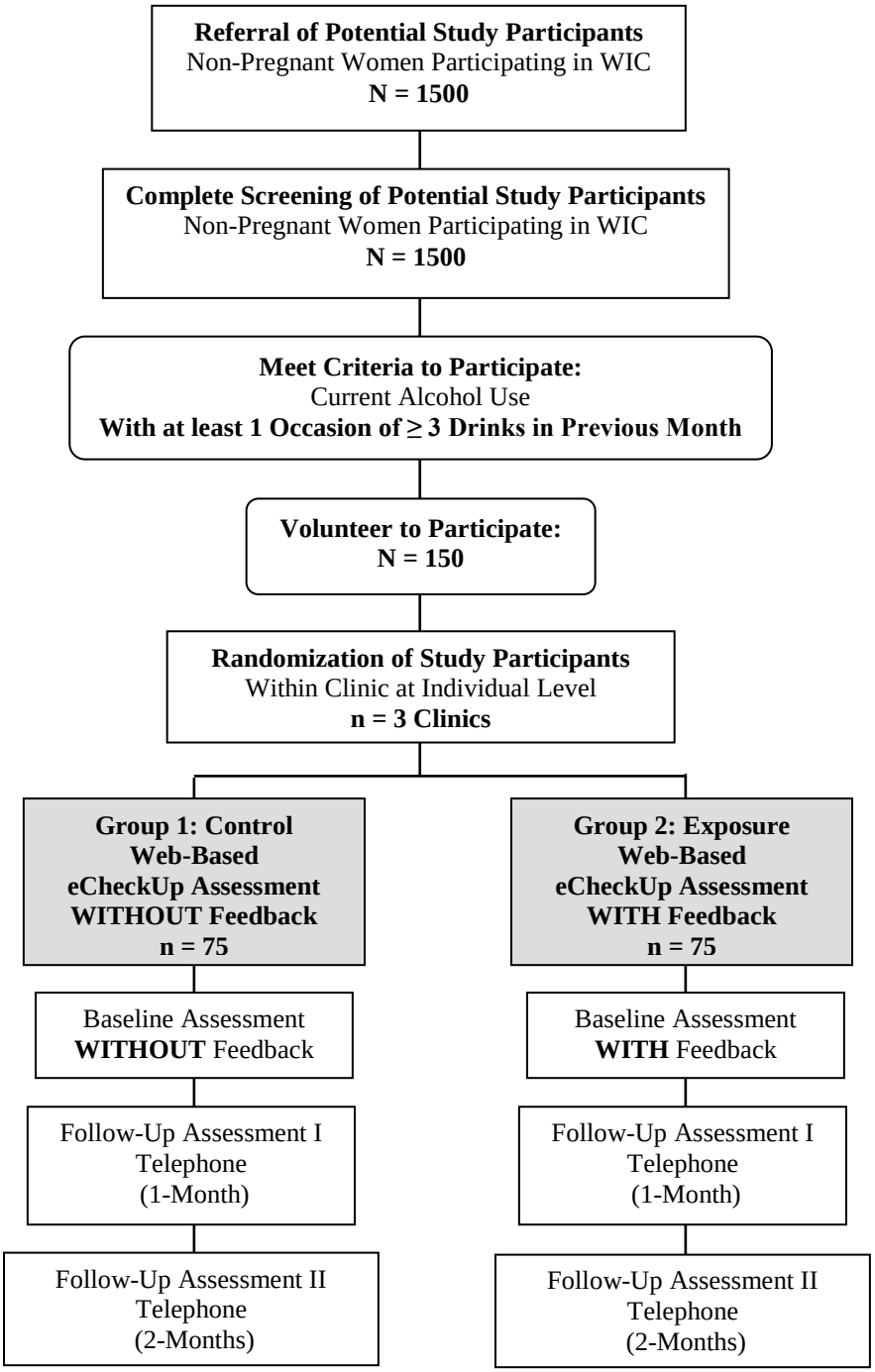



**Figure 2: Projected Sample Sizes Needed to Recruit to Achieve Power & Study Activities**

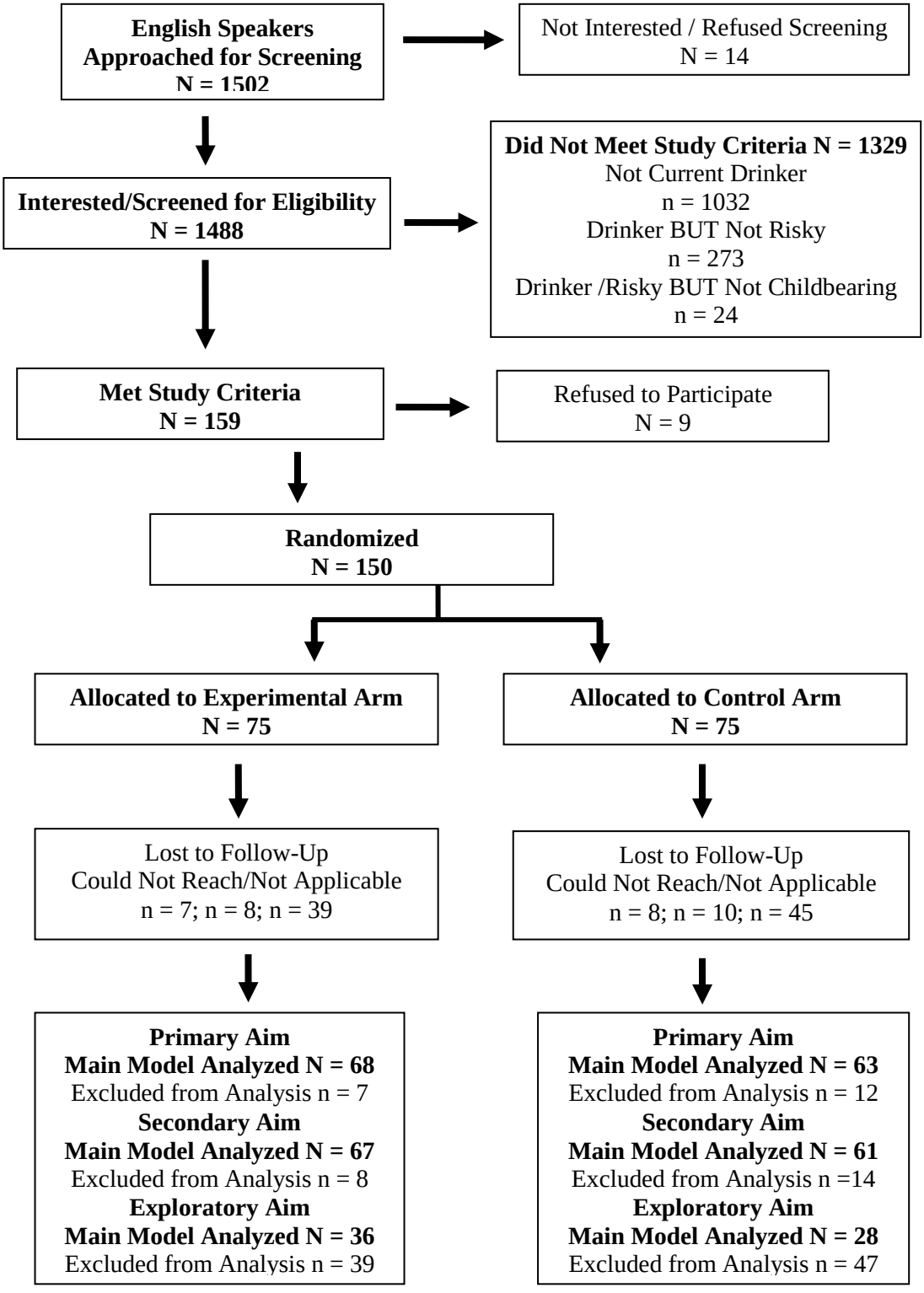



**Figure 3: Recruitment and Randomization of Study Participants**

**Table 1: Agreement Between Web-Based Tool and Paper-and-Pencil Version in the Report of Quantity and Frequency of Alcohol Consumption (N=30)**

| Variable | No Difference in Response N (%) |
|---|---|
| Typical Week Total Drinks | 27 (90.0) |
| Typical Week Total Drinking Hours | 28 (93.3) |
| Past Week Total Drinks Using TLFB* | 29 (96.7) |
| Past Week Total Drinking Hours Using TLFB* | 30 (100) |
| Past Week Total Drinks in Occasion When Drank Most | 30 (100) |
| Past Week Total Drinking Hours in When Drank Most | 30 (100) |
| Number of Days in Past Week When had ≥ 1 Drink | 28 (93.3) |
| Number of Days in Past Week When had > 1 Drink | 28 (93.3) |
| Number of Days in Past Week When had ≥ 3 Drinks | 28 (93.3) |
| Number of Days in Past Week When had ≥ 6 Drinks | 30 (100) |

*TLFB = time-line follow-back method of recalling previous week's consumption

## Table 2: Cross Analysis of Original e-CHUG Program & Adapted eCheckUp Version

| Category | Original Version | Category | Adapted Version |
|---|---|---|---|
| **Theoretical Framework** | Motivational Interviewing & Social Norms Feedback | **Theoretical Framework** | Health Belief Model & Social Norms Theory |
| **Drinking Profile** | Summary of drinking behaviors and consequences. Comparison to other US men or women provided using data from Alcohol Research Group's 1995 National Alcohol Survey. | **Drinking Profile** | Summary of drinking behaviors and consequences. Comparison to women in U.S. using 2002 data from CDC Behavioral Risk Factor Surveillance System. |
| **Level of Intoxication** | Feedback on probable level of intoxication for reported behaviors.<br>- Projected BAC Levels<br>- Time Needed to Sober Up<br>- Medication Interactions | **Level of Potential Impact** | Feedback on alcohol consumption impact on health and health of an unborn child.<br>- Impact on Health<br>- Impact on Pregnancy<br>- Impact on Unborn Child |
| **Laws & Regulations** | Information on legal limit of intoxication in respective state and/or institution and alternatives to driving if intoxicated. | **Laws & Regulations** | Recommendation of Surgeon General on prenatal alcohol use and consequences on pregnancy health outcomes. |
| **Risk Factors** | Estimates for: Tolerance, Family Risk, and Risk of Negative Consequences. | **Risk Factors** | Estimates for: Individual Risk, Family Risk, Risk of Negative Consequences |
| **Comparisons** | Comparisons to other college students' alcohol use, 2003 CORE Alcohol and Drug Survey. | **Comparisons** | Comparisons to other women in the general population matched to key demographic characteristics. |
| **Tobacco Use** | Reflects use of cigarettes and provides information about the danger of using tobacco and alcohol simultaneously. | **Tobacco Use** | Data captured, but risk increases due to simultaneous use of tobacco and alcohol are not yet known. |
| **Making Changes & Resources** | Self-reported importance of changing drinking behaviors and confidence in making changes is reflected. Additional resources at national and local level are provided. | **Making Changes & Resources** | Associated health risks are reflected. Additional resources at local, state and national level are provided. |

