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PREDICTORS OF EXPERIMENTAL AND CONTROL GROUP ATTENDANCE: FINDINGS FROM AN HIV/STD PREVENTION RCT WITH PREGNANT WOMEN AT RISK FOR SUBSTANCE USE

Jaclyn S. Sadicario
Virginia Commonwealth University

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A thesis submitted in partial fulfillment of the requirements for the degree of Master of
Science at Virginia Commonwealth University.

by
Jaclyn Sara Sadicario
Bachelor of Arts, Temple University, May 2011

Director: Dace S. Svikis, Ph.D.
Professor
Department of Psychology

Virginia Commonwealth University
Richmond, Virginia
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Abstract

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Efforts to improve inclusion in research have included mandating the recruitment of

ethnic minorities and women into NIH funded studies. However, little research has been

completed on who attends such interventions. This is particularly worrisome in populations for

which attendance to interventions can have dire consequences. HIV is a public health concern for

pregnant women in substance using communities, as pregnant women are much less likely to use

condoms during intercourse to prevent HIV. Group modular HIV prevention interventions have

long been the standard for HIV prevention. However, little attention in research on HIV

prevention interventions RCTs has been focused on attendance to these interventions. This study

examined predictors of intervention and control group attendance in a randomized controlled

trial comparing a 5-session Safer Sex Skill Building (SSB) intervention to a 1-session HIV

education control group in a sample of pregnant women at risk for prenatal substance use. This

study identified psychosocial and mental health variables associated with both 1 session control

group and 5-session SSB intervention attendance as well as endeavored to identify the number of sessions necessary to attend to achieve an adequate dose in treatment. Findings include younger age and marital status as being predictive of participation in the one session HE control group and having a trade, skill, or profession as being predictive of participation in the five session SSB intervention group. Further research is needed to understand what factors may impact five-session SSB group attendance.

Keywords: attendance, RCT, HIV prevention, research participation, perinatal substance use, pregnant women, health behavior intervention

Predictors of Experimental and Control Group Attendance: Findings from an HIV/STD

Prevention RCT with Pregnant Women at Risk for Substance Use

One problem endemic to the field of clinical research is that of the historical focus on homogenous, white populations. Advocates for inclusivity of women and ethnic minorities in study samples found themselves heard when legislation passed mandating that all government funded research projects make a concerted effort to diversify their samples. While this legislation is pivotal in promoting lasting change in the makeup of participants, there is still concern with those populations we may not be reaching with our work; this is not just an issue of research integrity but also of ensuring that our interventions are appropriately tailored to the populations we intend on serving. While work is being completed to understanding the differences between who consents to participation in research studies of clinical interventions as compared with those who do not, there is scant research being completed regarding who attends these interventions. Understanding psychosocial and mental health correlates of attendance to interventions could potentially offer researchers insight into improving not only the impact of their interventions, but also understanding how they could improve their interventions. This is of concern for those participants for which intervention could potentially prove but a life-extending and cost-efficient impact.

In the last three decades, a great deal of consideration has been given to diversifying randomized controlled trial samples in order to make results more generalizable to the population at large. In 1993, the National Institutes of Health (1993) passed the Revitalization Act, which issued guidelines on the inclusion of women and ethnic minorities in research. The policy mandates the inclusion of women and members of minority groups in all NIH funded research grants. While this policy has largely influential in creating an increasingly inclusive body of

research, more work is to be done on reaching those individuals who could feasibly benefit from these interventions. Current research is focused on improving these gaps in studies, as research has been conducted on the potential psychosocial and mental health factors that might correlate with not consenting to participate in research (Kelpin, Ondersma, & Svikis, 2017). Although policies have sought to continue to push for the inclusion of individuals from different backgrounds, there is inconclusive information in regard to who attends, or is retained during the intervention period, in randomized control trials of behavioral health related interventions. However, attrition, for which non-attendance during the intervention can contribute to, continues to be an issue in many trials. Dumville and colleagues (2006) state that much attrition prevents a full intention to treat analysis being carried out and can introduce bias and serves as a threat to both internal and external validity.

The challenges of rigor and integrity to research that are posed by attrition to health behavior change interventions limit our ability to generalize results, however, the general issue of non-attendance in clinical settings results in pour outcomes. Generally speaking in clinical populations, non-adherence to medical interventions is estimated to cause 125,000 deaths and constitutes at least 10% of hospitalizations and has been estimated to cost the U.S. healthcare system "between $100 billion and $289 billion annually" (Viswanathan et. al, 2012). Non-adherence extends to psychiatric and substance use patients as well, as one study found that among patients with co-occurring mental health and substance use disorders, about 40% had issues adhering to their treatment regimen, with other studies demonstrating a range of drop-out from 23–50% in outpatient treatment (Herbeck et. al, 2005).

There are gender-based variables that may be implicated when discussing treatment drop-out. Women are more likely than men to drop out of substance abuse treatment (Stark, 1992) and

women attend fewer substance use treatment sessions than men (McCaul, Svikis, & Moore, 2001). Several factors may be implicated in these gender differences in retention in treatment. Women who were referred to treatment for legal reasons or by an agency were more likely to complete treatment than others. In one study, women with less favorable employment arrangements were less found to be likely to complete treatment than other women (Green et. al, 2002). One area where this is particularly relevant is in the retention of women who screen at risk for substance use to HIV prevention interventions.

Though the subgroup that is leading in new infections is men who have sex with men (MSM), the incidence of HIV in women has grown considerably (CDC, 2015). Women contracting HIV from heterosexual contact has become a growing issue in the U.S. (CDC, 2015). Pregnancy in women can alone increase risk of HIV even in women who are not using injection drugs themselves, as pregnant women are significantly less likely to use condoms during sexual activity (Deren, Beardsley, Davis, & Tortu, 1993). Thus, both pregnancy and exposure to drug use settings, put women at high risk for HIV. Drug use treatment itself has served as a means of preventing HIV risk behaviors in a number of studies (Tross et. al, 2008). One evidence-based approach to reducing HIV risk behaviors in the context of a treatment clinic is "Safer Sex Skill Building" (SSB), a manual-driven 5-session group HIV/STD prevention intervention that was designed for females who use drugs (CDC, 2009; Tross et al., 2008). In a multi-site clinical trial, SSB was found to be effective in reducing sexual risk behaviors of women at 6-month follow-up when compared to a one-session, 60-minute Health Education (HE) control group (Tross et al., 2008). The SSB consists of five ninety-minute group sessions that are aimed at teaching women skills related to condom use, identifying abuse patterns in relationships, and sexual health promotion. The intervention is cumulative in nature, meaning that skills from one session are

built upon in the sessions thereafter. Still, little is known about what may make a participant more or less likely to attend the intervention or control groups of these or related interventions. As with drug use treatment, there are variables that can be implicated when discussing intervention attendance. For instance, several studies cite lower income and less familial support as barriers to completing treatment (Prado, Pantin, Schwartz, Lupei, & Szapocznik, 2005; Liu, 2014). In addition to those two factors, another study found that individuals with inconsistent housing also may have difficulties attending (Lauby et. al 1996). Financial insecurity and lack of social support may be implicated in a woman's ability to attend such an intervention.

In addition to the literature on attendance predictors, little is known about how much "dose" (operationalized as "treatment attendance") is needed to provide a significant outcome in this population (Tross et al. 2008). Previous studies of the SSB in drug use treatment settings have implicated the importance attendance in achieving outcomes but have only specific a range of sessions attended (i.e.: 3-5) to achieve what can be estimated as an adequate dose of attendance (Tross et. al, 2008). The previous studies analyzed if increasing amounts of treatment attendance produce more robust effects of treatment in this specific intervention (Tross et. al 2008; Crits-Christoph et. al, 2014). Additionally, the role of dose of the SSB intervention in prenatal care settings with women who are at risk for using drugs (not just those currently using substances) and are pregnant is unknown.

The purpose of this study was to identify demographic. psychosocial, and mental health variables associated with attendance to an HIV prevention intervention specifically engineered for pregnant women at risk for substance use. Specifically, this study assesses the predictors of attendance to the study control group, a one session education session (HE) as well as predictors of attendance to the five session Safer Sex Skills Building intervention (SSB). Additionally, this

study aims to identify what dose of treatment (i.e. how many sessions attended) is needed to establish outcomes in an urban prenatal care clinic. Specifically, this analysis intended to address how many sessions patients need to attend in order to improve condom use intention between intervention and post-study follow-up. Specific psychosocial factors will be chosen based on the literature regarding retention, attendance, and attrition for other multi-session HIV prevention interventions.

Review of the Literature

Brief History

In the last three decades, a great deal of consideration has been given to diversifying randomized controlled trial samples to make results more generalizable to the population at large. Prior to the 1980's clinical trials often enrolled homogenous samples of white male participants, and results were assumed to generalize to female and ethnic minority populations. However, persons of different backgrounds have different socialization, experiences, expectations, and cultural influences; all of these factors can lead to differences in health. The continued exclusion of people of color and women from clinical research was an oversight in that the purpose of these clinical trials is to understand how to support individuals in order to improve their health outcomes and translate those outcomes into practice and policy. The research does not prove useful if it does not reflect the populations it serves. In 1993, the National Institutes of Health (1993) passed the Revilitization Act, which issued guidelines on the inclusion of women and ethnic minorities in research. The policy was introduced because there was a growing recognition that the quality and generalizability of research depended on the inclusion of participants across the continuum of psychosocial and biological variables, such as race, ethnicity, sex, as well as biomarkers. The policy mandates the inclusion of women and members of minority groups in all NIH funded research grants. Additionally, the grantees are responsible for indicating if the treatment differentially affected groups based on variables of identity (Bennet, 1993). This requirement was a big advancement towards inclusion of women and ethnic minority groups in research, however, it was not without fault. While the lofty goals of this mandate seem ideal, they can be a challenge practically. Many academic researchers fail to capture diversity in their samples on their own without partnering with other external

organizations, which makes studies more expensive. Therefore, a chasm was created between the intention of the care being studied and the quality of care samples actually received in the community.

The first area that warrants more attention is informed consent and representativeness of those who do and do not enroll in studies. Research in this field is focused on improving this gap in clinical studies, as research has been conducted on the potential psychosocial and mental health factors that might correlate with not consenting to participate in research (Kelpin, Ondersma, & Svikis, 2017). Despite what was speculated in previous literature, one such study by Kelpin and colleagues (2017) found that individuals belonging to an ethnic minority were not less likely to consent than those who were white. Additionally, individuals who were of a lower socioeconomic status were not less likely than those of a higher socioeconomic status to consent to study participation. These findings present a great insight to our perspective on enrollment, but more work is yet to be done; the efforts spent in recruiting participants who are of varied groups might not be reflected in those that continue to participate in interventions after the enrollment period.

Attrition: What is Lost?