**Table 3: Standard Drink Size Conversion Calculations**

| Beverage | Vessel | Picture | Ounces | Standard Drinks | NIAAA Reference |
|---|---|---|---|---|---|
| BEER | BOTTLE | 1 | 40 | 3.3 | 12 oz = 1 Std. Drink @ 5% Alcohol by Volume |
| | | 2 | 22-24 | 2 | |
| | | 3 | 12 | 1 | |
| | CAN | 1 | 24 | 2 | |
| | | 2 | 25.4 | 2.3 | |
| | | 3 | 12 | 1 | |
| | GLASS | 1 | 14-16 | 1.3 | |
| | | 2 | 30-32 | 3 | |
| | | 3 | 12 | 1 | |
| | | 4 | 20-22 | 2 | |
| | | | | | |
| WINE | GLASS 1 | 1 | 5 | 1 | 5 oz = 1 Std. Drink @ 12% Alcohol by Volume |
| | | 2 | 10 | 2 | |
| | | 3 | 15 | 3 | |
| | GLASS 2 | 1 | 5 | 1 | |
| | | 2 | 7.5 | 1.5 | |
| | | 3 | 10 | 2 | |
| | GLASS 3 | 1 | 5 | 1 | |
| | | 2 | 7.5 | 1.5 | |
| | | 3 | 10 | 2 | |
| | | | | | |
| LIQUOR | SHOTS | | | | 1.5 oz = 1 Std. Drink @ 40% Alcohol by Volume |
| | GLASS | 1 | 2.25 | 1.5 | |
| | | 2 | 3.75 | 2.5 | |
| | | 3 | 1.5 | 1 | |
| | | 4 | 1.5 | 1 | |
| | MIXED/COCKTAILS | | | | |
| | GLASS 1 | 1 | 1.5 | 1 | |
| | | 2 | 3 | 2 | |
| | | 3 | 6 | 4 | |
| | GLASS 2 | 2- Martini | 3 | 2 | |
| | GLASS 3 | 3- Margarita | 2.25 | 1.5 | |
| | GLASS 4 | 1 | 3 | 2 | |
| | | 2 | 4.5 | 3 | |
| | | 3 | 9 | 6 | |
| | | | | | |
| MALT BEVERAGES | MALT BEER/ MALT LIQUOR | | | | 12 oz = 1.5 Std. Drinks @ 5-7% Alcohol by Volume |
| | BOTTLE | 1 | 40 | 4.5 | |
| | | 2 | 11.2 | 1.5 | |
| | | 3 | 12 | 1.5 | |
| | CAN | 1 | 24 | 2.5 | |
| | | 2 | 16 | 2 | |
| | MALT ENERGY | | | | 12 oz = 2 Std. Drinks @ 9-10 % Alcohol by Volume |
| | CAN | 1 | 24 @ 9.9% | 4 | |
| | | 2 | 16 @ 7% | 2 | |

**Table 4: Pertinent Theoretical Concepts and Assessment Questions**

| Concept | Definition | Measurement | Application |
|---|---|---|---|
| Perceived Susceptibility* | Subjective perception of risk of health condition/behavior | True/False Questions | Defining the population at risk and risk level of the individual, personalizing risk based on the characteristics and behaviors of the individual, bring the perception of risk in line with actual risk |
| Perceived Severity* | Feelings concerning the seriousness of condition/behavior and consequences | True/False Questions | Specifying consequences of the behavior/risk |
| Cues to Action/ Social Norms | Internal or external strategies or messages to activate action | Not Usually a Measured Construct | Providing educational information, correction of misperceptions of norms and local resources |
| Other Factors | Demographic or structural variables that have a direct effect on perception and therefore indirect effect on behavior | Assessment: TLFB, T-ACE, Demographics | Tailored Feedback |
| **Questions Assessing Perceived Susceptibility/Severity→Threat*: True/False** | | | |
| Women are at greater risk for developing alcohol-related problems than men. | | | |
| On average, you drink more than other women your age in the U.S. | | | |
| Just having a few drinks during pregnancy is safe for the baby. | | | |
| Babies of women who drink alcohol during pregnancy are at risk for developing physical, mental and behavioral problems. | | | |
| When a woman drinks alcohol when she is pregnant, the alcohol enters the baby's bloodstream. | | | |
| If a pregnant women drinks before she knows she is pregnant, she can have a child with an Alcohol Related Birth Defect. | | | |
| Drinking alcohol is OK during the last trimester of pregnancy. | | | |

*The combination of perceived susceptibility and perceived severity has been labeled *perceived threat*.

**Table 5: Participant Program Satisfaction Affirmative Ratings [YES], N = 150**

| Satisfaction Question | Control | Experimental | *p*-Value |
|---|---|---|---|
| Were you **comfortable using** the program?: n (%) | 75 (100%) | 75 (100%) | N/A |
| Was the program **easy to use**?: n (%) | 75 (100%) | 75 (100%) | N/A |
| Do you feel that the program was **useful**?: n (%) | 72 (96%) | 72 (96%) | 1.000 |
| Were you **satisfied with the quality** of the program?: n (%) | 75 (100%) | 74 (99%) | 0.316 |
| Did the program take **too long** to finish?: n (%) | 5 (7%) | 2 (3%) | 0.246 |
| Did you find this type of program **interesting**?: n (%) | 71 (95%) | 73 (97%) | 0.405 |
| Would you **use** this type of program **again**?: n (%) | 72 (96%) | 73 (97%) | 0.649 |

**Note:** *p* values for differences between treatment groups were calculated using Chi-square analyses.

**Table 6: Demographic Characteristics of Participants, N = 150**

| Variable | Control | Experimental | *p*-Value |
|---|---|---|---|
| Age in Years: *Mean* (± *SD*) | 25.75 (5.228) | 26.91(5.335) | 0.181 |
| Age Category: n (%) | | | 0.330 |
| 18-20 Years | 7 (9%) | 6 (8%) | |
| 21-30 Years | 58 (77%) | 52 (69%) | |
| 31-45 Years | 10 (13%) | 17 (23%) | |
| Ethnicity: n (%) | | | 0.271 |
| Caucasian/White | 27 (36%) | 24 (32%) | |
| Hispanic/Latina | 36 (48%) | 30 (40%) | |
| African American/Black | 3 (4%) | 9 (12%) | |
| Multi-Racial | 4 (5%) | 8 (11%) | |
| Other | 5 (7%) | 4 (5%) | |
| Years of Education: *Mean* (± *SD*) | 12.85 (1.865) | 12.84 (2.181) | 0.980 |
| Education Category: n (%) | | | 1.000 |
| Less Than High School | 13 (17%) | 13 (17%) | |
| High School | 26 (35%) | 26 (35%) | |
| Above High School | 36 (48%) | 36 (48%) | |
| Marital Status: n (%) | | | 0.259 |
| Single/Not Living with Partner | 27 (36%) | 16 (21%) | |
| In a Relationship/Not Living with Partner | 9 (12%) | 9 (12%) | |
| Single or In a Relationship/Living with Partner | 18 (24%) | 18 (24%) | |
| Married | 16 (21%) | 26 (35%) | |
| Married BUT Separated or Divorced | 5 (7%) | 6 (8%) | |
| Number of Living Children: n (%) | | | 0.690 |
| 0 | 7 (9%) | 7 (9%) | |
| 1 | 33 (44%) | 28 (37%) | |
| >1 | 35 (47%) | 40 (53%) | |
| Currently Using Contraceptives [YES]: n (%) | 50 (67%) | 51 (68%) | 0.862 |
| Contraceptive Effectiveness: n (%) | | | 0.141 |
| Not Effective (not using) | 15 (20%) | 14 (19%) | |
| Somewhat Effective (condoms) | 19 (25%) | 17 (23%) | |
| Effective (shot, pill, ring, patch) | 32 (43%) | 24 (32%) | |
| Very Effective (IUD, implant) | 9 (12%) | 20 (27%) | |
| Cell Phone Use [YES]: n (%) | 67 (89%) | 65 (87%) | 0.615 |
| SMS Messaging Use [YES]: n (%) | 60 (80%) | 62 (83%) | 0.802 |

**Note:** *p* values for differences between treatment groups were calculated using Chi-square analyses for dichotomous data, independent *t*-tests for continuous data, and nonparametric analyses (Mann Whitney U) for non-normally distributed data.

**Table 7: Baseline Substance Use Characteristics of Participants, N = 150***

| Variable | Control | Experimental | *p* -Value |
|---|---|---|---|
| Tobacco Use [YES]: n (%) | 30 (40%) | 29 (39%) | 0.867 |
| Illicit Drug Use [YES]: n (%) | 6 (8%) | 5 (7%) | 0.790 |
| Age First Started Drinking: n (%) | | | 0.765 |
| 21+ Years | 11 (15%) | 14 (19%) | |
| 17-20 Years | 27 (36%) | 24 (32%) | |
| ≤16 Years | 37 (49%) | 37 (49%) | |
| Family Member with Alcohol Problem [YES]: n (%) | 54 (74%) | 53 (72%) | 0.749 |
| T-ACE Score: *Mean* (± *SD*) | 1.72 (1.298) | 1.79 (1.312) | 0.797 |
| T-ACE Positive [YES]: n (%) | 49 (66%) | 49 (67%) | 0.907 |
| Knowledge Questions Correct [out of 7]: *Mean* (± *SD*) | 5.41 (0.737) | 5.20 (1.053) | 0.153 |
| Overall Perceived Threat [Low]: n (%) | 0 (N/A) | 4 (5%) | 0.120 |
| Health & Alcohol Perceived Threat [Low]: n (%) | 69 (92%) | 68 (91%) | 0.772 |
| Pregnancy & Alcohol Perceived Threat [Low]: n (%) | 1 (1%) | 5 (7%) | 0.209 |
| # RDOs in Last Month: *Mean* (± *SD*) | 4.43 (4.300) | 4.59 (4.081) | 0.620 |
| Total # of Drinks in Past 2 Weeks: *Mean* (± *SD*) | 12.07 (10.726) | 11.31 (10.571) | 0.584 |
| MDPO in Past 2 Weeks: *Mean* (± *SD*) | 3.27 (1.887) | 2.87 (1.334) | 0.134 |
| # RDOs in Past 2 Weeks: *Mean* (± *SD*) | 2.05 (2.160) | 1.81 (1.914) | 0.464 |
| Most # of Drinks in Past 2 Weeks: *Mean* (± *SD*) | 4.44 (2.539) | 3.96 (2.017) | 0.207 |
| Mean Standard DPO in Past 2 Weeks: *Mean* (± *SD*) | 6.82 (6.791) | 6.07 (4.917) | 0.898 |

*Variations in N(Decline to Answer Option) Control, Experimental: Illicit Drug Use: 74, 72; Family Member Alcohol Problem: 73, 74; T-ACE Score and Positive: 74, 73; All Variables for Past 2-Weeks: 73, 74

**Note:** *p* values for differences between treatment groups were calculated using Chi-square analyses or Fisher's Exact Test for dichotomous data, independent *t*-tests for continuous data, and nonparametric analyses (Mann Whitney U) for non-normally distributed data.

**Table 8: Comparison of Participant Characteristics at Follow-Up I, N = 135**

| Variable | Control | Experimental | *p* -Value |
|---|---|---|---|
| # RDOs in Last Month: *Mean* (± *SD*) | 2.87 (3.316) | 2.51 (2.751) | 0.475 |
| Total # of Drinks in Past 2 Weeks: *Mean* (±*SD*) | 6.96 (8.454) | 5.37 (5.518) | 0.592 |
| MDPO in Past 2 Weeks: *Mean* (±*SD*) | 2.28 (1.898) | 1.96 (1.643) | 0.298 |
| # RDOs in Past 2 Weeks: *Mean* (±*SD*) | 1.21 (1.737) | 0.96 (1.177) | 0.651 |
| Most # of Drinks in Past 2 Weeks: *Mean* (±*SD*) | 2.84 (2.233) | 2.56 (2.242) | 0.389 |
| Currently Pregnant [YES]: n (%) | 2 (3%) | 2 (3%) | 0.988 |
| Currently Using Contraceptives [YES]: n (%) | 35 (52%) | 44 (65%) | 0.142 |
| Contraceptive Effectiveness: n (%) | | | 0.317 |
| Not Effective (not using) | 32 (48%) | 24 (35%) | |
| Somewhat Effective (condoms) | 8 (12%) | 6 (9%) | |
| Effective (shot, pill, ring, patch) | 18 (27%) | 23 (34%) | |
| Very Effective (IUD, implant) | 9 (13%) | 15 (22%) | |

**Note:** Follow-Up was conducted via telephone using selected measurements from Baseline;
*p* values for differences between treatment groups were calculated using Chi-square analyses for dichotomous data, independent *t*-tests for continuous data, and nonparametric analyses (Mann Whitney U) for non-normally distributed data.