Although NIH policies have sought to continue to push for the inclusion of individuals from different backgrounds, there is inconclusive information in regard to who attends, or is retained during the intervention period, in randomized control trials of behavioral health related interventions. Specifically, it is known that researchers laud the RCT for its evaluative strength due, to its balancing of participant characteristics across groups, with any differences being attributable to chance. However, attrition, for which non-attendance during the intervention can contribute to, continues to be an issue in many trials. Attrition is defined as "a loss of subjects

over the course of an experiment that can change the composition of [experimental] groups"
(Kazdin, 2016). Dumville and colleagues (2006) state that attrition can introduce bias and serves
as a threat to both internal and external validity. Attrition threatens internal validity because
patient attrition could be due to an unknown variable making it more difficult to detect if
selection bias has occurred, which would result in a loss of group comparability (Kazdin, 2016).
That is, changes in outcomes might be attributable to the absence of those who have dropped out.
Additionally, attrition can lead to a smaller sample size which may impact the power of
statistical analysis. Attrition threatens external validity by further narrowing the slice of the
population from which data is being analyzed, therefore potentially decreasing the
generalizability of the results. Further, differential attrition between intervention and control
groups may mean that control groups entail a 'unique and different [experience] from general
participation in research' (Noguchi, Albarracín, Durantini, & Glasman, 2007). One analysis of
several health promotion interventions demonstrated that control conditions had, on average, a
10% higher attrition than intervention conditions (Crutzen et. al, 2004). This is particularly
problematic because it can be deduced that participants may perceive the difference in treatment
administered, which may affect their attendance, and is therefore a viable threat to validity.
Though there are a number of studies that support the use of psychosocial treatment for mental
health issues (i.e. mood disorders and anxiety disorders), as well as behavioral health issues like
substance use, pain, weight management, exercise, STI preventions, insomnia, and others,
attrition is still common (Anderson, 2004). That is, despite the impact of attrition on outcomes,
as well as the evidence that supports the relationship between positive outcomes and
interventions, attrition remains a common problem.

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How bad is it? Compliance with interventions

Quoting a paper published by Haynes et. al, the report indicated that: "increasing the effectiveness of adherence to interventions may have a far greater impact on the health of the population than any improvement in specific medical treatments" (Sabate, 2003). Despite the potential for robust population health improvements, the majority of the treatment research literature has consistently focused on outcomes of treatments rather than methods of improving adherence to existing efficacious treatments (Brown & Bussell, 2011). For instance, current epidemiological data suggests that 20% to 30% of medication prescriptions are never filled to whom they have been prescribed (Viswanathan et. al, 2012). A number of studies have demonstrated that patients with chronic conditions adhere to about 50-60% of medications, despite the evidence that supports the medication may help decrease morbidity and improve quality of life (Bosworth et. al, 2011). Non-adherence to medical interventions is estimated to cause 125,000 deaths and constitutes at least 10% of hospitalizations (Viswanathan et. al, 2012). In addition to the increase in mortality and morbidity, this lack of adherence has been estimated to cost the U.S. healthcare system "between $100 billion and $289 billion annually" (Viswanathan et. al, 2012). Addressing the issue of nonadherence can have major implications for health outcomes. This issue is not limited to medication adherence in chronically ill populations; it is also an issue within mental health and substance use populations.

Treatment attendance in substance use populations

An estimated 136.9 million people 12 years and older (52.2%) report current alcohol use (past 30 days), 66.9 million (25.5%) report current tobacco use, and 24.6 million (9.4%) report current use of illicit drugs in the United States (SAMHSA, 2013). Based on criteria detailed in the Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV), approximately

21.6 million persons aged 12 or older (8.2 percent) were classified with substance dependence or abuse in the past year, in 2013. The annual costs to the U.S. economy associated with these problems is estimated to exceed $600 billion (Bouchery, Harwood, Sacks, Simon, & Brewer, 2011). In order to address the issue of drug and alcohol use disorders, addiction treatments have been, and are continuing to be, developed. These treatments are aimed at reducing substance abuse or achieving abstinence, preventing or reducing the frequency and severity of relapse, and improving adaptive functioning (APA, 2007). The treatment is multimodal, integrating psychological, pharmacological and social approaches and can last from a few months through the lifetime depending on each person's need (APA, 2007). Despite the variety of treatment options and lengths available, one of the most consistent factors that can account for favorable outcomes is the completion of treatment; completing treatment is associated with abstinence form use as well as lower crime rate and higher levels of employment (APA, 2007).

Despite treatment completion leading to favorable outcomes for those who use drugs, drop-out from treatment is common. Treatment adherence is also a challenge for persons with substance use disorders seen in psychiatric practice. One study found that among patients with co-occurring mental health and substance use disorders, about 40% had issues with adherence to their treatment regimen (Herbeck et. al, 2005). Some studies have found the rate of drop-out ranges from 23–50% in outpatient treatment (McHugh et al., 2013; Santonja-Gómez et al., 2010) and 17–57% in inpatient treatment (Deane, Wootton, Hsu, & Kelly, 2012; Samuel, LaPaglia, Maccarelli, Moore, & Ball, 2011). The outcome of patients after they drop-out of addiction treatment is unfavorable compared to those who complete treatment.

Predictors of attendance to substance use treatment

Despite the common nature of drop-out in treatment of substance use populations, the literature on factors that might predict drop-out remains small. This is probably due to limitations in the treatment literature. However, common factors among substance use treatment studies include to social stability, socioeconomic status, employment, social resources supporting recovery, and motivation/expectations as variables related to attendance to treatment (Mattson et. al, 1998). Stark suggests that underlying the differences in socioeconomic status may serve as a proxy for practical considerations like the ease and availability of treatment (Stark, 1992). In this clinical review, Stark (1992) concluded that attendance to treatment may also be partially accounted for by treatment level factors like clinic environment, staff, and convenience of the clinic to the patient. Additional studies have found that a client's relationship with their provider may account for some of the variance in dropout rates (Palmer, Murphy, Piselli, & Ball, 2009). These treatment level factors may play a role in drop-out, with financial resources, insurance coverage, early treatment, and shorter treatment duration associated with treatment attendance in both men and women (Beckman & Bardsley, 1986). Findings associated with financial issues and transportation has since been corroborated (Palmer, Murphy, Piselli, & Ball, 2009). However, patient level factors like demographics may also play a role in drop out. Gender is one patient level factor that has been demonstrated to have an impact on who completes treatment.

Attendance of women to substance use treatment programs

The literature is replete with evidence of gender playing a role in treatment engagement and attendance. For example, women are more likely than men to drop out of substance abuse treatment (Stark, 1992). Additionally, women attend fewer substance use treatment sessions than men (McCaul, Svikis, & Moore, 2001). However, the manner by which gender impacts time

spent in treatment is complex, depending on personal factors, social factors, and treatment modality (Stark, 1992). For instance, the DATOS (Drug Abuse Treatment Outcome) study found that women had low retention in outpatient methadone treatment whereas men were more likely to drop out of outpatient drug-free programs (Simpson et. al, 1997). Type of program may interact with gender to have an impact on treatment retention.

Gender related differences in treatment attendance also interact with patient level factors to predict attendance. One study found that being married, living with a spouse, being unemployed, or having higher income were predictive of treatment attendance (Mertens & Weisner, 2000). This study also found that black women were has lower treatment attendance than other women, which is consistent with the work of Mammo and Weinbaum (1993), which found that black women were at greater risk of not completing treatment than other women. Employment and type of employment may also be related to completion of treatment, as with one study women in skilled/semiskilled positions were less likely than men to complete treatment. This study found that matching patients based on needs that are often differentiated by gender (housing, training, and childcare) supported better retention outcomes.

Predictors of treatment completion were also quite different for men and women in outpatient substance use treatment programs. One study found that women with higher incomes were more likely to complete treatment than women with lower incomes (Green et. al, 2002). Additionally, women who were referred to treatment for legal reasons or by an agency were more likely to complete treatment than others. Women with less favorable employment arrangements, as indicated by higher ASI Employment scores at baseline, were less found to be likely to complete treatment than other women (Green et. al, 2002) This is consistent with previously mentioned studies, that the different challenges facing women, as well as their

available resources, may impact treatment retention. There is a scarcity of work on the impact of attendance for women in substance use treatment. This scarcity is in spite of the success of substance use treatment in not only improving outcomes related to substance use and mental health, but also in preventing HIV. There is little in the way of work that interrogates predictors of retention in women who screen at risk for substance use as well. One area where this is particularly relevant is the attendance of women who screen at risk for substance use entering HIV prevention interventions.

HIV: The Scope of the Problem

According to recent estimates, there are greater than 1.2 million people living in the United States with an HIV diagnosis. In the year 2015, approximately 39,513 people were diagnosed with HIV infection in the United States. (CDC, 2015). HIV is an incredibly costly health problem, as the medical cost saved by avoiding one HIV infection is $229,800 (Schnakman et. al, 2015). According to the Center for Disease Control, the number of HIV infections reported annually fell twelve percent from 2010 to 2015 (CDC, 2015). While the incidence of new infections has gone down significantly over the past decade, the progress in HIV prevention has been uneven as HIV has disproportionately affected historically disadvantaged communities. Though the subgroup that is leading in new infections is men who have sex with men (MSM), the incidence of HIV in women has grown considerably (CDC, 2015). Women contracting HIV from heterosexual contact has become a growing issue in the U.S. (CDC, 2015). Additionally, the disease remains a leading cause of death in African American women aged 20-44 in the United States (CDC, 2015). The research specifically states the subgroups of women remain at increased risk for contracting HIV despite the lowering incidence of HIV in the general population. Women who are at risk for substance use, or with a

prior history of use, as well as women in the perinatal period are at an increased risk for HIV (Tross et. al 2008).

Pregnancy alone increases the risk of HIV even in women who are not using injection drugs themselves. Pregnant women are significantly less likely to use condoms during sexual activity, thereby increasing their risk of HIV infection (Deren et al., 1993). The prevalence of HIV infection in women has been increasing steadily. In 2010, women's heterosexual contact with an HIV positive partner accounted for over 25% of all new infections, the method by which most women (86%) contract the virus (Stone, 2012). Women in high drug use communities are currently among the fastest growing groups of people with AIDS in the U.S. (Tross et. al, 2008). While there are many public health programs implemented to decrease HIV infection through the use of injection drugs, injection drug use is still responsible for 14% of new HIV diagnoses in women (Stone, 2012). Thus, both pregnancy and exposure to drug use settings, put women at high risk for HIV. Drug use treatment itself has served as a means of preventing HIV risk behaviors in a number of studies (Tross et. al, 2008). However, pregnant women tend to fare poorly in standard drug treatment settings (Svikis, Lee, Haug, & Stitzer, 1997). Additionally, research studies have demonstrated a relatively low success in reducing sexual risk behaviors in this population (Tross et. al, 2008). The most promising strategy for slowing the rising incidence of new HIV infections is prevention.

Evidence Based Practices for HIV Prevention

HIV prevention interventions are the primary target of reducing HIV infection in the USA. HIV prevention interventions were the product of the ingenuity of the gay communities in New York in San Francisco, along with early initiatives at the Centers for Disease control in the early 1980's (CDC, 2006). Since then, there has been an immense proliferation of HIV

prevention intervention implementation and research, resulting in a large body of literature that details several evidence-based practices for HIV risk reduction. The frontline of HIV prevention intervention is the proliferation and normalization of testing for HIV and subsequent linkage to care for HIV infected individuals. Research has demonstrated that when individuals are made aware of their HIV status, they make an effort to support their health and to protect others (Weinhardt, Carey, Johnson, & Bickham, 1999). Providing individuals with a link to care not only helps individuals who have been infected with HIV linkage to care helps ensure people living with HIV receive life-saving medical care and treatment and helps reduce their risk of transmitting HIV. Efforts are underway to expand HIV testing and linkage to care, especially in those populations in which new infections are occurring in high numbers. In addition to testing, the provision of and education about condom use is a big part of HIV prevention efforts, as having protected sex is linked to a lower chance of contracting HIV.

According to recent estimates, HIV prevention intervention has certainly seen a return on their investment. Intervention efforts between 1991-2006 have resulted in the prevention of 350,000 new infections (Farnham, Holtgrave, Sansom, & Hall, 2010). According to the statistics, averting these infections has saved an estimated 125 million dollars in direct medical costs. Because research has demonstrated that the current interventions have been useful in preventing additional infections, research on these interventions has become increasingly concerned with factors that may improve their success or reach to those communities who may not be reached currently. While basic components of the interventions have been established, including the appropriateness of groups, tailoring interventions to the population by making them gender specific, and providing individuals with incentives for participation, it is important that for attention to turn to the inclusivity of the sample groups (i.e.: who is attending the intervention).

Retention to HIV Prevention Interventions

Group modular interventions for the prevention of HIV transmission have been found effective. However, interventions are only effective so long as they are attended. When individuals enrolled in interventions do not engage or do not attend the program, it is not likely they will receive the maximal benefits of the program. Additionally, the efficacy of an intervention may be estimated inaccurately when there are not enough participants completing a full dosage of the intervention, which can threaten the intervention's internal validity (Prado et. al, 2005). Thus, tailoring interventions to target populations successfully requires an understanding of the factors that predict attendance to these interventions.

Attendance to treatment protocols is a necessary component of an effective HIV prevention intervention outside of its life as a clinical trial (i.e.: as an HBC program without participation incentives). It has been demonstrated that without attendance, HIV-prevention interventions have less impact on behavior (Albarracin, Wilson, Durantini, & Livingood, 2013). A meta-analysis of HIV prevention interventions that did not use monetary incentives demonstrated an association between higher attendance to programs and increases in safe sex behaviors, including less unprotected sex occasions (Albarracin et. al, 2005). In fact, one analysis estimated that interventions with low retention (less than 50%) may lead to a decrease in HIV safe-sex behaviors, long-term, while interventions with high retention (100%) are associated with an increase in HIV safe behavior (Johnson et. al, 2009). Additionally, research suggests multi-session HIV prevention interventions to reduce HIV risk are often more efficacious than single-session ones (Johnson et. al, 2009). However, under real-world conditions (without incentives), multi-session HIV prevention interventions show low retention, some even only show 50% retention (Albarracin et al., 2013). Although it would seem plain that attendance to an

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intervention would be an important piece of data to understand, many studies fail to report adherence rates or at most do so descriptively.

Few studies have provided information directly regarding what psychosocial factors predict (1) attendance to interventions and (2) how much of an intervention is needed to produce an impact on outcomes. However, some researchers have completed work that could at least shed some light on the issue of retention to interventions. One early study sought to understand determinants of attrition both from a two-session HIV prevention intervention as well as during the six-month follow-up period (Lauby et. al 1996). The authors noted there was significant differential completion between the intervention (87%) and the control group (69%). Those who completed the intervention were more likely to have endorsed HIV risk behaviors and also have had a negative HIV test screen. Those who continued in data collection, a 6-month follow-up period, were more likely to have stable lives, including income and housing (Lauby et. al 1996). Thus, patient level factors related to financial stability influenced the ability for patients to complete study follow-up. Those individuals who were deemed at highest risk for contracting HIV were significantly less represented in the research follow-up data, therefore threatening the internal validity of the study.

One meta-analysis of several HIV prevention interventions verified that many authors do not include exact attrition in their research reports about interventions (Durantini & Albarracín, 2009). With the reports they were able to analyze, this meta-analysis found that the odds of attendance to interventions were higher in the intervention than control conditions, which is consistent with the work of Lauby & colleagues (1996). Groups who had relatively high baseline knowledge regarding HIV prevention were less likely to continue attending an intervention than those individuals with a low amount of knowledge. This study also found that individuals who

had low or high motivation to use condoms or had low or high levels of condom use were less likely to continue attending an intervention than those with medium motivation and use (Noguchi et. al, 2007). However, the authors posited that it is possible that other psychological factors may have mediated these relationships, like impulsivity (Noguchi et. al, 2007).

Noguchi and colleagues (2007) also performed a meta-analysis of HIV prevention interventions with multiple sessions and with what reports they could find with relevant information, identified correlates of intervention retention. They found a number of correlates of attendance within samples. Those samples that had more males, college students, participants with mental illness, were young, married, more women from privileged backgrounds, contained men who have sex men, less participants of Asian descent, fewer female sex workers, and more multiple partner participants were more likely to be retained. Larger retention was associated with interventions with fewer and shorter sessions (compared to more and longer), as well as a smaller interval between sessions (Noguchi et. al, 2007). While monetary incentives were associated with higher retention, other incentives and facilitators were not.

It is possible that participants may be more reticent to attend one arm of an RCT than another when they are aware of the group in which they have enrolled. The EXPLORE intervention was a multisite two-group randomized controlled trial of a HIV prevention intervention among men who have sex with men in the USA (Klobin, 2004). The authors identified differential rates of attendance, where in more participants attended the control group, a one-time, standard, HIV education session (87%) than the majority of the multi-session intervention group (83%). This disparity contradicts the Lauby et. al (2006) paper as well as the work of Albarracin and colleagues (2013), with differential attendance going in the other direction. In addition to group assignment, lower retention also was significantly associated with

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minority group status, younger age, reporting female sex partners at baseline, and reporting of unprotected receptive anal intercourse at baseline, regardless of condition in the EXPLORE intervention. While this study focuses on a narrowly defined population, several of the factors here, including minority group status, age, types of sexual partners, and types of sexual encounters could be applied to other groups to see if the results generalize.

A few of the studies focused on attendance to HIV prevention interventions focused specifically at high risk subgroups. Liu and colleagues (2014) sought to understand the psychosocial determinants of retention in HIV prevention interventions, specifically aimed at younger individuals. The authors found that younger participants and males were more likely to return than older participants and females. The authors indicated that the "poorest" income level was associated with dropout as well and indicated that future studies should focus on strategies to help retain these individuals (Liu, 2014). Though hypothesized, prior health knowledge and education levels were not associated with retention in an HIV prevention intervention in this specific study. Another study by Prado and colleagues (2005) examined engagement and retention in a parent-focused teen HIV prevention intervention in a Hispanic population. Within this study, the authors focused on common psychosocial barriers to engagement and consenting to participate in a study: family income and family stress, with higher income and higher stress being associated with greater engagement with the study (Prado et.al, 2005). The authors hypothesize that those from lower income might be less likely to continue attending an intervention due to their inability to miss work, or their working several jobs. Additionally, the authors sought to understand what factors were associated with intervention retention. The authors found that group cohesion was positively related to continuing attendance in the intervention as well. Both of these studies elucidated some of the psychosocial characteristics

that might be associated with engagement in an intervention for a high-risk HIV population, including income level and stress within the family. However, this study has limited application in that it focuses on (1) teenage HIV prevention and (2) it is limited to in ethnic and geographic diversity. These factors may not apply to the current study, which seeks to understand the factors associated with retention for pregnant women from a large, Mid-Atlantic City.

Albariccin and colleagues also attempted to understand the psychosocial factors that contribute to the continued attendance of individuals to HIV prevention interventions. One study examined the function of "busyness" in impacting participants' likelihood to continue to attend an HIV prevention intervention (Albarracin et. al, 2013). Busyness was defined as "the average of number of hours working outside the home and number of children" all of which were standardized across studies. The results suggested that even in a sample with poverty, racial segregation, and a lack of resources available, return rates depended on whether participants expressed a desire to return. In discussion, the authors indicated that work should be done to strengthen intention to participate and complete a program for those enrollees who are less busy, but that "structural modifications" should be put in place to make programs more accessible for those who are busy (Albarracin et. al, 2013). One modification suggested reaching participants in primary care settings to cut down on extra visits. However, other studies indicate that research that occurs in hospital settings is less successful than in other settings (educational settings) (Noguchi et. al, 2007). This work does well to highlight the importance of contextual, treatment level factors for those attending HIV Prevention Intervention; however, it neglects to address the possibility that supportive relationships with family and children may allow said busy persons to participate in an intervention. Additionally, it does not examine mental health or substance use correlates that also may be implicated in a person's ability to continue attending an intervention.

In these studies, retention also differed by demographics. The aforementioned meta-analysis of studies also found that interventions that recruited ethnic minority participants or those samples that are at higher risk also had lower retention rates (Noguchi et. al, 2007). Another study found that women were more likely to attend HIV prevention interventions if they were in a group format and had longer sessions. It should be noted the authors speculated that "women may experience social environmental difficulties attending sessions and thus researchers may unsuccessfully attempt to attract them by increasing the financial/instrumental incentives" thought they did not cite what specific difficulties were present in the studies they analyzed. (Durantini & Albarracín, 2009). Though some of the literature speaks to gender differences in retention for HIV prevention interventions, little research has been completed. It is imperative that work be undertaken to address this gap in the literature, specifically pertaining to those who women are at an increased risk for HIV contraction, pregnant women at risk for substance use.

The Current Study

Use of condoms, correctly and consistently, reduces the risk of HIV infection (Strathdee & Sherman, 2003). However, many women report using condoms inconsistently or not at all (Bedimo, Bennet, Kissinger, & Clark, 1998). Previous literature has found that effective HIV intervention and prevention programs for women are most effective when they:(1) target women, (2) focus on negotiation and relationship skill building, (3) have multiple contacts that are not brief in duration, and (4) focus on teaching skills that reduce risky sexual behavior (Robin et al., 2004). One evidence-based approach to reducing HIV risk behaviors is "Safer Sex Skill Building" (SSB), a manual-driven 5-session group HIV/STD prevention intervention that was designed for female drug users (CDC, 2009; Tross et al., 2008; El-Bassel & Schilling, 1992; Schilling, El-Bassel, Schinke, Gordon, & Nichols, 1991). The 90-minute SSB sessions are aimed

at teaching women skills related to condom use, identifying abuse patterns in relationships, and sexual health promotion. The intervention is cumulative in nature, meaning that skills from one session are built upon in the sessions thereafter. Compared to the traditional, 60-minute, one session HIV education intervention (HE), SSB provides a much more comprehensive five-session model consisting of HIV risk assessment. A multi-site clinical trial comparing SSB to a one session HIV education session was found to be effective in reducing sexual risk behaviors of women at 6-month follow-up, specifically, women in the SSB (intervention) condition have significantly increased condom use than the health education control group (Tross et. al, 2008; Schilling et al., 1991). These findings, less unprotected sex occasions, were still present at 3-month follow-up (Tross et. al, 2008).

Little is known about what factors may make a participant more or less likely to attend these SSB intervention or HE control group sessions or how much "dose" (operationalized as "treatment attendance") is needed to provide a significant outcome in this population (Tross et al. 2008). Previous studies of the SSB in drug use treatment settings have implicated the importance attendance in achieving outcomes but have only specific a range of sessions attended (i.e.: 3-5) and have not specified exactly how many sessions are necessary to demonstrate specific, significant treatment outcomes, like lower incidence of unprotected sex occasions, which were found at 3 months post follow-up in the original outcomes paper (Tross et. al, 2008). Nor have the previous studies analyzed if increasing amounts of treatment attendance produce more robust effects of treatment in this specific intervention (Tross et. al 2008; Crits-Christoph et. al, 2014). Additionally, little research has examined the role of dose of the five session SSB intervention or the health education (HE) group in prenatal care settings with women who are at risk for using drugs (not just those currently using substances) and are pregnant in the reduction of unprotected

sex occasions via an improvement in condom use intention. Though attendance could be impacted by motivation for treatment, other practical concerns or psychosocial may be implicated in non-attendance, like socioeconomic status or social support which can serve as a proxy for lack of transportation or child care.

The specific aims of this analysis secondary data analytic study were to: (1) identify psychosocial mental health factors related to attendance of both the HE control and SSB intervention groups; (2) identify what dose of treatment (i.e. how many sessions attended) is needed to establish significant outcomes in an urban prenatal care clinic. Specific psychosocial factors will be chosen based on the literature regarding retention, attendance, and attrition for other multi-session HIV prevention interventions.