**Table 9: Logistic Regression Analysis Predicting Reduction of Risky Drinking Occasions at Follow-Up I Main Effect of Interest Model, N = 131**

| **Variable** | ***B* (*SE*)** | ***df*** | ***Wald*** | ***Odds Ratio*** | **95%*CI*** | ***p* - value** |
|---|---|---|---|---|---|---|
| Condition (Experimental Group) | 0.182 (0.382) | 1 | 0.226 | 1.200 | 0.567 – 2.539 | 0.634 |
| Constant | 0.765 (0.271) | 1 | 7.999 | 2.150 | -- | 0.005 |

*df* = degrees of freedom

**Table 10: Analysis of Covariance for Mean Drinks per Occasion at Follow-Up I as a function of Treatment Condition, Using Baseline Mean Drinks per Occasion as a Covariate**
**Main Effect of Interest Model, N = 128**

| **Source** | ***Sum of Squares*** | ***df*** | ***Mean Square*** | ***F* - Ratio** | ***p* - value** | $\eta_{p2}$ |
|---|---|---|---|---|---|---|
| Baseline Mean Drinks per Occasion | 26.623 | 1 | 26.623 | 9.094 | 0.003** | 0.068 |
| Condition (Experimental Group) | 2.057 | 1 | 2.057 | 0.703 | 0.403 | 0.006 |
| Error | 365.937 | 125 | 2.927 | -- | -- | -- |
| **Condition** | **Adjusted *Mean* (*SE*)** | | | | **95% *CI*** | |
| Control | 2.238 (0.220) | | | | 1.804-2.672 | |
| Experimental | 1.983 (0.209) | | | | 1.569-2.398 | |

*df* = degrees of freedom and $\eta_{p2}$ = Partial ETA Squared
$R^2$= 0.076 (Adjusted = 0.062)
**significant at $p \leq 0.05$

**Table 11: Chi-Square Test Evaluating Sustainability of Effect at Follow-Up II, N = 64**

| Variable | Control | Experimental | $X^2$ | *df* | *p* -Value |
|---|---|---|---|---|---|
| Sustained Reduction in Number of RDO in previous month [YES]: n (%) | 21 (75%) | 28 (78%) | 0.068 | 1 | 0.795 |

**Note:** Using subset of particpants that reported reduction in RDO at Follow-Up I and completed Follow-Up II assessment

**Table 12: Logistic Regression Analyses Evaluating Impact of Theoretical Constructs on Treatment Effect for Reduction of Risky Drinking Occasions at Follow-Up I**
**Three Separate Models, N = 131**

| Model | Variable | *B* (*SE*) | *df* | *Wald* | *Odds Ratio* | 95%*CI* | *p* - value |
|---|---|---|---|---|---|---|---|
| | Condition (Experimental Group) | 0.194 (0.387) | 1 | 0.252 | 1.214 | 0.568 – 2.595 | 0.616 |
| 1 | Perceived Threat: Overall (Low) | -0.267 (1.256) | 1 | 0.045 | 0.766 | 0.065 – 8.976 | 0.832 |
| | Constant | 0.765 (0.271) | 1 | 7.999 | 2.150 | -- | 0.005** |
| | Condition (Experimental Group) | 0.186 (0.383) | 1 | 0.235 | 1.204 | 0.568 – 2.552 | 0.628 |
| 2 | Perceived Threat: Health and Alcohol (Low) | -0.571 (0.815) | 1 | 0.491 | 0.565 | 0.114 – 2.793 | 0.484 |
| | Constant | 1.396 (0.812) | 1 | 2.551 | 3.655 | -- | 0.110 |
| | Condition (Experimental Group) | 0.163 (0.385) | 1 | 0.179 | 1.177 | 0.554 – 2.501 | 0.672 |
| 3 | Perceived Threat: Prenatal Alcohol Use (Low) | 0.499 (1.141) | 1 | 0.191 | 1.647 | 0.176 – 15.406 | 0.662 |
| | Constant | 0.758 (0.271) | 1 | 7.823 | 2.135 | -- | 0.005** |

*df* = degrees of freedom
**significant at $p \leq 0.05$

**Table 13: Analysis of Covariance for Mean Drinks per Occasion at Follow-Up I as a function of Treatment Condition Using Baseline Mean Drinks per Occasion and Theoretical Constructs as a Covariates Three Separate Models, N = 128**

| Model | Source | *Sum of Squares* | *df* | *Mean Square* | *F* - Ratio | *p* - value | $\eta_{p2}$ |
|---|---|---|---|---|---|---|---|
| 1 | Baseline Mean Drinks per Occasion | 27.422 | 1 | 27.422 | 9.358 | 0.003** | 0.070 |
| | Perceived Threat: Overall (Low) | 2.592 | 1 | 2.592 | 0.885 | 0.349 | 0.007 |
| | Condition (Experimental Group) | 2.722 | 1 | 2.722 | 0.929 | 0.337 | 0.007 |
| | Error | 363.346 | 124 | 2.930 | -- | -- | -- |
| 2 | Baseline Mean Drinks per Occasion | 27.115 | 1 | 27.115 | 9.218 | 0.003** | 0.069 |
| | Perceived Threat: Health and Alcohol (Low) | 1.187 | 1 | 1.187 | 0.404 | 0.526 | 0.003 |
| | Condition (Experimental Group) | 2.086 | 1 | 2.086 | 0.709 | 0.401 | 0.006 |
| | Error | 365.937 | 124 | 2.927 | -- | -- | -- |
| 3 | Baseline Mean Drinks per Occasion | 26.641 | 1 | 26.641 | 9.028 | 0.003** | 0.068 |
| | Perceived Threat: Prenatal Alcohol Use (Low) | 0.018 | 1 | 0.018 | 0.006 | 0.983 | 0.000 |
| | Condition (Experimental Group) | 2.075 | 1 | 2.075 | 0.703 | 0.403 | 0.006 |
| | Error | 365.919 | 124 | 2.951 | -- | -- | -- |

*df* = degrees of freedom and $\eta_{p2}$ = Partial ETA Squared

Model 1: $R^2 = 0.083$, Adjusted = 0.061; Model 2: $R^2 = 0.079$, Adjusted = 0.057; Model 3: $R^2 = 0.076$, Adjusted = 0.054

**significant at $p \leq 0.05$

**Table 14: Hierarchical Logistic Regression Predicting Reduction of Risky Drinking Occasions at Follow-Up I, N = 123**

| Variable | *B* (*SE*) | *df* | *Wald* | *Odds Ratio* | 95%*CI* | *p*-Value |
|---|---|---|---|---|---|---|
| [a] **Block 1: Socio-demographic Variables** | | | | | | |
| Age Category: | | | | | | |
| 18-20 Years | -- | 2 | 0.700 | -- | -- | 0.705 |
| 21-30 Years | 0.582 (0.844) | 1 | 0.475 | 1.789 | 0.342-9.345 | 0.491 |
| 31-45 Years | 0.258 (1.137) | 1 | 0.052 | 1.295 | 0.139-12.029 | 0.820 |
| Ethnicity: | | | | | | |
| Caucasian/White | -- | 4 | 11.167 | -- | -- | 0.025** |
| Hispanic/Latina | -0.549 (0.614) | 1 | 0.799 | 0.677 | 0.173-1.925 | 0.371 |
| African American/Black | -3.184 (1.070) | 1 | 8.850 | 0.041 | 0.005-0.337 | 0.003** |
| Multi-Racial | -2.368(1.123) | 1 | 4.447 | 0.094 | 0.010-0.846 | 0.035** |
| Other | -1.141 (1.270) | 1 | 0.807 | 0.319 | 0.027-3.850 | 0.369 |
| Education Category: | | | | | | |
| Less Than High School | -- | 2 | 3.397 | -- | -- | 0.183 |
| High School | 1.294 (0.784) | 1 | 2.721 | 3.647 | 0.784-16.963 | 0.099 |
| Above High School | 1.268 (0.737) | 1 | 2.962 | 3.554 | 0.839-15.057 | 0.085 |
| Marital Status: | | | | | | |
| Single/Not Living with Partner | -- | 4 | 3.156 | -- | -- | 0.532 |
| In a Relationship/Not Living with Partner | 1.368 (0.909) | 1 | 2.265 | 3.928 | 0.661-23.336 | 0.132 |
| Single or In a Relationship/Living with Partner | 0.557 (0.673) | 1 | 0.685 | 1.746 | 0.467-6.532 | 0.408 |
| Married | 0.261 (0.698) | 1 | 0.140 | 1.298 | 0.331-5.101 | 0.708 |
| Married BUT Separated or Divorced | 1.158 (1.033) | 1 | 1.259 | 3.185 | 0.421-24.101 | 0.262 |
| [b] **Block 2: Alcohol Knowledge Variable** | | | | | | |
| Number of Knowledge Questions Correct | 0.221 (0.291) | 1 | 0.575 | 1.247 | 0.705 – 2.206 | 0.448 |

*df* = Degrees of Freedom
**significant at $p \leq 0.05$

**Table 14: Hierarchical Logistic Regression Predicting Reduction of Risky Drinking Occasions at Follow-Up I, Continued**

| Variable | *B* (*SE*) | *df* | *Wald* | *Odds Ratio* | 95%*CI* | *p*-Value |
|---|---|---|---|---|---|---|
| [c] **Block 3: Health Behavior Variables** | | | | | | |
| Number of Lifetime Pregnancies | 0.469 (0.184) | 1 | 6.495 | 1.598 | 1.114-2.293 | 0.011** |
| Currently Not Using Contraceptives | -1.192 (0.846) | 1 | 1.983 | 0.304 | 0.058-1.595 | 0.159 |
| Contraceptive Effectiveness: | | | | | | |
| Not Effective (not using) | 2.317 (1.103) | 1 | 4.411 | 10.142 | 1.167-88.098 | 0.036** |
| Somewhat Effective (condoms) | 0.788 (0.798) | 1 | 0.974 | 2.199 | 0.460-10.415 | 0.324 |
| Effective (shot, pill, ring, patch) | 1.923 (0.760) | 1 | 6.413 | 6.844 | 1.545-30.329 | 0.011** |
| Very Effective (IUD, implant) | -- | 3 | 8.260 | -- | -- | 0.041** |
| Baseline Mean Drinks per Occasion | -0.043(0.224) | 1 | 0.037 | 0.958 | 0.618-1.485 | 0.848 |
| Age First Started Drinking: | | | | | | |
| 21+ Years | -- | 2 | 2.697 | -- | -- | 0.260 |
| 17-20 Years | -1.100 (0.906) | 1 | 1.472 | 0.333 | 0.056-1.968 | 0.225 |
| ≤16 Years | -1.474 (0.898) | 1 | 2.694 | 0.229 | 0.039-1.331 | 0.101 |
| T-ACE Positive | 0.755 (0.591) | 1 | 1.634 | 2.128 | 0.668-6.775 | 0.201 |
| Family Member Has History of Drinking Problem | -0.007 (0.559) | 1 | 0.000 | 0.993 | 0.668-6.775 | 0.990 |
| [d] **Block 4: Treatment Condition** | | | | | | |
| Condition (Experimental Group) | 1.072 (0.552) | 1 | 3.780 | 2.922 | 0.991-8.613 | 0.052*** |
| Constant | -3.259 (2.387) | 1 | 1.864 | 0.038 | -- | 0.172 |

*df* = Degrees of Freedom
**significant at $p \leq 0.05$
***marginally significant at $p \leq 0.05$
[a] – 2LL = 137.726, $\chi^2$ =14.364; $p$ = 0.278
[b] – 2LL = 137.561, $\chi^2$ = 14.529; $p$ =0.338
[c] – 2LL = 121.204, $\chi^2$ = 30.887; $p$ = 0.126
[d] – 2LL = 117.147, $\chi^2$ = 34.944; $p$ = 0.069