The study utilized data from a 2-arm randomized controlled trial (RCT), which compared risky sexual behavior outcomes at 1, 3, and 6 months post-intervention. The treatment group received the Safer Sex Skills building intervention as compared with the control group who received a one session HIV education intervention (HE). Participants were identified using screeners that were routinely administered by the Prenatal Care Clinic. Data was collected on a diverse range of variables including lifetime and recent drug and alcohol use, family history of substance use, previous and current condom use and attitudes, social supports and current living environment. Based on the RCT literature, the study will test the following hypotheses: 1) Women with lower income will be less likely to attend the intervention group than those with higher income 2) Women without a close relationship with partner will be less likely to attend the intervention group than those who have one 3) Women will need to attend at least 3 sessions to improve condom use intention at three months post study follow-up. In addition, given the paucity of research on characteristics associated with research participation in this specific

population in this research setting, univariate logistic regression will be used to identify other potential correlates of RCT study participation in both the control and intervention groups in order to achieve an adequate dose of intervention.

Statement of the Problem and Hypotheses

In RCTS of interventions for HIV prevention the primary focus has been on evaluating effectiveness, less attention has been focused on dose of intervention received as it relates to outcomes; even less attention has been on factors that contribute to attendance in control and intervention groups. If control and intervention groups differ in substantive ways, the outcome of such studies can be called into question, minimizing the generalizability of results to the larger population. The aim of this study is to identify psychosocial and mental health variables associated with research participation in treatment and control arms of an HIV prevention intervention. This study will first identify variables associated with control and intervention group attendance. Second, it will assess the dose, defined by number of SSB sessions attended, that is needed to produce a positive outcome related to HIV and STD prevention. The present study examined improvement in condom use intention at 3-month follow-up relative to baseline. This measure has been examined in previous research reports on SSB (Tross et. al, 2008).

The present study was a secondary analysis of a data set from an RCT comparing the five session Safer Sex Skill Building intervention to a one session health education control group. Both study arms targeted HIV and STI related risky sexual behavior in pregnant women at risk for perinatal substance use. To our knowledge, no previous studies have focused on this target patient population to examine predictors of attendance to an HIV prevention intervention. Based on findings for participants enrolled more broadly in HIV interventions, the study tested the following hypotheses: 1) Women with lower income will be less likely to attend the intervention

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group than those with higher income 2) Women without a close relationship with partner will be less likely to attend the intervention group than those who have one 3) Women will need to attend at least 3 sessions to have improved condom use intention at three months post study follow-up. Given the paucity of published research on correlates of attendance for the target population, univariate analyses were also used to identify potential demographic, mental health and psychosocial correlates of RCT study participation in both the intervention and control groups.

Methods

Participants

In this secondary data analytic study, participants were a sample of pregnant women who were identified as at risk for perinatal substance use who consented to an RCT comparing the Safer Sex Skills Building Intervention to a Health Education control group on sexual risk and substance use behaviors in women randomized to either the SSB or HE groups. Participants were recruited in an urban Prenatal Care Clinic (PCC) (N=255) within an academic health care system.

Inclusion criteria. RCT enrollment criteria included: patients 18 years of age or older, residing within the City of Richmond or the surrounding counties, able to speak and understand English, currently pregnant, seeking OB care in the target clinic, and screened at risk for perinatal drug and/or alcohol use or problems.

Exclusion criteria. Women were ineligible for the RCT if they presented with a cognitive impairment that prevented them from providing informed consent. The study was approved by Virginia Commonwealth University's Institutional Review Board and all participants provided informed consent.

Design and Procedures

Participants were recruited from an urban clinic in an academic health care system. Pregnant women who met study criteria were informed about the study and were invited to participate in the RCT. Those interested first passed an 8-item true or false test to confirm patient understanding of the study. Informed consent for study participation was obtained at the time of study recruitment, prior to baseline assessment. The current proposal will utilize a subset of these measures described below. After completion of the baseline assessment, participants were randomly assigned to either the intervention (SSB) or Health Education Control (ED) group.

Intervention Group

The Safer Sex Skill Building (SSB) intervention consisted of five, ninety-minute group sessions (Tross et. al, 2008). The intervention assists women in the development of safer sexual decision-making skills and behaviors through active engagement in behavioral modeling, role play rehearsal, problem-solving, troubleshooting, and peer feedback. The SSB was found to be effective in reducing sexual risk behaviors of women at 6-month follow-up, specifically, women in the SSB (intervention) condition had significantly increased condom use more than the health education control group (Tross et. al, 2008; Schilling et al., 1991). These findings were still present at 15-month follow-up. The intervention group was closed, so that the same participants were attending the same groups and others could not join late. If participants were unable to come to a session, make-up sessions were scheduled by the therapists with time allotted for up to two make-up sessions per week.

Control Group

The single session, sixty-minute health education (ED) group provided HIV education information that is provided in the first session of SSB utilizing discussion, flip chart visual

materials, and informational/resource handouts. The sixty-minute session topics included HIV definitions, transmission, testing, counseling, treatment, and prevention.

Follow up Assessments

Follow up assessments were performed at 1, 3, and 6 months post-randomization. Primary outcomes were assessed at 3- and 6-months post-randomization. The length of each visit has been kept as short as possible, with a focus on primary outcomes at 3- and 6- month follow-up.

Compensation

Women received $20 compensation for their time and effort upon completion of the baseline assessment. Women in both groups were compensated $30 for brief one-month follow-up; $40 for 3-month follow-up and $50 for 6-month follow-up.

Screening

Potential risk for problematic alcohol use drug use were assessed using the below screening tools.

T-ACE. The T-ACE is a 4-item questionnaire that was developed in 1989 (Sokol, Martier, & Ager). It is used to detect alcohol consumption in pregnant women that could potentially harm a fetus. The letters in T-ACE stand for: Tolerance, Annoyed, Cut down, and Eye opener. Two points are assigned when a woman reports needing over two drinks in order to feel the intoxicating effects of alcohol or to feel "high," indicating tolerance. One point is assigned for the remaining questions. The present study used a cut-point of ≥ 2 on the T-ACE to screen at risk for problem drinking (Sokol, et al., 1989).

Drug CAGE. The Drug CAGE is a 4-item questionnaire developed by Brown and Rounds (1995) that identifies women at risk for prenatal use of drugs. The Drug CAGE items

reflect the letters in the acronym: Cut down, Annoyed, Guilt, and Eye-Opener. The present study used a cut-point of ≥ 1 on the Drug CAGE to identify women at risk for drug use and problems (Brown & Rounds 1995).

Measures

Participants screened positive on either the T-ACE for alcohol or the CAGE for other drugs and agreed to participate, they were oriented to the study procedures by the RA. Participants completed an in-person clinical interview at baseline (ASI; McClellan et al, 1992). Baseline assessment measure for this secondary data analytic study included both personal interviews and surveys. They included:

Demographic Survey. Demographic variables included age, race, education, employment, income, marital status, current living situation, and social services,

The Addiction Severity Index (ASI). The Addiction Severity Index (ASI) is a semi-structured interview that assesses seven domains impacted by alcohol and drug use disorders and possesses psychometrically good qualities (McLellan et. al, 1992). The seven domains assessed are: employment, medical, alcohol, drugs, legal, family/social, and psychological. This study will focus on variables related to mental health, social support, socio-economic status, and family history of mental health and substance use issues.

The Sexual Experiences and Risk Behavior Assessment (SERBAS). The SERBAS is an extensively studied instrument which contains the primary outcome measure for the overall study, condom use intention. Additionally, it assesses: number of unprotected penetrative intercourse occasions by (main versus casual) partner type, number of partners, gender of partners, HIV serostatus, and HIV risk characteristics of partners. It also asks questions regarding pursuit of HIV testing and counseling (Meyer-Bahlburg et al., 1991; Sohler et al.,

2000). This study will focus on sexual experiences assessed at baseline and three months. It was administered by study staff.

The Family Alcohol and Drug Survey (FADS). The FADS is a fifteen-minute interview in which the participant is asked to characterize drinking and drug use of first and second-degree relatives (Andreasen et al., 1981). This study will utilize variables related to family history of substance use.

Treatment Attendance. Treatment attendance for the HE control group will be measured categorically as attended or did not attend the single session Health Education session. For the SSB intervention group, treatment attendance can range from zero (no groups) to a maximum of five sessions.

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Data Analysis Plan

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Statistical analyses were performed with SPSS version 25 (SPSS Inc., Chicago, IL, USA). Descriptive statistics were run for demographic data including age, race, and ethnicity. The first analysis examined correlates of attendance of the one-session HIV education intervention vs. non-attendance of this control group. These correlates were identified with univariate analyses of variables from various domains of interest including patient demographics, psychosocial factors, mental health factors, drug and alcohol use, family history of substance use, and current living environment and social supports. For this analysis, variables that are continuous were examined using a point bi serial correlation and for dichotomous variables, a chi square analysis were used. Variables reaching a significance level of ≤ 0.2 in the univariate analysis were included in a logistic regression model. If multiple items from the same domain (i.e.: variables with indistinguishable constructs) reach significance, the strongest predictor was included in the multivariate analysis to avoid issues of multicollinearity. Significance was set at

0.05 for the multivariate analysis. The outcome of interest was the dichotomous variable of whether patients attended or did not attend the one session, HE intervention. The data for the univariate analysis was treated as is, with missing values excluded from the analyses. For the multivariate analysis, modern imputation method, expectation maximization was used to account for missing data.

The second portion of the analysis examined correlates of attendance of the five session Safer Sex Skills Building HIV education intervention. These correlates were identified with univariate analyses of variables from various domains of interest including patient demographics, psychosocial factors, mental health factors, drug and alcohol use, family history of substance use, and current living environment and social supports. For this analysis, variables that are continuous were examined using a Pearson product moment correlation and for dichotomous variables, a point by serial correlation was used. Variables reaching a significance level of ≤ 0.2 in the univariate analysis was included in a stepwise linear regression model. If multiple items from the same domain (i.e.: variables with indistinguishable constructs) reach significance, the strongest predictor was included in the multivariate analysis to avoid issues of multicollinearity. Significance was set at 0.05 for the multivariate analysis. The outcome of interest was the continuous variable of number of sessions patients attended in the SSB intervention. For each variable in the univariate analyses, cases with missing data were excluded in the analysis. For the multivariate analysis, missing data was dealt with using a modern imputation method, expectation maximization.

The third procedure was a receiver operating characteristic (ROC) curve analysis, represented by The Youden Index (*J*). This analysis was intended to identify potential clinical cut-off for adequate dose of the intervention, how many sessions participants have to attend in

the experimental group as measured by the primary study outcomes of interest. The outcome variable was improvement in condom use intention, comparing baseline data to three-month follow-up. This outcome was chosen based on previous literature that found primary SSB to HE group differences at 3 months post intervention (Tross et. al, 2008).

Results

Descriptive Statistics

Demographics. Demographic characteristics of the study sample are summarized in Table 1 (N=254). Overall, women were predominantly Black (79.6%) with an average age of 25.89 years (SD=1.35); 16.9% identified as White, 1.6% identified as Hispanic, and 1.6% were Other/Unknown. The sample had a wide range of years of education (7-24), with a mean of 12.35 years (SD =2.09), and over three-quarters of the sample were never married (77%). There were no significant differences in demographic characteristics for the SSB and HE groups, including age, t (251) = -.07, $p = 0.95$, years of education t (251) = -.11, $p = 0.92$, race χ^2(4, N = 254) = 6.68, $p = 0.15$, and marital status χ^2(4, N = 254) = 8.90, $p = 0.06$. Because of the lack of variability in marital status, the variable was dichotomized for the univariate and multivariate analysis, with individuals being classified as never married or the reference group not never married, which included individuals who were: divorced, separated, married, widowed, or living as married in a committed partnership.

Mean income from employment was calculated for both groups. Income from employment was not normal and thus was further examined, as over half of the sample endorsed receiving no income from employment (n=162). First, z scores were calculated to determine outliers and those with z scores above 2.5 were coded as missing (n=9). Skewness was assessed with the outliers removed and the data remained not normal. Z scores were recalculated and an

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additional (n=11) group were marked as missing. The distribution remained not normal, with n=

15 additional individual data points meeting criteria for deletion; this would result in the deletion

of n=35 data points or 14% of the sample. In order to preserve the economic diversity

represented in the sample, this variable was not modified for this analysis.

Table 1

Demographic Characteristics of Health Education and Safer Sex Skills Building Group

	Health Education (N=123)	Safer Sex Skills Building (N=131)	p value
Age (years)	25.86 (123)	25.91 (130)	0.95
Race			0.15
Black	75% (92)	85% (111)	
White	22% (27)	12% (16)	
Hispanic	2% (3)	<1% (1)	
Other	<1% (1)	2% (3)	
Education (years)	12.33 (123)	12.36 (130)	0.92
Marital Status			
Never Married	73% (90)	80% (105)	0.06
Married	15% (18)	10% (13)	
Divorced	2% (3)	6% (8)	
Widowed	<1% (1)	2% (2)	
Separated	9% (11)	2% (3)	
Income	385	339	.42

*Note. ** denotes statistical significance*

Psychosocial Variables. Descriptive statistics for the remainder of the psychosocial

variables in the analysis are summarized in Table 2. For all variables, percentages represent the

number of participants per group who endorsed this variable, as all variables represented below

are dichotomous (yes/no). Some variables were recoded to be dichotomous to aid in the ease of

comparison between groups; specifically, the following changes to variables were made: number

of times you have been arrested for shoplifting or vandalism was recoded into has been arrested

for shoplifting or vandalism, similarly number of months you have been incarcerated has also

been recoded into has a history of incarceration. Additionally, for those variables that measure

close reciprocal relationships with others, those responses of "don't know" or "not applicable"

were coded as missing. For close reciprocal relationship with mother n=3 were excluded, father

n=11 were excluded, for siblings n=12 were excluded, and for partner n=7 were excluded.

Similarly, the variables assessing recent serious problems (within the last 30 days of interview)

with others coded "no contact" and "deceased" were missing. Serious recent problems with

father was excluded from the analysis due to the amount of missing data in the variable.

Differences between groups were assessed as well; HE and SSB groups differed significantly on

only one of the 25 variables, maternal psychiatric issues, with more SSB participants reporting

than HE Controls, $\chi2$ (1) = 4.77, p < .05.

Table 2

Psychosocial Variable Frequencies across HE and SSB Groups

Variable	Health Education (N=123)	Safer Sex Skills Building (N=131)	*p*
Resources			
Has a Trade/Skill/Profession	37% (45)	44% (58)	.212
Has a Driver's License	41% (50)	40% (52)	.916
Has Access to a Car	34% (42)	32% (40)	.719
Has Someone to Help Support Them Financially	75% (92)	69% (89)	.264
History of Legal Issues			
Has been on Probation/Parole	8% (10)	13% (17)	.210
Has been Arrested for Shoplifting/Vandalism	15% (18)	16% (21)	.738
Has been Incarcerated	27% (33)	20% (26)	.199
Lifetime Parental Mental Health & Substance Use			
Maternal Alcohol Use	26% (31)	23% (30)	.664
Maternal Drug Use	29% (35)	35% (45)	.334
Maternal Psychiatric Issues	19% (23)	31% (40)	.029**
Paternal Alcohol Use	49% (53)	54% (62)	.389
Paternal Drug Use	43% (47)	44% (50)	.864
Paternal Psychiatric Issues	16% (17)	16% (18)	.900
Recent Alcohol & Drug Use in the Home			
Do you live with anyone who has a current alcohol problem?	12% (14)	16% (21)	.283

Do you live with anyone who uses non-prescribed drugs?	7% (9)	12% (16)	.191
Social Support			
Close Relationship with Mother	76% (93)	73% (95)	.566
Close Relationship with Father	51% (61)	42% (53)	.166
Close Relationship with Sibling	83% (100)	79% (97)	.374
Close Relationship with Partner	88% (105)	85% (110)	.492
Close Relationship with Friends	88% (106)	81% (104)	.168
Serious problems getting along with mother in the past 30 days	17% (18)	18% (22)	.766
Serious problems getting along with sibling in the past 30 days	14% (15)	15% (18)	.786
Serious problems getting along with spouse in the past 30 days	30% (34)	37% (46)	.235

*Note. ** denotes statistical significance*

Substance Use and Mental Health Variables. Descriptive statistics for participant substance use and mental health problems are summarized in Table 3. For all variables, percentages represent the number of participants per group who endorsed this variable. Substance use variables assess for both recent (use in the last 30 days) and lifetime (regular use, 3 or more times a week, for 6 months or longer, prior to the 30 days). Similarly, both recent and lifetime mental health and abuse variables assess experiences in the last 30 days or lifetime history, any time before the 30 days. Some variables were recoded to become dichotomous for ease of interpretation. Specifically, the variables that assess both recent use and lifetime regular use of substances have been recoded to indicate whether someone has used instead of the number of days used or years used regularly. Mental health variables included recent and lifetime: serious depression, sadness, hopelessness, loss of interest, serious anxiety, tension, uptight,

unreasonably worried, inability to feel relaxed, and concentration and memory issues. When HE

and SSB groups were compared they differed on three variables: recent marijuana use $\chi2$ (1) =

3.86, p < .05, lifetime regular alcohol use $\chi2$ (1) = 4.12, p < .05, and recent anxiety $\chi2$ (1) = 4.49,

p < .05. In all cases, prevalence was higher for the SSB than the HE controls. There were no

differences across any other substance use or mental health variables.

Table 3

Substance Use and Mental Health Frequencies across HE and SSB Groups

Variable	Health Education (N=123)	Safer Sex Skills Building (N=131)	p
Substance Use			
Alcohol			
Recent	18% (22)	21% (28)	.485
Lifetime	48% (59)	61% (80)	.042**
Marijuana			
Recent	21% (26)	32% (42)	.049**
Lifetime	61% (75)	60% (78)	.816
Nicotine			
Recent	42% (46)	44% (52)	.732
Lifetime	71% (79)	72% (83)	.867
Polysubstance Use			
Recent	10% (12)	14% (18)	.315
Lifetime	36% (44)	39% (51)	.604
Trauma History			
Emotional Abuse			
Recent	27% (33)	28% (36)	.907
Lifetime	76% (93)	70% (92)	.335
Sexual Abuse			
Recent	2% (2)	2% (2)	.949
Lifetime	37% (46)	44% (57)	.321
Physical Abuse			
Recent	6% (7)	6% (8)	.888
Lifetime	46% (56)	54% (71)	.167
Mental Health			
Depression			
Recent	32% (39)	41% (53)	.147
Lifetime	75% (92)	80% (105)	.307
Anxiety			
Recent	37% (45)	50% (65)	.036**
Lifetime	64% (79)	72% (94)	.198

Concentration & Memory Issues			
Recent	15% (18)	23% (30)	.093
Lifetime	28% (34)	34% (45)	.248

*Note. ** denotes statistical significance*

Attendance. Group attendance frequencies for the HE and SSB conditions are summarized in Table 4. For the HE group, 87% of participants attended the single session group. For the SSB group attendance varied, with over half (51%) of women attending all five groups while one-fourth (25%) attended no sessions. Women failed to attend the intervention group at a higher rate than the control group, $\chi 2$ (1) = 6.05, p =.01.

Table 4

Number of sessions attended by participants in the HE and SSB Groups

	HE Control Group Attendance (n=123)	SSB Intervention Group Attendance (n=131)
No Sessions	13% (16)	25% (33)
One Session	87% (107)	12% (15)
Two Sessions	--	6% (8)
Three Sessions	--	2% (2)
Four Sessions	--	5% (6)
Five Sessions	--	51% (67)

Univariate Analyses

Demographics. Correlations between demographic variables and either Health Education Control Group and the Safer Sex Skill Building attendance are summarized in Table 5. For this analysis, age, education (in years), and income were continuous variables; race (black or other) and marital status (never married or other) were dichotomous.

For the HE control group, two variables met inclusion criterion for the regression analysis: age, with lower age being associated with a higher likelihood of attending r (N = 130) = -.198, p = 0.03 and marital status χ^2(1, N =123) =1.92, p = 0.165. No variables met inclusion for the SSB regression analysis.

Table 5

Demographic Correlates of Attendance for the HE and SSB Groups

	Control Group Attendance	p value	SSB Intervention Group Attendance (n=131)	p value
Age (years)	-.198	.028*	.064	.469
Race	.486^	.524	.043	.627
Education (years)	.027^	.764	.027	.762
Marital Status	1.924^	.165*	.108	.222
Income	-.050^	.582	.002	.997

*Note. * denotes meeting inclusion criteria for regression model, ** denotes statistical significance, ^ denotes chi square statistic*

Supportive Resources. For supportive resources, variables are shown in Table 6. For this analysis, all test variables are dichotomous. For the control group, none of the resource measures were associated with HE group attendance. For the SSB group, attendance was associated with a participant having a trade, skill, or profession. That is, women reporting a trade, skill or profession had a higher likelihood of attending the SSB group r = .179 p = 0.04. Two additional variables met threshold for inclusion in the regression analysis for the SSB; they were having a driver's license r = .125 p = 0.16 and having access to a car r = .153 p = 0.09.

Table 6

Supportive Resource Correlates of Attendance to the HE and SSB Groups

	HE Control Group Attendance	p value	SSB Intervention Group Attendance	p value
Trade/Skill/Profession	1.427^	.232	.179	.041**
Has a Driver's License	.073^	.787	.125	.156*
Access to a Car	.092^	.762	.153	.088*
Help with Income	1.475^	.225	-.080	.356

*Note. * denotes meeting inclusion criteria for regression model, ** denotes statistical significance, ^ denotes chi square statistic*

Legal Issues. Legal correlates of attendance to the HE Control and SSB groups are summarized in Table 7. For this analysis, all test variables are dichotomous. Both having been arrested for shoplifting/vandalism and having been incarcerated did not demonstrate enough variability to be included in the analysis for the HE group. One variable met threshold for

inclusion in the regression analysis for the SSB group, having a history of previous incarceration,

r = -.122 p = 0.17.

Table 7

Legal Correlates of Attendance for HE and SSB Groups

	HE Control Group Attendance	p value	SSB Intervention Group Attendance	p value
Probation/Parole	.087^	.768	-.107	.224
Has been Arrested for Shoplifting/Vandalism	--		.022	.802
Has been Incarcerated	--		-.122	.167*

*Note. * denotes meeting inclusion criteria for regression model, ** denotes statistical significance, ^ denotes chi square statistic*

Family Mental Health & Substance Use. Family mental health and substance use

correlates of attendance for the HE Control and the SSB groups are summarized in Table 8. Both

partner alcohol and partner drug use did not demonstrate enough variability to be included in the

analysis for the HE group. No significant correlations were found between HE attendance and

this set of variables. Having a mother with psychiatric issues met inclusion for the HE regression

analysis, $\chi^2(1, N =121) =1.694$, $p = 0.193$, that is women with maternal psychiatric issues were

more likely to attend the HE group than those who without. For SSB group, no correlations were

found between any family mental health and substance use variables and group attendance.

Table 8.