**Table 15: Logistic Regression Analysis Evaluating Impact of Drinking Level on Treatment Effect for Reduction of Risky Drinking Occasions at Follow-Up I, N = 128**

| **Variable** | ***B* (*SE*)** | ***df*** | ***Wald*** | ***Odds Ratio*** | **95%*CI*** | ***p* - value** |
|---|---|---|---|---|---|---|
| Condition (Experimental Group) | -0.201 (0.538) | 1 | 0.139 | 0.818 | 0.285 – 2.347 | 0.709 |
| Drinking Level (Moderate) | -0.446 (0.549) | 1 | 0.660 | 0.640 | 0.218 – 1.977 | 0.417 |
| Drinking Level * Condition | 0.848 (0.775) | 1 | 1.197 | 2.334 | 0.511 – 10.659 | 0.274 |
| Constant | 0.938 (0.393) | 1 | 5.695 | 2.556 | -- | 0.017 |

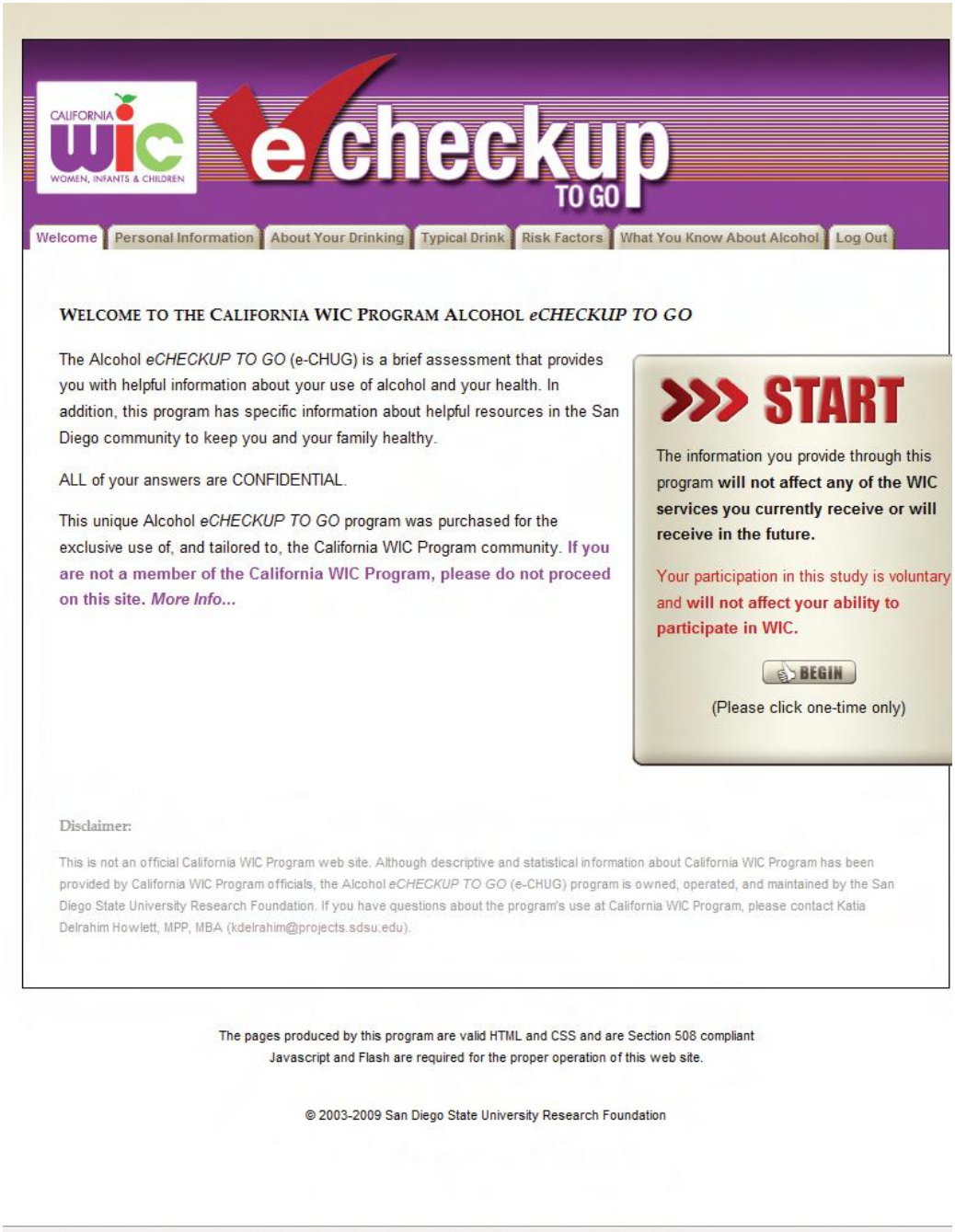
*df* = degrees of freedom

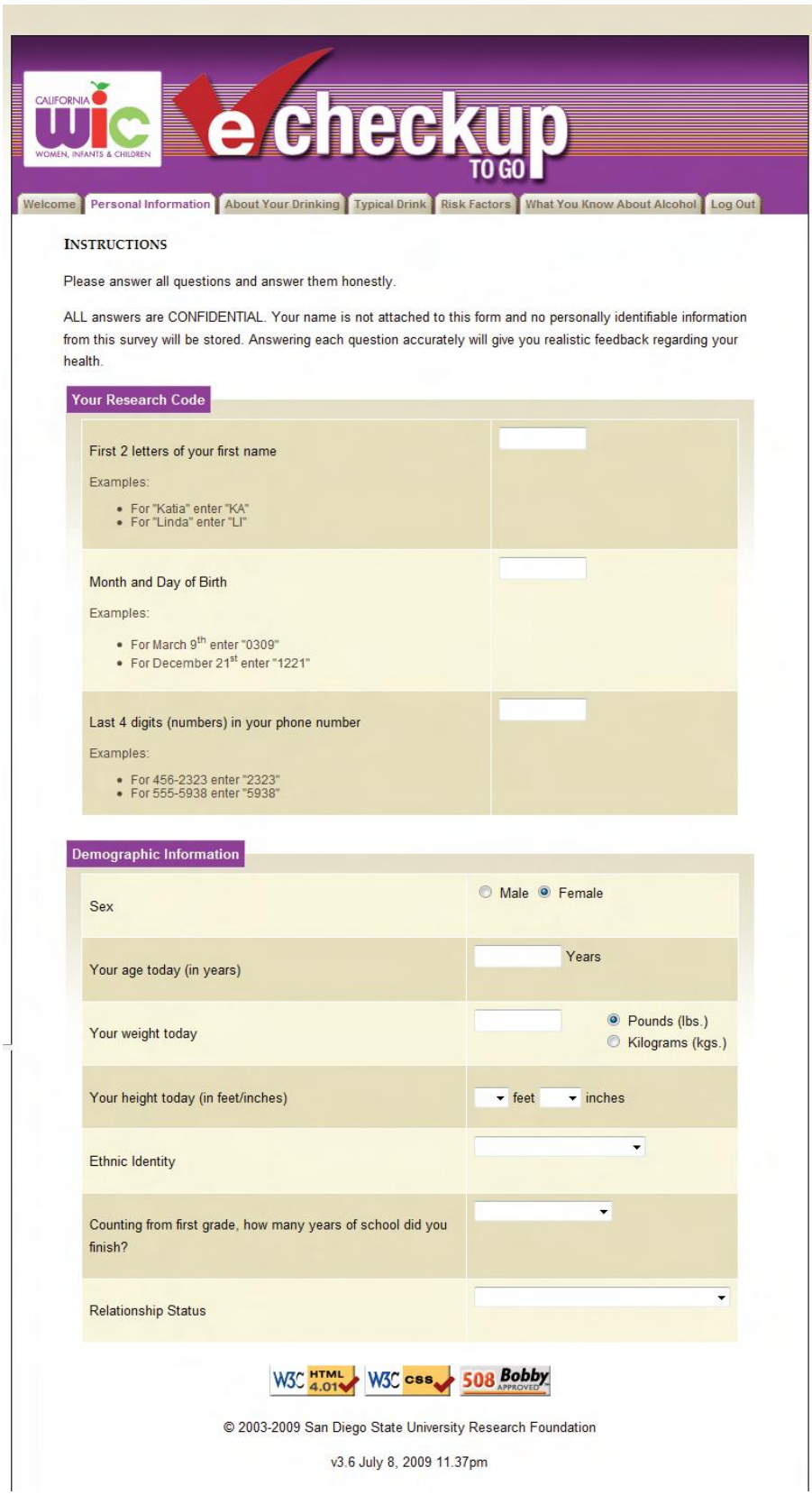
**Table 16: Analysis of Covariance for Mean Drinks per Occasion at Follow-Up I, Using Baseline Mean Drinks per Occasion and Drinking Level as a Covariates, N = 128**

| **Source** | ***Sum of Squares*** | ***df*** | ***Mean Square*** | ***F* - Ratio** | ***p* - value** | $\eta_{p2}$ |
|---|---|---|---|---|---|---|
| Baseline Mean Drinks per Occasion | 10.717 | 1 | 10.717 | 3.835 | 0.052*** | 0.030 |
| Condition (Experimental Group) | 2.306 | 1 | 2.306 | 0.825 | 0.366 | 0.007 |
| Drinking Level (Moderate) | 21.094 | 1 | 21.094 | 7.547 | 0.007** | 0.058 |
| Drinking Level * Condition | 0.449 | 1 | 0.449 | 0.161 | 0.689 | 0.001 |
| Error | 343.779 | 123 | 2.795 | -- | -- | -- |

*df* = degrees of freedom and $\eta_{p2}$ = Partial ETA Squared
$R^2$ = 0.132, Adjusted = 0.104
**significant at $p \leq 0.05$
***marginally significant at $p \leq 0.05$

## APPENDIX B – Screen Shot of Sample Assessment Input





CALIFORNIA WIC WOMEN, INFANTS & CHILDREN

eCheckup TO GO

Welcome | Personal Information | About Your Drinking | Typical Drink | Risk Factors | What You Know About Alcohol | Log Out

INSTRUCTIONS

Please answer all questions and answer them honestly.

ALL answers are CONFIDENTIAL. Your name is not attached to this form and no personally identifiable information from this survey will be stored. Answering each question accurately will give you realistic feedback regarding your health.

**Your Research Code**

| | |
|---|---|
| First 2 letters of your first name<br>Examples:<br>• For "Katia" enter "KA"<br>• For "Linda" enter "LI" | |
| Month and Day of Birth<br>Examples:<br>• For March 9th enter "0309"<br>• For December 21st enter "1221" | |
| Last 4 digits (numbers) in your phone number<br>Examples:<br>• For 456-2323 enter "2323"<br>• For 555-5938 enter "5938" | |

**Demographic Information**

| | |
|---|---|
| Sex | Male Female |
| Your age today (in years) | Years |
| Your weight today | Pounds (lbs.) Kilograms (kgs.) |
| Your height today (in feet/inches) | feet inches |
| Ethnic Identity | |
| Counting from first grade, how many years of school did you finish? | |
| Relationship Status | |

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v3.6 July 8, 2009 11.37pm

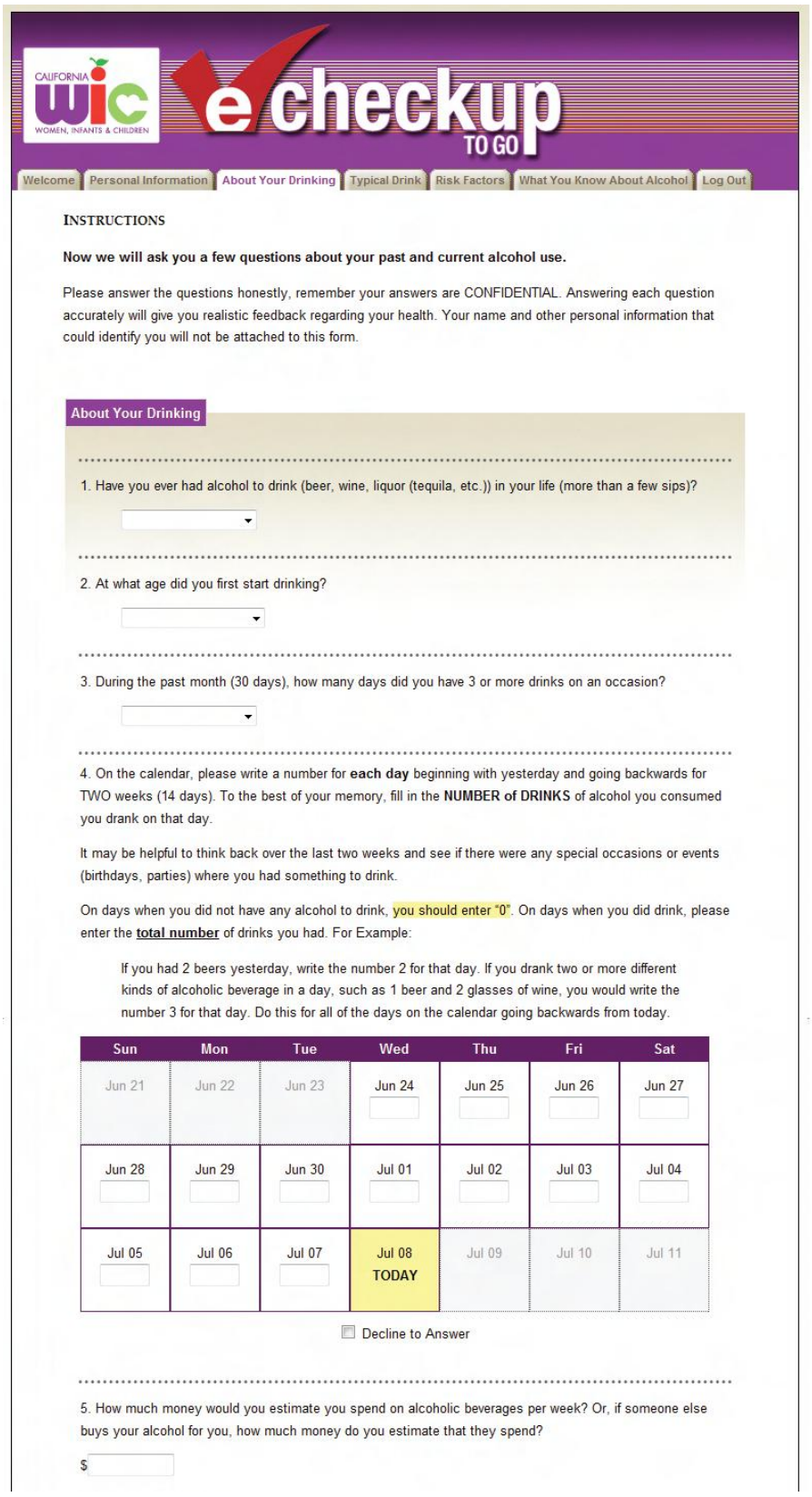
**Health Information**

| | |
|---|---|
| Do you use birth control? | ○ Yes ○ No<br>○ Decline to Answer |
| If you use birth control, what type do you use?<br>(Check all that apply) | ☐ Condoms<br>☐ Pill<br>☐ IUD<br>☐ Other<br>☐ Not Applicable<br>☐ Decline to Answer |
| Other than birth control, are you currently taking any medications prescribed by your doctor? | ○ Yes ○ No<br>○ Decline to Answer |
| Other than birth control, are you currently taking any medications NOT prescribed by your doctor? | ○ Yes ○ No<br>○ Decline to Answer |
| Do you use any drugs that could be considered illegal, such as marijuana, cocaine, methamphetamine, crack, etc? | ○ Yes ○ No<br>○ Decline to Answer |
| Total number of times you have been pregnant in your life<br>*(if pregnant now, include this pregnancy in the total)* | ▾ |
| Total number of living children | ▾ |

**Research Questions**

| | |
|---|---|
| Do you own a mobile (cell) phone? | ○ Yes ○ No<br>○ Decline to Answer |
| Do you use text messaging on your mobile (cell) phone? | ○ Yes ○ No<br>○ Decline to Answer |

NEXT ☞


CALIFORNIA
WIC
WOMEN, INFANTS & CHILDREN
eCheckup
TO GO
Welcome
Personal Information
About Your Drinking
Typical Drink
Risk Factors
What You Know About Alcohol
Log Out
INSTRUCTIONS
Now we will ask you a few questions about your past and current alcohol use.
Please answer the questions honestly, remember your answers are CONFIDENTIAL. Answering each question accurately will give you realistic feedback regarding your health. Your name and other personal information that could identify you will not be attached to this form.
About Your Drinking
1. Have you ever had alcohol to drink (beer, wine, liquor (tequila, etc.)) in your life (more than a few sips)?
2. At what age did you first start drinking?
3. During the past month (30 days), how many days did you have 3 or more drinks on an occasion?
4. On the calendar, please write a number for each day beginning with yesterday and going backwards for TWO weeks (14 days). To the best of your memory, fill in the NUMBER of DRINKS of alcohol you consumed you drank on that day.
It may be helpful to think back over the last two weeks and see if there were any special occasions or events (birthdays, parties) where you had something to drink.
On days when you did not have any alcohol to drink, you should enter "0". On days when you did drink, please enter the total number of drinks you had. For Example:
If you had 2 beers yesterday, write the number 2 for that day. If you drank two or more different kinds of alcoholic beverage in a day, such as 1 beer and 2 glasses of wine, you would write the number 3 for that day. Do this for all of the days on the calendar going backwards from today.
Sun Mon Tue Wed Thu Fri Sat
Jun 21 Jun 22 Jun 23 Jun 24 Jun 25 Jun 26 Jun 27
Jun 28 Jun 29 Jun 30 Jul 01 Jul 02 Jul 03 Jul 04
Jul 05 Jul 06 Jul 07 Jul 08 TODAY Jul 09 Jul 10 Jul 11
Decline to Answer
5. How much money would you estimate you spend on alcoholic beverages per week? Or, if someone else buys your alcohol for you, how much money do you estimate that they spend?
$

CALIFORNIA WIC WOMEN, INFANTS & CHILDREN

eCHECKUP TO GO

Welcome | Personal Information | About Your Drinking | Typical Drink | Risk Factors | What You Know About Alcohol | Log Out

**INSTRUCTIONS**

Now, please answer the following questions.

**What is Your "Typical Drink"**

What **type** of alcoholic beverage did you typically drink in the last month? (**Click the picture.**)

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CALIFORNIA WIC WOMEN, INFANTS & CHILDREN

eCheckup TO GO

Welcome | Personal Information | About Your Drinking | Typical Drink | Risk Factors | What You Know About Alcohol | Log Out

INSTRUCTIONS

Now, please answer the following questions.

**What is Your "Typical Drink"**

You stated that you typically drink **liquor/spirits**. Please look at the pictures and choose the one that looks **most like the type of glass** you usually drink from.

CALIFORNIA WIC WOMEN, INFANTS & CHILDREN

eCHECKUP TO GO

Welcome | Personal Information | About Your Drinking | Typical Drink | Risk Factors | What You Know About Alcohol | Log Out

INSTRUCTIONS

Now, please answer the following questions.

**What is Your "Typical Drink"**

Please select which **size** container do you typically use, or what **amount** do you typically drink? (**Click the picture.**)