Lifetime Parental Mental Health and Substance Use and Recent Household Substance Issue Correlates of Attendance to the HE and SSB

	HE Control Group Attendance	p value	SSB Intervention Group Attendance	p value
Maternal Alcohol Use	.284^	.594	-.076	.391
Maternal Drug Use	.974^	.324	-.018	.842
Maternal Psychiatric Issues	1.694^	.193*	-.044	.618
Paternal Alcohol Use	.985^	.321	.010	.919
Paternal Drug Use	.347^	.556	.064	.499
Paternal Psychiatric Issues	.680^	.410	.072	.449
Do you live with anyone who has	.013^	.911	.062	.482

a current drug problem?				
Do you live with anyone who has	.389^	.533	.046	.605
a current alcohol problem?				

Note. * denotes meeting inclusion criteria for regression model, ** denotes statistical significance, ^ denotes chi square statistic

Social Support. Social support correlates of attendance for participants for both the

Health Education Control Group and the Safer Sex Skill Building group are summarized in Table

9. Having recent problems with father did not demonstrate enough variability to be included in

the analysis for the HE or SSB group. The present study did not find any variables significantly

associated with the HE control group. Three variables met inclusion for the HE regression:

having a close relationship with mother $\chi^2(1, N =121) =3.12, p = 0.08$, having a close

relationship with partner $\chi^2(1, N =121) =2.29, p = 0.13$, and having recent issues with a spouse

or partner $\chi^2(1, N =121) =5.29, p = 0.07$. For the SSB, no variables were associated with

attendance.

Table 9

Social Support Correlates of Attendance to the HE and SSB

	HE Control Group Attendance	p value	SSB Intervention Group Attendance	p value
Close Relationship with Mother	3.120^	.077*	-.027	.760
Close Relationship with Father	.935^	.334	-.082	.365
Close Relationship with Sibling	.065^	.799	-.007	.938
Close Relationship with Partner	2.288^	.130*	-.034	.703
Close Relationship with Friends	.641^	.423	.070	.433
Problems with Mother-Recent	2.288^	.515	-.077	.380
Problems with Sibling-Recent	2.468^	.481	.048	.591
Problems with Spouse-	5.292^	.071*	-.057	.523

Note. * denotes meeting inclusion criteria for regression model, ** denotes statistical significance, ^ denotes chi square statistic

Mental Health, Substance Use, & Abuse History. Mental health, Substance use, and Abuse History correlates of attendance for participants for both the Health Education Control Group and the Safer Sex Skill Building group are summarized in Table 10. For correlates of the HE control group, only recent emotional abuse reached significance $\chi^2(1, N = 123) = 3.97$, $p = 0.05$. Three additional variables met inclusion for the HE regression analysis: recent marijuana use $\chi^2(1, N = 121) = 2.446$, $p = 0.19$, lifetime sexual abuse $\chi^2(1, N = 121) = 2.73$, $p = 0.10$, and lifetime physical abuse $\chi^2(1, N = 121) = 3.125$, $p = 0.08$. For the SSB, five variables met inclusion for the regression analysis: a history of lifetime sexual abuse $r = .116$ $p = 0.19$, recent depression, $r = -.121$ $p = 0.17$, history of depression, $r = .118$ $p = 0.18$, history of anxiety, $r = .152$ $p = 0.082$, difficulties with concentration and memory recently, $r = -.113$ $p = 0.2$, and difficulties with concentration and memory in lifetime, $r = -.146$ $p = 0.1$.

Table 10

Mental Health and Substance Use Correlates of Attendance to the HE and SSB

	HE Control Group	p value	SSB Intervention Group	p value
Substance Use				
Alcohol				
Recent	.363^	.547	-.031	.728
Lifetime	1.474^	.225	.001	.989
Marijuana				
Recent	2.446^	.118*	-.037	.677
Lifetime	.173^	.678	.107	.223
Nicotine				
Recent	.246^	.620	-.037	.693
Lifetime	.370^	.543	-.115	.222
Polysubstance Use				
Recent	.157^	.692	-.049	.581
Lifetime	.016^	.898	.083	.346
Trauma History				

Emotional Abuse				
Recent	3.968^	.046**	-.099	.259
Lifetime	.469^	.493	-.069	.435
Sexual Abuse				
Recent	.304^	.581	-.086	.330
Lifetime	2.732^	.098*	.116	.186*
Physical Abuse				
Recent	1.110^	.292	-.032	.721
Lifetime	3.125^	.077*	-.108	.218
Mental Health				
Depression				
Recent	.382^	.536	-.121	.168*
Lifetime	.357^	.550	.118	.180*
Anxiety				
Recent	.226^	.635	.031	.724
Lifetime	1.620^	.203	.152	.082*
Concentration & Memory Issues				
Recent	.249^	.617	-.113	.200*
Lifetime	.064^	.800	-.146	.097*

*Note. * denotes meeting inclusion criteria for regression model, ** denotes statistical significance, ^ denotes chi square statistic*

Multivariate Analysis

All variables included in the univariate analyses are summarized in Table 11, with the

variables selected for the multivariate analysis for the Health Education Control Group italicized

and those for the SSB group underlined.

Table 11

Variables Included in Regression Analyses

Demographics	Substance Use	Trauma History	Family History
Age	Alcohol	Sexual Abuse	Alcohol
Race	Recent	Recent	Mother
Education	Lifetime	*Lifetime*	Father
Marital Status	Marijuana	Emotional Abuse	Partner
Income	*Recent*	*Recent*	Drug Use
	Lifetime	Lifetime	Mother
	Nicotine	Physical Abuse	Father
	Recent	Recent	Partner
	Lifetime	*Lifetime*	Psychiatric
	Polysubstance Use		*Mother*
	Recent		Father

	Lifetime		
Resources	**Mental Health**	**Social Support**	**Legal Issues**

Trade/Skill/Profession
Driver's License
Access to a Car
Help with Income
	Anxiety
	  Recent
	  Lifetime
	Depression
	  Recent
	  Lifetime
	Concentration and
	Memory
	  Recent
	  Lifetime
		Close Relationship
		  with Mother
		  with Father
		  with Sibling
		  with Partner/Spouse
		  with Friends
		Problems with
		  Mother- Recent
		  Sibling-Recent
		  Spouse-Recent
			Probation/Parole
			Shoplifting/Vandalism
			Previous Incarceration

Multivariate Logistic Regression: Attendance in the HE Group. For this analysis,

missing dating was dealt with using a modern imputation technique, expectation maximization.

After data were imputed, a binary logistic regression was used to identify significant baseline

predictors of Health Education Control group attendance (did not attend vs. attended). The

independent variables were Age, Marital Status, Recent Marijuana Use, Lifetime Sexual Abuse,

Recent Emotional Abuse, Lifetime Physical Abuse, Mother Psychiatric Issues, Close

Relationship with Mother, Close Relationship with Spouse, and Problems with Spouse. Based on

a classification threshold predicted probability of target group membership of .5, the overall

model was statistically significant, $\chi^2(10) = 28.89$, $p = .001$. The Nagelkerke pseudo R^2 suggested

that the model accounted for approximately 38.8% of the total variance in attendance.

Classification success for the cases based on a classification cutoff value of .5 for predicting

attendance was high, with an overall prediction success rate of 87% and correct prediction rates

of 18.8% for those who did not attend participants and 97.1% for those who did attend. When

controlling for the other predictors, a 1-year decrease in age was associated with .840 times

greater likelihood of attending ($p = .01$; b = -.174; .95% CI = .734, .960). Marital status was also

a significant predictor of attendance, with attendance being lower for those who have never

married vs. those with other marital statuses ($p = .036$; b = -2.164; .95% CI = .015, .871). No

other predictors exerted a unique effect on attendance (all $ps \geq .099$) as shown in Table 12.

Table 12

Binary Logistic Regression, Predictors of Attendance to HE Group

Variable	β	S.E.	*p*	Odds Ratio [95% CI]
Age	-.174	.07	.010**	.840 [.734, .960]
Marital Status	-2.164	1.034	.036**	.115 [.015, .871]
Recent Marijuana Use	1.552	1.16	.181	4.722 [.486, 45.856]
Lifetime Sexual Abuse	.305	.898	.734	1.356 [.233, 7.882]
Recent Emotional Abuse	1.528	1.243	.219	4.610 [.403, 52.722]
Lifetime Physical Abuse	.266	.828	.748	1.305 [.257, 6.620]
Mother Psychiatric Issues	.557	1.309	.670	1.746 [.134, 22.709]
Close Relationship with Mother	-1.468	1.184	.215	.230 [.023, 2.343]
Close Relationship with Spouse	-4.823	8.501	.570	.008 [.000, 138427.606]
Problems with Spouse	1.433	1.147	.212	4.190 [.443, 39.663]

Note. $R^2=.39$ (N=123, $p=.001$)

Multivariate Linear Regression: Attendance in the SSB Group. For this analysis,

missing dating was replaced using a modern imputation technique, expectation maximization. A

stepwise multivariate linear regression analysis was conducted to examine the predictors of

attendance to the SSB intervention. The independent variables of Lifetime Sexual Abuse,

Trade/Skill/Profession, Driver's License, Access to a Car, Recent Depression, Lifetime

Depression, Recent Concentration/Memory Difficulties, Lifetime Concentration/Memory

Difficulties, Close Relationship with Mother, and Previous History of Incarceration. The

resulting final model eliminated all but one variable, having a trade, skill, or profession. Having

a trade, skill, or profession was associated with a higher likelihood of attending the 5-session

SSB intervention,, F(1, 129) = 4.253, p=.041, R^2 = .032. Beta weight estimates and p values for the final analysis are shown in Table 13.

Table 13

Multivariate Stepwise Linear Regression, Predictors of Attendance to SSB Group

Variable	B	95% C.I. for Exp (B)		Exp (B)	t	p
		Lower	Upper			
Having a Trade/Skill/Profession	.794	2.164	3.178	.179	2.062	.041

Note. R^2=.032 (N=131, p=.041)

Dose of Intervention: ROC Curve Analysis. To determine the amount of attended sessions needed for an adequate dose of the intervention to improve condom use intention from baseline to 3- months follow-up, the predicted probabilities of attendance were subjected to a receiver operating characteristic (ROC) analysis. The ROC curve is presented in Figure 1, and the area under the curve (AUC) was .597 (SE = .065; p=.160), shown in Table 15. Both visual inspection and the AUC statistic both suggest that the fit of the logistic regression model provides no discrimination (Meyers et al., 2017). Coordinates of the ROC curve corresponding to actual numerical predictions of condom use intention are shown in Table 14.