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WOMEN, INFANTS & CHILDREN
eCheckup
TO GO
Welcome
Personal Information
About Your Drinking
Typical Drink
Risk Factors
What You Know About Alcohol
Log Out
INSTRUCTIONS
Now, please answer the following questions.
What is Your "Typical Drink"
Thank you. Click "NEXT" to continue.
NEXT
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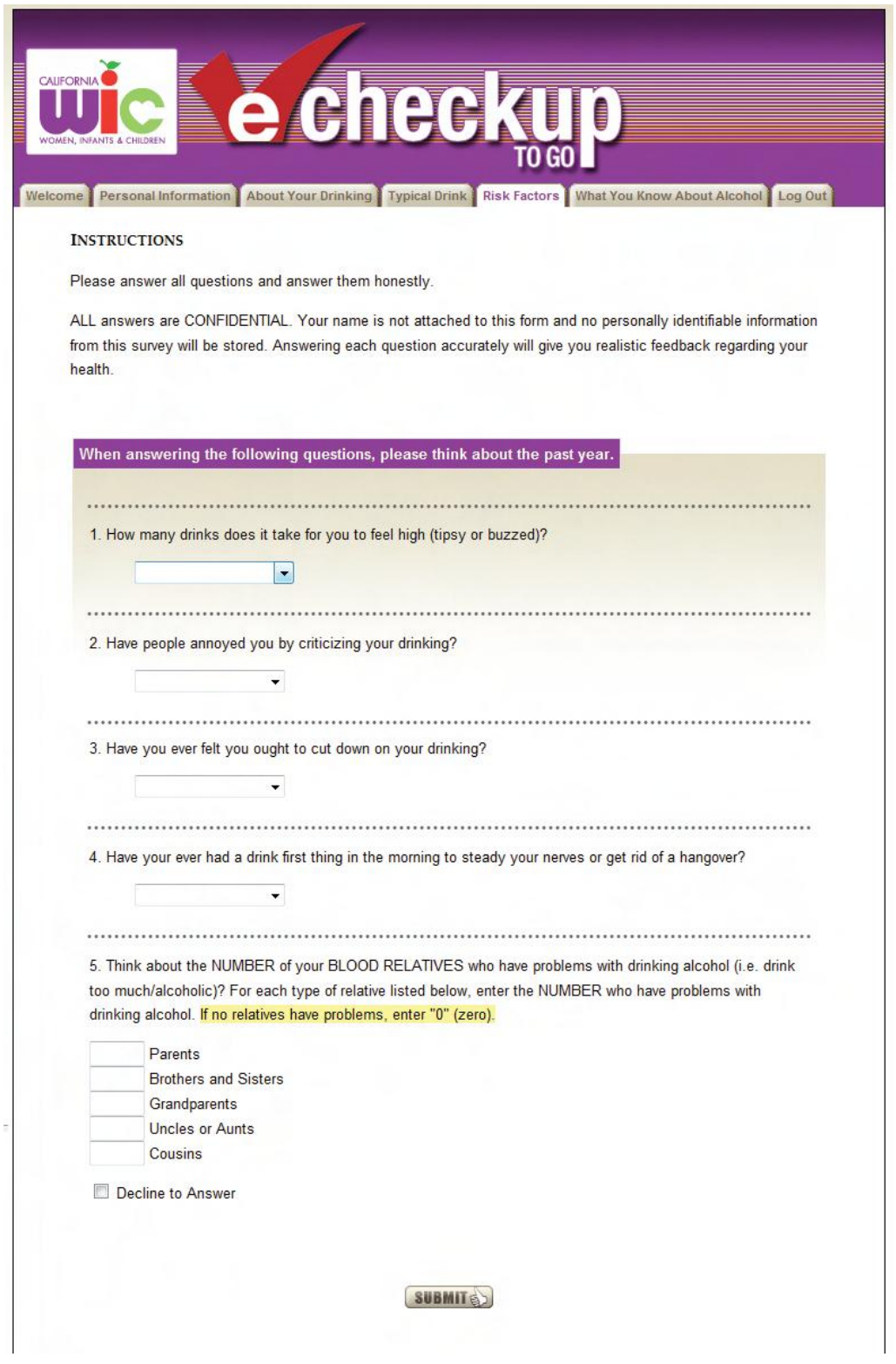
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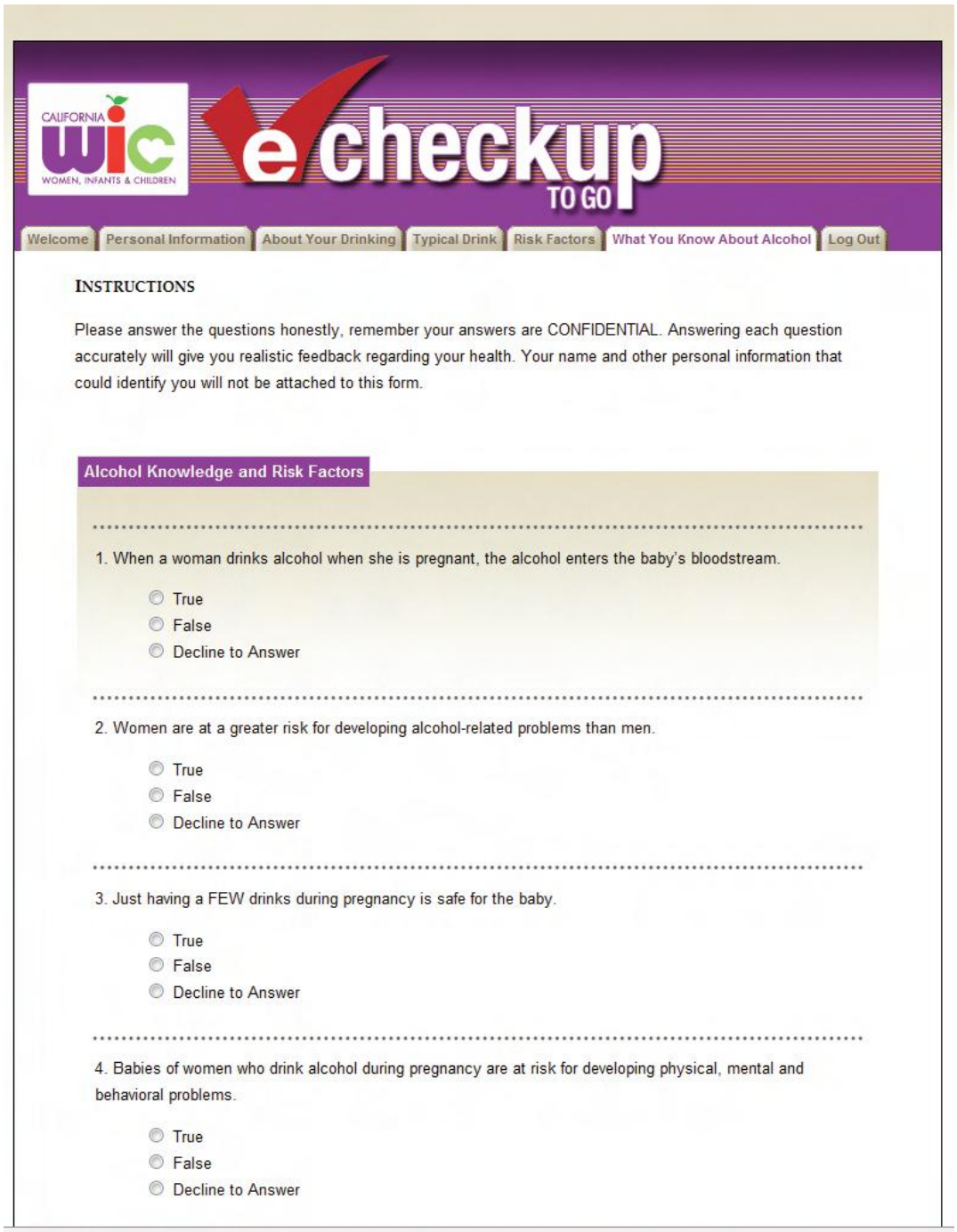
WIC
WOMEN, INFANTS & CHILDREN
eCheckup
TO GO
Welcome
Personal Information
About Your Drinking
Typical Drink
Risk Factors
What You Know About Alcohol
Log Out
INSTRUCTIONS
Please answer all questions and answer them honestly.
ALL answers are CONFIDENTIAL. Your name is not attached to this form and no personally identifiable information from this survey will be stored. Answering each question accurately will give you realistic feedback regarding your health.
When answering the following questions, please think about the past year.
1. How many drinks does it take for you to feel high (tipsy or buzzed)?
2. Have people annoyed you by criticizing your drinking?
3. Have you ever felt you ought to cut down on your drinking?
4. Have your ever had a drink first thing in the morning to steady your nerves or get rid of a hangover?
5. Think about the NUMBER of your BLOOD RELATIVES who have problems with drinking alcohol (i.e. drink too much/alcoholic)? For each type of relative listed below, enter the NUMBER who have problems with drinking alcohol. If no relatives have problems, enter "0" (zero).
Parents
Brothers and Sisters
Grandparents
Uncles or Aunts
Cousins
Decline to Answer
SUBMIT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WIC
WOMEN, INFANTS & CHILDREN
eCheckup
TO GO
Welcome
Personal Information
About Your Drinking
Typical Drink
Risk Factors
What You Know About Alcohol
Log Out
INSTRUCTIONS
Please answer the questions honestly, remember your answers are CONFIDENTIAL. Answering each question accurately will give you realistic feedback regarding your health. Your name and other personal information that could identify you will not be attached to this form.
Alcohol Knowledge and Risk Factors
1. When a woman drinks alcohol when she is pregnant, the alcohol enters the baby's bloodstream.
True
False
Decline to Answer
2. Women are at a greater risk for developing alcohol-related problems than men.
True
False
Decline to Answer
3. Just having a FEW drinks during pregnancy is safe for the baby.
True
False
Decline to Answer
4. Babies of women who drink alcohol during pregnancy are at risk for developing physical, mental and behavioral problems.
True
False
Decline to Answer

5. Drinking alcohol is OK during the last trimester of pregnancy.

- ○ True
- ○ False
- ○ Decline to Answer

6. On average, you drink More Than other women your age in the U.S.

- ○ True
- ○ False
- ○ Decline to Answer

7. If a pregnant woman drinks before she knows she is pregnant, she can have a child with an Alcohol Related Birth Defect.

- ○ True
- ○ False
- ○ Decline to Answer

8. During the PAST MONTH, how many cigarettes did you smoke on a typical day?
*(If you do not smoke, enter "0")*

_____ Cigarettes

☐ Decline to Answer

9. If you're a smoker, for how many years have you smoked regularly?
*(If you do not smoke, enter "0")*

_____ Years

☐ Decline to Answer

NEXT ☞

Referral information about Alcoholics Anonymous can be obtained by visiting AASanDiego.org or by contacting the **San Diego AA Central Office** at (619) 265-8762 (7075 Mission Gorge Road, Suite B, San Diego, CA 92120). Other treatment options (such as SMART Recovery) may also be available.

Additional information can be found on-line at:

- Center for Disease Control, Tobacco Information and Prevention Sourcepage
- Cocaine Anonymous
- Mothers Against Drunk Driving
- Narcotics Anonymous
- National Clearinghouse for Alcohol and Drug Information
- National Council on Alcoholism and Drug Dependence
- National Institute on Alcohol Abuse and Alcoholism
- National Institute on Drug Abuse
- National Women's Health Resource Center
- Office of Minority Health Resource Center

## CREDITS

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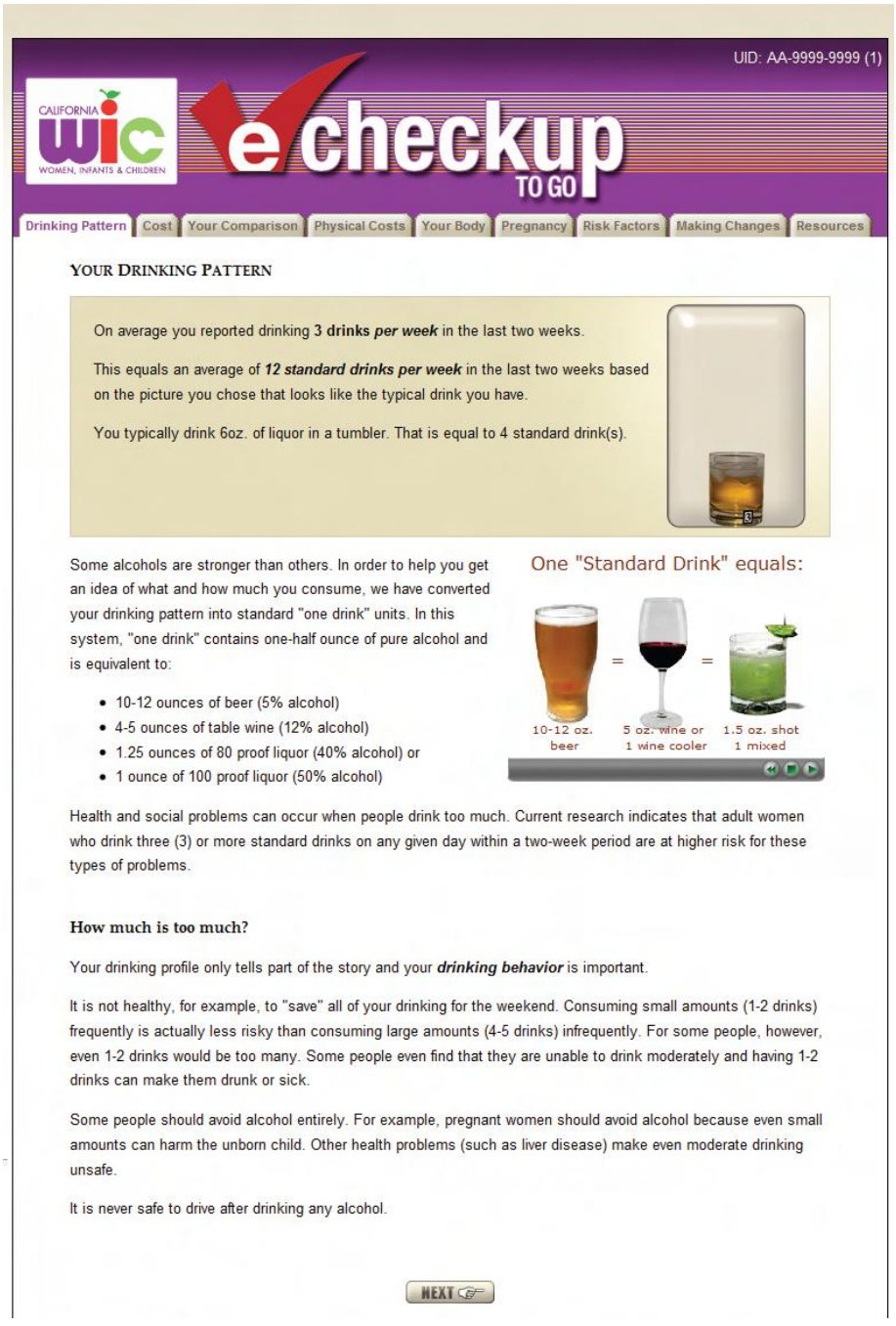
## APPENDIX C – Screen Shot of Sample Experimental Group Feedback



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CALIFORNIA WIC WOMEN, INFANTS & CHILDREN

eCheckup TO GO

Drinking Pattern | Cost | Your Comparison | Physical Costs | Your Body | Pregnancy | Risk Factors | Making Changes | Resources

## The Cost to You

You reported that you (or whoever buys alcohol for you) spend(s) **$520.00** on alcohol every year.

**Did you know...**
By volume, alcohol is more expensive than other drinks. It's more expensive than water, soda, and milk.

It's even more expensive than oil or gasoline!

If you had this money now, you could have purchased about:

**4 weeks of groceries** to feed a family of 4!
(The average cost of groceries for a family of four is $109.50 (USDA))

A **$520.00 shopping spree** for new cloths or shoes!

**2 birthday parties** for your child(ren)!
(The average cost for a child's birthday party is $200.00 (familycorner.com))

A family vacation to Disneyland for **1 day(s)** for a family of four!
(The average cost for of a family vacation to Disneyland is $500.00 per day (family of four; Fodor's Travel Guide))

NEXT

UID: AA-9999-9999 (1)
CALIFORNIA WIC WOMEN, INFANTS & CHILDREN
eCheckup TO GO
Drinking Pattern
Cost
Your Comparison
Physical Costs
Your Body
Pregnancy
Risk Factors
Making Changes
Resources
HOW DOES YOUR DRINKING COMPARE?
Did you know...only 48.1% of women in the US drink alcohol.
49%
98.1% of women in the US who are about your age and of the same ethnic background drink less than you.
99%
This tells you what percent of American women drink less than you in a typical month. This information is from a nationwide survey in the US (Behavioral Risk Factor Surveillance System (BRFSS) sponsored and conducted by the Centers for Disease Control and Prevention (CDC) in 2007).
The BRFSS is the world's largest, on-going telephone health survey system, tracking health conditions and risk behaviors in the United States yearly since 1984. Currently, data are collected monthly in all 50 states, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and Guam.
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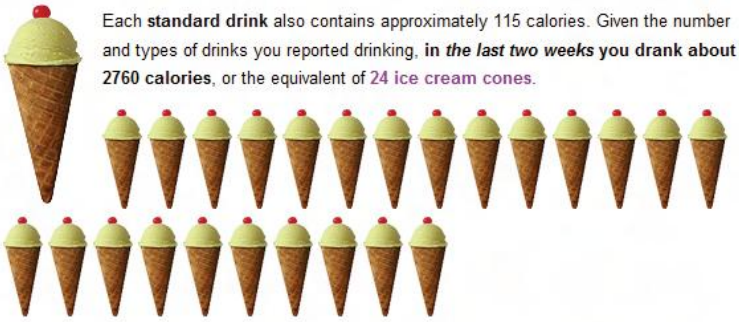
CALIFORNIA WIC WOMEN, INFANTS & CHILDREN

eCHECKUP TO GO

Drinking Pattern | Cost | Your Comparison | Physical Costs | Your Body | Pregnancy | Risk Factors | Making Changes | Resources

## PHYSICAL COSTS

**How many ice cream cones did you *drink* in the last two weeks?**



Each **standard drink** also contains approximately 115 calories. Given the number and types of drinks you reported drinking, **in *the last two weeks* you drank about 2760 calories**, or the equivalent of 24 ice cream cones.

If you ran at a pace of 6 miles per hour (a 10-minute mile) you would have to run for **5 hours and 18 minutes** to burn off all of the calories you accumulated from drinking alcohol.

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## WHAT YOU KNOW ABOUT: ALCOHOL & YOUR BODY

**You got 2 out of 2 right!**

**Women are at a greater risk for developing alcohol-related problems than men.**

**You Said:** TRUE **Answer:** TRUE

With any health issue, accurate information is very important. There are times and ways to drink that are safer than others. Every woman is different. No amount of drinking is 100 percent safe, 100 percent of the time, for every woman. With this in mind, it's important to know how alcohol can affect a woman's health and safety.

Even in small amounts, alcohol affects women differently than men. In some ways, heavy drinking is much more risky for women than it is for men.

Why are lower levels of drinking recommended for women than for men? Because differences in the way a woman's body works as compared to a man places women at greater risk than men for developing alcohol-related problems. A woman's brain and other organs are exposed to more of the toxic byproducts from alcohol that result when the body breaks down and eliminates alcohol.

Some people should not drink at all, including:

- Anyone under age 21
- People of any age who are unable to restrict their drinking to moderate levels
- Women who may become pregnant or who are pregnant
- People who plan to drive, operate machinery, or take part in other activities that require attention, skill, or coordination
- People taking prescription or over-the-counter medications that can interact with alcohol.

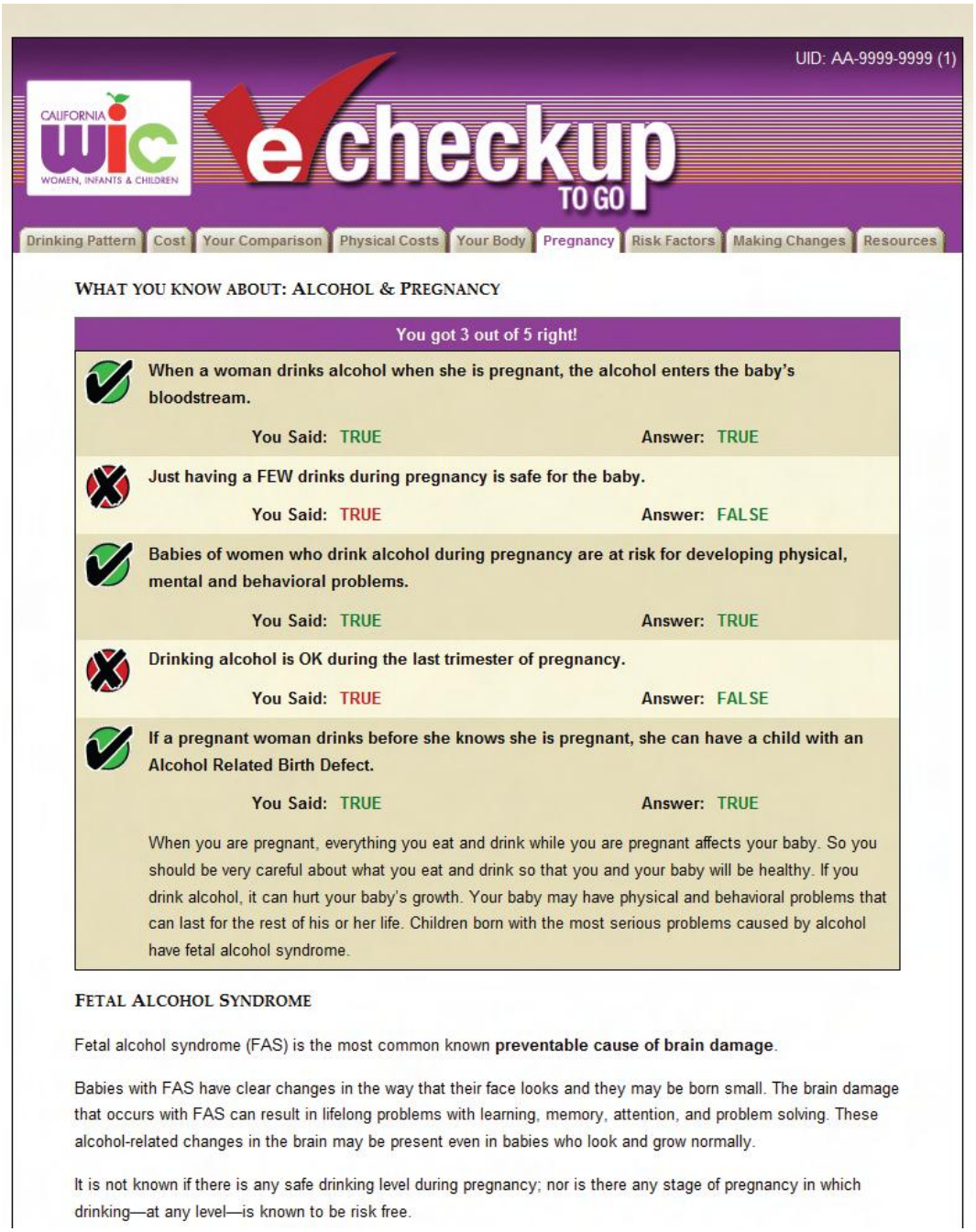
**On average, you drink MORE than other women your age in the U.S.?**

**You Said:** TRUE **Answer:** TRUE

Only **48.1% of women in the US drink alcohol**. Of these women who drink, only one out of ten (1/10) averages two or more drinks a day.

For women, two drinks a day is above what the Dietary Guidelines for Americans call "moderate," which recommends no more than one drink a day for women. Young women in their 20's and early 30's are more likely to drink than older women. No one factor predicts whether a woman will have problems with alcohol, or at what age she is most at risk.

The guidelines for moderate drinking form part of the Dietary Guidelines for Americans issued jointly by the U.S. Department of Agriculture and the U.S. Department of Health and Human Services. (The Dietary Guidelines can be viewed on–line at the website www.nutrition.gov) The Guidelines point out that drinking more than one drink per day for women or two drinks per day for men can raise the risk for motor vehicle crashes, other injuries, high blood pressure, stroke, violence, suicide, and certain types of cancer.


UID: AA-9999-9999 (1)
CALIFORNIA WIC WOMEN, INFANTS & CHILDREN
eCheckup TO GO
Drinking Pattern
Cost
Your Comparison
Physical Costs
Your Body
Pregnancy
Risk Factors
Making Changes
Resources
WHAT YOU KNOW ABOUT: ALCOHOL & PREGNANCY
You got 3 out of 5 right!
When a woman drinks alcohol when she is pregnant, the alcohol enters the baby's bloodstream.
You Said: TRUE
Answer: TRUE
Just having a FEW drinks during pregnancy is safe for the baby.
You Said: TRUE
Answer: FALSE
Babies of women who drink alcohol during pregnancy are at risk for developing physical, mental and behavioral problems.
You Said: TRUE
Answer: TRUE
Drinking alcohol is OK during the last trimester of pregnancy.
You Said: TRUE
Answer: FALSE
If a pregnant woman drinks before she knows she is pregnant, she can have a child with an Alcohol Related Birth Defect.
You Said: TRUE
Answer: TRUE
When you are pregnant, everything you eat and drink while you are pregnant affects your baby. So you should be very careful about what you eat and drink so that you and your baby will be healthy. If you drink alcohol, it can hurt your baby's growth. Your baby may have physical and behavioral problems that can last for the rest of his or her life. Children born with the most serious problems caused by alcohol have fetal alcohol syndrome.
FETAL ALCOHOL SYNDROME
Fetal alcohol syndrome (FAS) is the most common known preventable cause of brain damage.
Babies with FAS have clear changes in the way that their face looks and they may be born small. The brain damage that occurs with FAS can result in lifelong problems with learning, memory, attention, and problem solving. These alcohol-related changes in the brain may be present even in babies who look and grow normally.
It is not known if there is any safe drinking level during pregnancy; nor is there any stage of pregnancy in which drinking—at any level—is known to be risk free.

**If a woman is pregnant, or wants to become pregnant, she should not drink alcohol.** Even if she is pregnant and already has consumed alcohol, it is important to stop drinking for the rest of her pregnancy. Stopping can reduce the chances that her child might be harmed by alcohol.

- No amount of alcohol consumption can be considered safe during pregnancy.
- Alcohol can damage a baby at any time during pregnancy.
- If you drank alcohol before you knew you were pregnant, stop drinking now. You will feel better, and your baby will have a good chance to be born healthy. If you want to get pregnant, do not drink alcohol.
- There are many ways to help you stop drinking. You do not have to drink when other people drink. If someone gives you a drink, it is OK say no. Stay away from people or places that make you drink. Do not keep alcohol at home.
- It is never too late to stop. Look for help to quit.

**DISCLAIMER:**

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CALIFORNIA WIC WOMEN, INFANTS & CHILDREN

eCheckup TO GO

Drinking Pattern | Cost | Your Comparison | Physical Costs | Your Body | Pregnancy | Risk Factors | Making Changes | Resources

## PERSONAL RISK FACTORS

There are several factors that may indicate your overall risk of developing alcohol-related problems. While there is no way to definitely predict whether a person will be harmed by alcohol or develop alcohol dependence, "high-risk" areas are areas to which you may want to give additional consideration in the future.

### Your Individual Risk

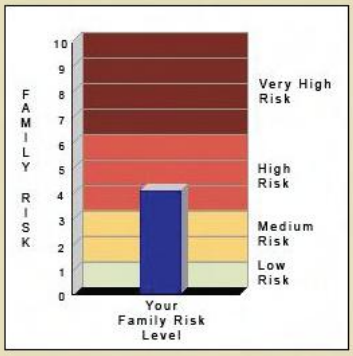
Your Individual Risk score is: **2 out of 5**.

Based on your Score, you have a **11.7** likelihood of risk-drinking.

Your individual risk was calculated using a risk assessment 'score card' especially developed for women who could get pregnant. On a scale ranging from 0 to 5, a score of 2 or more is considered positive for risky-drinking (for example, alcohol use that can potentially harm an unborn child).

### Your Family Risk

Your family risk level is: **4**.




Based on your family risk level, your risk of developing future alcohol dependence or related problems is: **high**.

Family Risk Scale

People with a history of alcohol or drug problems among their blood relatives are at higher risk themselves. This may happen through either inheriting a higher tolerance or a sensitivity to alcohol. The more relatives with alcohol problems you have, the higher *your* risk for problems with alcohol.