Table 14

ROC Curve Coordinates for dose of attendance needed for outcomes in SSB group

Positive if Greater Than or Equal To	Sensitivity	1 - Specificity
.0000000	1.000	1.000
.1493487	.962	.836
.1980564	.923	.800
.2577722	.885	.782
.3280565	.885	.691
1.0000000	.000	.000

Table 15

Area Underneath the Curve

Area	Standard Error	p	95% Confidence Interval
.597	.065	.160	[.470, .724]

Area Under the Curve, Coordinates of the ROC Curve Analysis
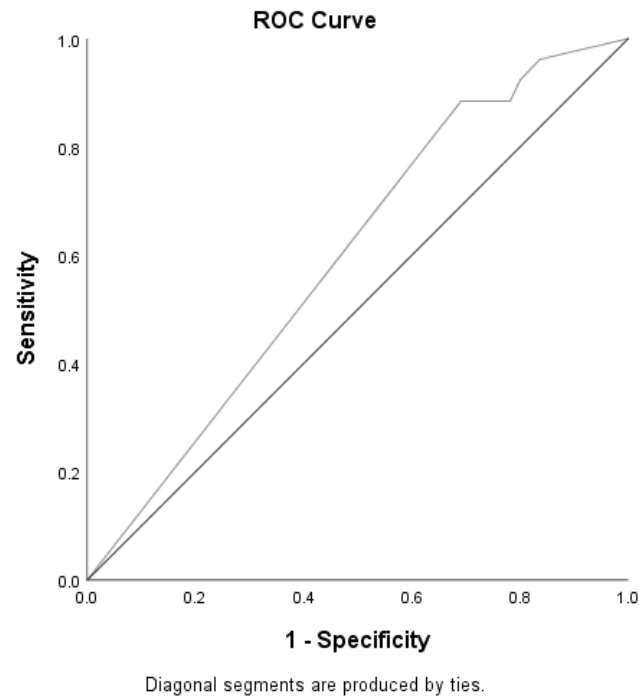
Figure 1. ROC Curve Analysis, ROC Curve

Discussion

The present study examined demographic, psychosocial, and mental health variables associated with attendance of a one session Health Education (HE) Control Group and five session Safer Skills Building (SSB) Intervention Group as a part of a two arm RCT focused on HIV prevention. Participants were N=254 pregnant women at risk for prenatal alcohol/drug use. First, descriptive statistics were run to assess variability of the selected variables and identify any

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HE vs. SSB group differences in the target measures. Second, univariate analyses, specifically Pearson product moment correlations, Point by serial correlations, as well as Chi Square statistics were calculated to identify potential associations between demographic, psychosocial, and mental health variables and attendance of either the HE control or SSB intervention conditions. Based on existing literature it was hypothesized that both women with lower income and women without a close relationship with a sexual partner will be less likely to attend the SSB intervention group than those with a higher income or those who have a close relationship with a partner. Other variables were examined and those at the $p \leq 0.2$ level in univariate analysis were included in multivariate regressions to determine the most parsimonious model to predict participation in either the HE or SSB groups. Finally, a ROC curve analysis was performed to test the hypothesis that women will need to attend at least 3 sessions to have improved condom use intention at three months post study follow-up.

Summary of Findings

Present study findings did not support any of the hypotheses tested for the SSB group. For the HE control group, age was correlated with attendance, with younger participants being more likely to attend than older participants. Marital Status met inclusion for the multivariate analysis. For SSB, there were no associations between demographic variables, including income, and attendance. When additional psychosocial factors were examined, few factors demonstrated an association with attendance and they are described below.

Multivariate regression analyses identified the most parsimonious models for predicting attendance of either the HE control or SSB intervention groups. For the HE controls, younger age was associated with session attendance. Additionally, having been previously married or currently living as married was associated with session attendance. The Nagelkerke pseudo R^2

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suggested that the model accounted for approximately 38.8% of the total variance in attendance. No other predictors included in this model were significant. For the SSB intervention group, a model predicting attendance based on the correlates identified from univariate analysis was not significant.

A Receiver Operating Characteristic Curve Analysis was used to identify the optimal dose of treatment needed to have an improved outcome, specifically to test the third hypothesis that women would need to attend at least 3 sessions to improve condom use intention at three months post study follow-up. The ROC Curve analysis yielded non- significant results, meaning there is no discrimination between sessions based on this outcome variable.

Discussion of Findings

Descriptive Statistics. First, descriptive statistics were run to assess variability of the selected variables and identify any HE vs. SSB group differences in the target measures. Comparable with current literature on demographic characteristics of those with perinatal substance use issues in the southern region of the United States, the mean age of study participants was 25 years old, most of the sample had never married, were unemployed, and completed high school (Hand, Short, Abatemarco, 2017). Though this sample did not necessarily meet criterion for substance use treatment, it is important to note that the recent prevalence estimates in the southern US demonstrate that while the predominant racial group in perinatal substance use treatment is white women, the majority of the current sample was black. This racial difference between current prevalence data for the region and that of the RCT may be due to the racial makeup of the catchment area for the study.

Given the nature of random assignment, no differences were expected in baseline demographic and psychosocial variables between the HE control and SSB intervention groups.

While group comparisons affirmed there were no differences on any demographic variables measured, differences were found on several psychosocial variables. Such differences while likely to be by chance, must be considered as they could impact interpretation of results. Between 30-50% of the sample reported a recent psychiatric issue (either recent anxiety or depression) and the majority of the sample endorsed a lifetime history of depression, which was true in both groups (HE 75%, SSB 80%). However, there was difference between HE and SSB groups on recent anxiety, with the SSB group (72%) endorsing a higher rate of recent anxiety (within the last 30 days) than the HE group (64%). Additionally, women in the SSB condition were more likely than the HE controls to endorse recent MJ use and lifetime history of regular drinking. SSB group women were also more likely to report a maternal anxiety/depression issue than the HE controls. It is possible that the severity of symptoms in the SSB group may contribute to differences in correlates of attendance between the HE and SSB groups.

Attendance. The present study examined attendance to both the HE control group and the SSB intervention group. Almost all of the participants enrolled in the HE control group (87%) attended the single session group, with only 13% not attending the one session intervention. For the SSB group attendance varied, with over half (51%) of women attending all five groups while one-fourth (25%) attended no sessions. It is possible this variability in number of sessions attended made it difficult to detect meaningful differences in the univariate and multivariate analyses.

Women failed to attend the SSB group at a higher rate than the HE control group. Based on the literature, there are a few reasons why this could have occurred. Women may have been more likely to attend a one session, 60-minute intervention because the time commitment expectation for the intervention is lower than for the SSB group. This is consistent with previous

literature that demonstrated that fewer and shorter sessions of an intervention is associated with increased rate of attendance (Noguchi et. al, 2007). The shorter single session intervention may have proved less of an obstacle for women to attend than a five, ninety-minute sessions. It is also possible that the first session of the SSB might be of less interest than women than a comprehensive one time, health education session. Additionally, it is possible that the name of the intervention group could elicit stigma from participants that may prevent them from attending; Safer Sex Skill Building could present more of a barrier to engagement via internalized stigma regarding sex practices than the Health Education group. Future research can engage in qualitative endeavors to assess women's willingness to attend interventions based on expectations based on time commitment, educational content, and the name of the intervention.

Univariate Analysis

Demographic Correlates. The literature demonstrates mixed results on the impact of age on attendance to interventions. For example, one study looking at the EXPLORE HIV prevention intervention found that drop-out was associated with younger age (Koban, 2004). Though, it should be noted that the EXPLORE intervention was an HIV prevention intervention for men who have sex with men. A recent meta-analysis of HIV prevention interventions found an association between intervention attendance and younger age (Durantini & Albaraccin, 2009). In the meta-analysis, authors speculated that younger age in participants might improve odds of attendance because younger participants may have fewer domestic responsibilities than their older counterparts. These domestic responsibilities may include taking care of children, taking care of a family member, or responsibilities associated with being the head of household. The present study found that younger age was associated with attendance to the one session HE controls group. This may be because there are fewer domestic responsibilities that may keep

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women from attending, as specific in the literature. However, because variables that describe domestic circumstances specifically (i.e.: number of children, number of people in the home) are absent from this data set, it would be difficult to more conclusively determine the mechanism by which younger age is associated with attendance. Additionally, because the disparity in number of attenders and non-attenders to the HE control group was so high, these results should be interpreted with caution. Finally, for the HE control group, marital status (never married vs. other, as described in the descriptive statistics section) met inclusion for the multivariate analysis but was not significant.

The present study did not find any differences on demographic variables for attendance to the five session SSB intervention group. The lack of variability in the demographics of the sample and in attendance that was previously discussed may have contributed to these results.

Supportive Resource Correlates. The present study did not find any differences on supportive resource variables for attendance to the HE control group. It is possible that the treatment burden associated with attending only one, sixty-minute intervention session may not necessitate the amount of resources required to attend a five session, ninety-minute intervention. The present study found that having a trade, skill, or profession was associated with attendance to the five session SSB intervention group. Two additional variables met threshold for inclusion in the regression analysis for the SSB, having a driver's license and having access to a car. These supportive resource correlate results are consistent with previous HIV prevention interventions that discuss how financial stability and access to resources could potentially contribute to a higher rate of attendance (Prado et.al, 2005). Women who have professions that may grant more stable income and employment may worry less about missing their job in order to attend an intervention, which may in turn increase likelihood of attendance. Women who have the ability

to transport themselves to an intervention may face one less barrier to attending than those who do not. Future research should assess the impact of supportive resources, as well as objective measures for the ease of attending interventions, in these populations to get a better picture of what factors might be helpful to address at a systems level.

Legal Correlates. The current literature has demonstrated that women who are legally encouraged to enter treatment are more likely to complete treatment. However, the literature does not have any information on how previous incarceration, arrests for shoplifting, or being on probation/parole might impact intervention attendance. The present study did not find any differences on legal variables for attendance to the HE control group, nor did it find any significant correlates of attendance for the SSB group. It should be noted that having a history of incarceration met inclusion for the multivariate analyses for the SSB group, with incarceration history associated with a lower likelihood of attendance. Future studies should explore how contact with the social justice system may impact the likelihood of attending treatments.

Family Mental Health & Substance Use. The current literature states that women with "social environmental difficulties" may be less likely to attend interventions (Durantini & Albaraccin, 2009). For that reason, parental mental health and substance use, as well as recent household substance use variables, were included in the exploratory analysis. The present study did not find any significant differences on parental mental health and recent household substance issue correlate variables for attendance to the HE control group. However, one variable, maternal psychiatric issues, met inclusion for the multivariate analysis, with those have had had a history of maternal psychiatric issues being less likely to attend the intervention than not. It is possible that women whose mothers have psychiatric issues may have more chaotic home environments

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or less support resources to attend the intervention. The present study did not find any significant correlates of attendance for the SSB group.

Social Support Correlates. The current literature states that women with supportive partners are more likely to attend substance use treatment and HIV prevention interventions; thus, one hypothesis of the current study was that women with a close relationship with their partner would be more likely to attend. Because the sample predominantly had never been married (73%) additional relationships were examined that may serve this supportive function as well. Although the sample was predominantly never married, almost all participants endorsed having had a close relationship with a sexual partner (>85%). Although they did not reach significance, having a close relationship with partner and having recent issues with a spouse or partner met inclusion for the multivariate analysis. It could be that having difficulties with this family member may in turn suggest a lack of support for childcare or transportation to be able to attend the intervention, as the literature has previously stipulated that the home social environment may potentially have a direct impact on attendance. Additionally, having a close relationship with mother met inclusion for the multivariate analysis for the HE control group. Three quarters of the sample endorsed having had a close relationship with their mothers at some point in their lifetime. This lack of variability may make it difficult to detect a difference in groups on other variables. The present study also did not find any significant correlates of attendance for the SSB group.

The item that assesses for close relationships, someone you could count on and vice versa, focused on lifetime (have you ever) and were added to the ASI as a screen for sociopathy. Specifically, they seek to identify individuals with superficial relationships with others and an inability to establish close, reciprocal bonds.

Mental Health, Substance Use, & Abuse History. In their meta-analysis, Noguchi and colleagues (2007) found that participants with mental illness were more likely to attend HIV prevention interventions than those without one, contrary to the large medication adherence literature that connects current depressive symptomology as a barrier to engagement with treatment. The current literature on HIV prevention interventions has not examined abuse history and substance use issues as they relate to intervention attendance. For correlates of attendance of the HE control group, only recent emotional abuse was significant. It is possible that women experience emotional abuse in the home may be less likely to have the support necessary to attend the intervention. This may be consistent with the literature that states women with more stable home environments are more likely to attend interventions; incurring emotional abuse may be associated with a chaotic home environment. Further research is needed to understand the mechanism by which emotional abuse affects research study attendance. Three additional variables met inclusion for the multivariate analysis of predictors of attendance to the HE control group: recent marijuana use, lifetime sexual abuse, and lifetime physical abuse. It is possible that those who have recently used marijuana would be less likely to attend the intervention due to potential stigma of use during pregnancy, or fear of consequences if they were to report such use (Stone, 2015). Further research is needed to discern how abuse history may impact a woman's willingness or ability to attend an intervention based on Safe Sex Skills Building.