Your risk increases if your relatives with alcohol problems are the same gender and/or are more closely related.

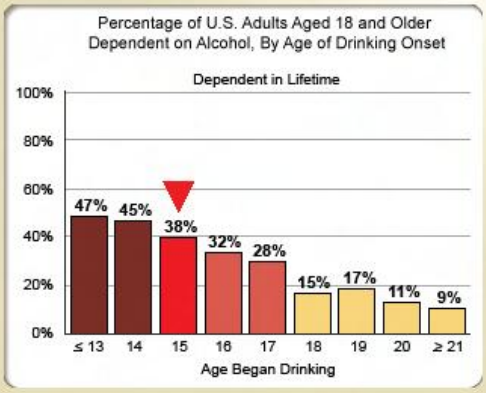
Your score is calculated based on the National Institute on Alcohol Abuse and Alcoholism's Project MATCH criteria.

**Early alcohol users are more likely to be alcohol dependent**

**You said that you began drinking alcohol at age 15.** In an analysis of data from the National Epidemiologic Survey on Alcohol and Related Conditions (NESARC), early alcohol users were more likely to develop alcohol dependence at a later age. Nearly one-half (47%) of persons who began drinking before age 14 were alcohol dependent at some point in their lifetime, and 13% were dependent in the past year, compared to 9% and 2%, respectively, of those who began drinking after age 20.

While it is not yet known if drinking at an early age actually causes later alcohol problems, there is a clear relationship between early alcohol use and later alcohol problems and dependency. **These data suggest that delaying drinking may reduce your risk of later alcohol problems and dependency**.

**More than one-third (38%)** of persons who began drinking at age 15 were **alcohol dependent** at some point in their lifetime.




Adapted by CESAR from Hingson, R.W., Heeren, T., and Winter, M.R. *Age at Drinking Onset and Alcohol Dependence*, Archives of Pediatrics and Adolescent Medicine160(7):739-746, 2006. Available online at archpedi.ama-assn.org/cgi/reprint/160/7/739. For more information, contact Dr. Ralph Hingson at rhingson@mail.nih.gov.

NEXT

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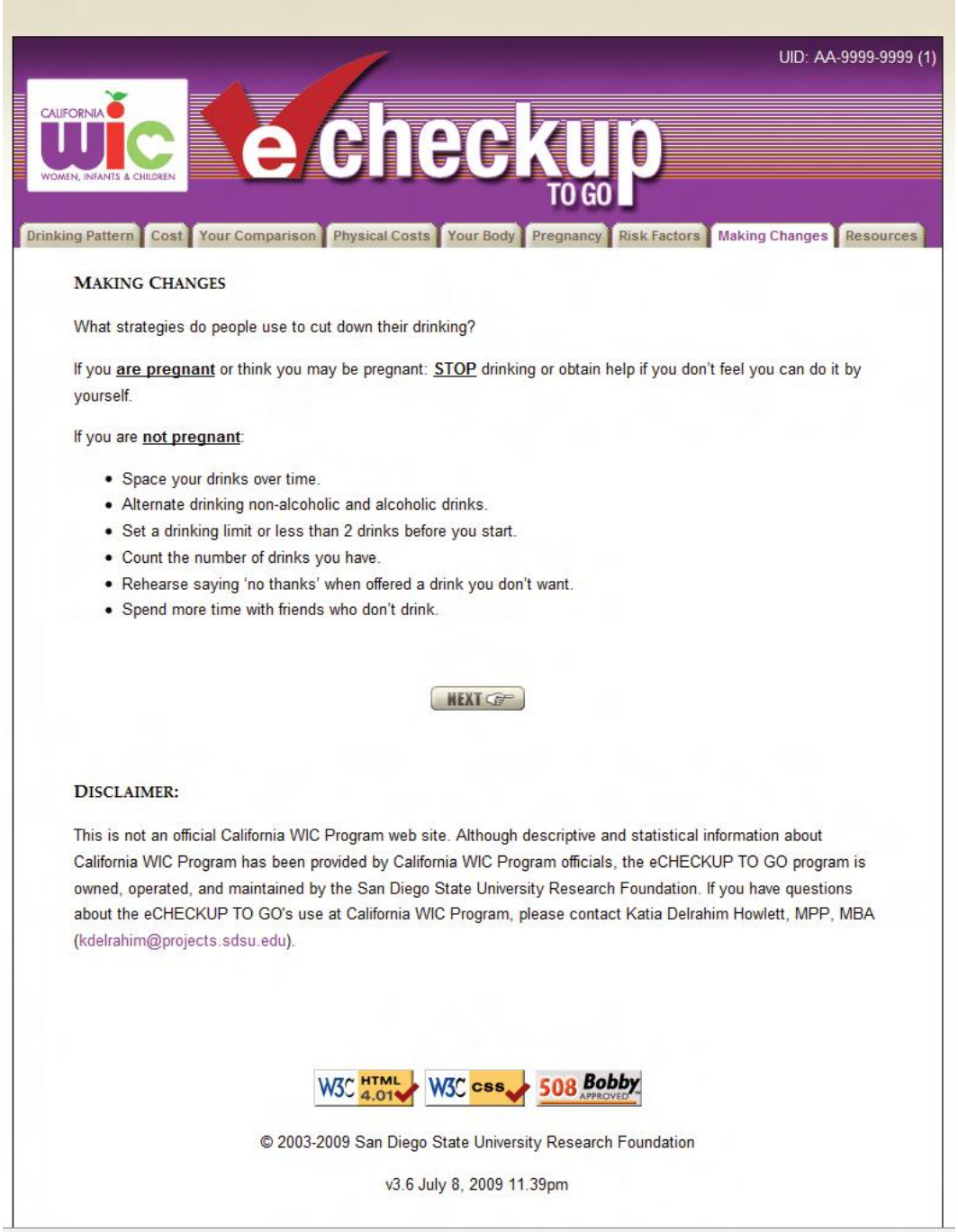
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CALIFORNIA WIC WOMEN, INFANTS & CHILDREN
eCHECKUP TO GO
Drinking Pattern
Cost
Your Comparison
Physical Costs
Your Body
Pregnancy
Risk Factors
Making Changes
Resources
MAKING CHANGES
What strategies do people use to cut down their drinking?
If you are pregnant or think you may be pregnant: STOP drinking or obtain help if you don't feel you can do it by yourself.
If you are not pregnant:
Space your drinks over time.
Alternate drinking non-alcoholic and alcoholic drinks.
Set a drinking limit or less than 2 drinks before you start.
Count the number of drinks you have.
Rehearse saying 'no thanks' when offered a drink you don't want.
Spend more time with friends who don't drink.
NEXT
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CALIFORNIA WIC WOMEN, INFANTS & CHILDREN
eCheckup TO GO
Drinking Pattern
Cost
Your Comparison
Physical Costs
Your Body
Pregnancy
Risk Factors
Making Changes
Resources
RESOURCES
Thank you for your participation in our research project! Please see more resources and numbers you can call below...
If you have any questions or concerns about the research, please feel free to contact Dr. Christina Chambers at 619-294-3791 OR Dr. John Clapp at 619-229-2396.
If you need information about the effects of alcohol and other drugs during pregnancy:
Call the Pregnancy Risk Information Line
1-800-532-3749
If you need help quitting alcohol, tobacco, or drugs:
Call the UCSD Perinatal Case Management and Street Outreach Program
1-858-514-7545
If you need help to start prenatal care, assistance in applying for Medi-Cal and other resources in the community:
Call the Perinatal Care Network
1-800-675-2229
PRINT RESULTS
PRINT CERTIFICATE
LOGOUT

Referral information about Alcoholics Anonymous can be obtained by visiting AASanDiego.org or by contacting the **San Diego AA Central Office** at (619) 265-8762 (7075 Mission Gorge Road, Suite B, San Diego, CA 92120). Other treatment options (such as SMART Recovery) may also be available.

Additional information can be found on-line at:

- Center for Disease Control, Tobacco Information and Prevention Sourcepage
- Cocaine Anonymous
- Mothers Against Drunk Driving
- Narcotics Anonymous
- National Clearinghouse for Alcohol and Drug Information
- National Council on Alcoholism and Drug Dependence
- National Institute on Alcohol Abuse and Alcoholism
- National Institute on Drug Abuse
- National Women's Health Resource Center
- Office of Minority Health Resource Center

## CREDITS

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## APPENDIX D – Screen Shot of Sample Control Group Feedback

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CALIFORNIA WIC WOMEN, INFANTS & CHILDREN

eCheckup TO GO

Important Things You Should Know | When You Are Pregnant | Resources

## WHEN YOU ARE PREGNANT…

## DRINKING CAN HURT YOUR BABY

When you are pregnant, everything you eat and drink while you are pregnant affects your baby. So you should be very careful about what you eat and drink so that you and your baby will be healthy. If you drink *alcohol*, it can hurt your baby's growth. Your baby may have physical and behavioral problems that can last for the rest of his or her life. Children born with the most serious problems caused by alcohol have *fetal alcohol syndrome*.

### Fetal Alcohol Syndrome

*Fetal alcohol syndrome* (FAS) is the most common known preventable cause of brain damage. Babies with FAS have clear changes in the way that their face looks and they may be born small. The brain damage that occurs with FAS can result in lifelong problems with learning, memory, attention, and problem solving. These alcohol-related changes in the brain may be present even in babies who look and grow normally. It is not known if there is any safe drinking level during pregnancy; nor is there any stage of pregnancy in which drinking - at any level - is known to be risk free. If a woman is pregnant, or wants to become pregnant, she should not drink alcohol. Even if she is pregnant and already has consumed alcohol, it is important to stop drinking for the rest of her pregnancy. Stopping can reduce the chances that her child might be harmed by alcohol.

- No amount of alcohol consumption can be considered safe during pregnancy.
- Alcohol can damage a baby at any time during pregnancy.
- If you drank alcohol before you knew you were pregnant, stop drinking now. You will feel better, and your baby will have a good chance to be born healthy. If you want to get pregnant, do not drink alcohol.
- There are many ways to help you stop drinking. You do not have to drink when other people drink. If someone gives you a drink, it is OK say no. Stay away from people or places that make you drink. Do not keep alcohol at home.
- It is never too late to stop. Look for help to quit.

NEXT

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CALIFORNIA WIC WOMEN, INFANTS & CHILDREN
echeckup TO GO
Important Things You Should Know
When You Are Pregnant
Resources
RESOURCES
Thank you for your participation in our research project! Please see more resources and numbers you can call below...
If you have any questions or concerns about the research, please feel free to contact Dr. Christina Chambers at 619-294-3791 OR Dr. John Clapp at 619-229-2396.
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1-800-532-3749
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1-858-514-7545
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1-800-675-2229
PRINT RESULTS
PRINT CERTIFICATE
LOGOUT

## APPENDIX E – Satisfaction Questionnaire

### eCheckUp Satisfaction Survey

**Please Fill Out the Following Information**

First 2 letters of your first name (example KA for KATIA) ___ ___

Month and Day of Birth (example 1221 for December 21, or 0309 for March 9) ___ ___ ___ ___

Last 4 digits (numbers) in your phone number (example 2323 for 456-2323) ___ ___ ___ ___

**Please answer all questions and answer them honestly.**
ALL answers are CONFIDENTIAL.
Your name is not attached to this form and no personally identifiable information from this survey will be stored.
Answering each question accurately will help the research team improve the program for future use.

**Please circle your answer to each question.**

| | | |
|---|---|---|
| **1)** Were you comfortable using the program? | Yes | No |
| **2)** Was the program easy to use? | Yes | No |
| **3)** Do you feel that the program was useful? | Yes | No |
| **4)** Were you satisfied with the quality of the program? | Yes | No |
| **5)** Did the program take too long to finish? | Yes | No |
| **6)** Did you find the program interesting? | Yes | No |
| **7)** Would you use this type of program again? | Yes | No |

**Thank you!**

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