The present study did not find any significant correlates of attendance for the SSB group. It could be that severity of the sample on mental health and psychosocial variables made it difficult to detect differences between groups due to high rates in psychiatric and substance use comorbidity in this sample. However, additional variables met inclusion for the regression analysis, with the following being associated with a lower likelihood of attendance: a history of

lifetime sexual abuse, difficulties with concentration and memory recently, difficulties with concentration and memory over the lifetime, and recent depression. However, lifetime history of depression and anxiety were associated with increased likelihood attendance to the intervention. It is possible that women who have a history of mental health issues may have sought effective treatment for these difficulties therefore giving them a positive impression of treatment. However, this study did not examine previous treatment seeking for mental health issues, or satisfaction with experiences with healthcare systems, and a relationship to intervention attendance. More research is needed on mechanisms by which such variables might influence intervention attendance.

Multivariate Analysis.

  Multivariate Logistic Regression: Attendance in the HE Group. The multivariate binary logistic regression analysis identified the variables included in a parsimonious model of predictors of attendance to the one session Health Education Control Group. Specifically, the final model found that younger age and marital status was associated with intervention attendance. All other variables included in the analysis were excluded from the final model. This finding is consistent with previous literature in both the substance use treatment and HIV prevention intervention literature that younger individuals are more likely to attend.

  Though marital status was not significant in the univariate analysis, it was significant in the final multivariate model, with having been married or living as married being predictive of study attendance. This could be consistent with previous literature in both substance use treatment attendance and HIV prevention intervention attendance. Previous literature on attendance by women to substance use treatment has found that women living with a spouse are more likely to attend treatment (Mertens & Weisner, 2000). Additionally, having support in the

home environment is associated with attending HIV prevention interventions (Durantini &

Albarracín, 2009). One potential issue with this analysis is that due to lack of variability, women

who were previously married and currently married were included in the same reference group.

Future research should endeavor to examine more specifically how marital status and quality of

relationships impacts intervention attendance.

The multivariate model provides the finding that (1) younger women were more likely to

attend the one session health education control group and (2) those who were never married were

less likely to attend the one session health education control group, accounting for 38.8%

(Nagelkerke R Square) of the variance of participants. While the variance accounted for is large,

it is important to remember the present study was secondary analysis of existing data and that

there was little variation in attendance in the HE control group. Thus, present study results

represent only the first step in a promising and important area of research with opportunities to

further explore potential differences between those who do and do not a one session Health

Education Control Group.

Multivariate Linear Regression: Attendance in the SSB Group. The multivariate

linear regression analysis identified the variables included in a parsimonious model of predictors

of attendance to the five session SSB group. Specifically, the final model found that having a

trade, skill, or profession was associated with intervention attendance. All other variables

included in the analysis were excluded from the final model. This finding may be consistent with

previous literature in both the substance use treatment and HIV prevention intervention fields,

with employment status related to intervention attendance (Mattson et. al, 1998). As previously

stated, one study found that women with less favorable employment arrangements, those who

were not able to consistently hold work and were not able to take time from work, were less

found to be likely to complete treatment than other women (Green et. al, 2002). It might be that women with a trade, skill, or profession may have more favorable employment arrangements. These arrangements may provide both the flexibility in work schedule to attend the intervention and the financial support women may need (i.e.: to pay child care during the intervention or for transportation to and from the intervention) in order to attend the intervention. Future research should endeavor to identify specific barriers that may keep women who are unable to hold consistent jobs from attending the intervention.

It is important to remember the present study was secondary analysis of existing data and that there was little variation in attendance in the SSB intervention group which may have limited the applicability of this analysis, specifically half of the sample attended all five sessions with one quarter not attending any sessions.

Dose of Intervention: ROC Curve Analysis Previous studies on the Safer Sex Skills Building Intervention found that attending 3-5 sessions of the intervention was sufficient enough to demonstrate an improvement in condom use (Crits-Christoph, et. al, 2014). The present study employed a receiver operating characteristic (ROC) analysis in order to determine the optimal number of sessions that constitute an adequate dose of the intervention to improve outcomes in condom use intention. The analysis was performed and found no discrimination. It is possible that baseline condom use intention may have been higher in this sample due to exposure to safe sex messages within their community and clinic for the health of their pregnancy, therefore using another outcome variable (i.e.: additional sexual risk behaviors) might lead to different results. It should be noted that condom use intention was not included in the primary study outcome analysis. Future research will look at other sexual risk behavior outcomes that demonstrate a steeper rate of improvement.

Study Implications and Applications

While few statistical differences were found between attenders and non-attenders, the final model for attendance to the HE control group accounted for about 38.8% of the variance in research attendance, with age and marital status being the only predictors included in the model. The model that assessed predictors of the SSB intervention group found an association between having a trade, skill, or profession and attendance. The present study serves as the first step exploring potential differences between attenders and non-attenders; given that the data across these broad domains accounted for variance in research participation, it affirms the need to explore these domains in greater detail in order to ensure the representativeness of HIV prevention intervention research through who may or may not be attending. Gaining a better understanding of the sample under investigation, and how to address potential barriers to their research attendance, would not only ensure the findings are generalized appropriately but also allow for us to broaden our target audience. This would allow us to tailor our retention for attendance to strategies to specific populations, and address barriers before interventions are fully implemented.

The present study provides important information about the characteristics of the patient population presenting at risk for perinatal substance use in OB/GYN clinics. Given that this specific HIV prevention interventions has historically been delivered in a substance use treatment setting, the present study provides a better understanding of the demographics, medical backgrounds, psychosocial characteristics, and substance use behaviors of those patients who traditionally may never present for substance abuse treatment services or may not be eligible for these services but could potentially benefit from this intervention. It is remarkable even that half of the women in the SSB group attended all five sessions of this intervention; it is possible that

this rate of attendance can speak to how relevant the intervention's content was to these women's lives. These findings can serve to inform the implementation and tailoring of HIV prevention interventions to meet patient needs in OB/GYN settings.

Study Strengths, Limitations, and Future Directions

Strengths

The present study had some important strengths. First, the Addiction Severity Index was used as a part of the original study's assessment battery. This assessment is completed using a trained interviewer. This format is more advantageous than self-report instruments insofar as its semi-structured nature allows the interviewer to probe further for an answer. Second, the RCT eligibility had few exclusion criteria, promoting heterogeneity and sample representativeness. The limited exclusion criteria also made patients with comorbidities, polysubstance use, and different ethnic backgrounds eligible for the study, providing information across severity. This enabled the data to reflect the complexities that are typically seen in perinatal care.

Limitations

Despite these strengths, some limitations were also present. First, although the majority of measures were administered by a trained interviewer with the ability to probe further than self-report measures, women were asked to report on some very sensitive issues in the context of the interview which may introduce response bias. This study sample was solely pregnant women at risk for perinatal substance use, a highly stigmatized group. This is particularly true when respondents are asked to report on stigmatized behaviors such as substance use and HIV risk behaviors (Harrison, 1995; Smith et al., 2008). It is possible women may have been influenced by social acceptability bias in their answers to the trained interviewer.

An additional potential limitation of this sample was that it was recruited from an urban clinic that serves predominately low-income, ethnic minorities. The lack of variability of patients served in this setting limited the range for several demographic variables, specifically race, marital status, and employment. It is possible that this sample may differ substantially than those in another area. A more heterogeneous sample may have revealed more information about the characteristics associated with attendance.

Some limitations of this study were due to the data available. Specifically, the majority of the women randomized to the one session HE control group attended the one session group, with only a few not attending. Additionally, more than half of the participants randomized to the SSB intervention group attended all five sessions of the intervention, with one quarter attending zero sessions. The skew of the attendance distribution could feasibly be influencing this current study outcomes. A larger sample from multiple sites might provide enough variability to understand better the dose appropriate to impact outcomes of this intervention.

The number of comparisons across groups made as a part of the univariate analysis increased the probability of a committing a Type I error. The larger the number of tests, the easier it is to detect an effect when in fact there is none (Abdi, 2007). The nature of the study necessitated a larger number of comparisons in order to fully explore what domains of interest, as prior research on this topic was limited and this study was exploratory.

Lastly, study eligibility was determined by a screener that asked specifically about substance use. It is possible that out of fear of legal repercussions or judgment, pregnant women did not endorse symptoms on these screeners that would have led to their inclusion. It is therefore possible that the study sample itself is biased.

Future Directions

This present study serves as an initial investigation into characteristics associated with attendance in a two arm RCT comparing Safer Sex Skill Building to a Health Education control group. Using secondary data analyses, the study was limited by variables included in the original assessment battery. However, despite these limitations, this study was able to test hypotheses put forth in the literature on a novel treatment population for the SSB intervention. To further this work, analyses may be completed again for the SSB group using the dose suggested in previous literature for the intervention.

Future research on this intervention should build upon these findings and include questions about explicitly ask about structural barriers that might prevent this population from attending interventions. The psychosocial variables presented in the current study only serve as a proxy for mechanisms by which women are able to attend or not attend the HIV prevention interventions; in order to be able to draw direct causation, directly assessing structural barrier constructs with women is important. Additionally, it may be helpful for researchers to assess participant expectations of both the control group and the intervention, including time commitment, educational content, and namesake, to determine whether these may be at play when considering attendance. Including measures of structural barriers to participation will allow researchers to specifically address these barriers to improve attendance to interventions.

Future research should also broaden the current study to a more diverse group of women at risk for perinatal substance use in order to see if these findings are the same in women of different racial, marital, education, or employment status. This expansion would necessitate multisite trials in order to obtain a broader diversity of women at risk for substance use who are seeking perinatal care. It would be helpful to understand what factors may differentially affect attendance across samples, which could impact clinical practice and potentially resources.

Conclusion

In summary, the present study offered a unique opportunity to compare RCT attendance in both the HE control and SSB intervention groups across a wider array of variables than previously found in the literature. Overall, different factors were associated with HE as compared to SSB attendance. For HE, younger age and marital status were found to be predictive of attendance. This finding is consistent with the previous literature on attendance to interventions. For SSB, having a trade, skill, or profession was the primary predictor of SSB intervention group attendance. The present study serves as a preliminary analysis of predictors of HIV prevention intervention attendance and highlights the need to explore these factors in future research. Such research can help to inform the design and implementation of more effective prevention and intervention programs for high risk samples like pregnant women at risk for perinatal substance use and HIV.

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Vita

Jaclyn Sara Sadicario was born on August 31, 1989 in Manhasset, New York. She graduated from Saint John the Baptist Diocesan High School in May of 2007. She went on to attend Temple University and graduated Summa Cum Laude with a Bachelor of the Arts in Psychology, English, and Women's Studies in May of 2011. She worked for the University of Pennsylvania in the Department of Psychiatry and Department of Health Policy. Since then, she has attended Virginia Commonwealth University as a clinical psychology doctoral student, as part of the behavioral medicine program. Her research interests include broadly integrated care for chronic illness, substance use treatment research, perinatal substance use, STI prevention, and cystic fibrosis. She currently serves her practica at Health Brigade, The Adult Cystic Fibrosis Clinic at VCU Medical Center, and CrossOver Healthcare Ministries.