BIOPSYCHOSOCIAL FACTORS ASSOCIATED WITH REDUCING HAZARDOUS DRINKING AMONG WOMEN WITH HIV INFECTION

By

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A DISSERTATION PRESENTED TO THE GRADUATE SCHOOL OF THE UNIVERSITY OF FLORIDA IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF DOCTOR OF PHILOSOPHY

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To the participants and staff who helped make this dissertation research possible.

And to my parents (Pamela and Willie), my husband (Armand), my siblings, family and extended family, friends, Pastor and church family, and supporters who prayed, encouraged, and never stopped believing in me.
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<table>
<thead>
<tr>
<th>SECTION</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACKNOWLEDGMENTS</td>
<td>4</td>
</tr>
<tr>
<td>LIST OF TABLES</td>
<td>10</td>
</tr>
<tr>
<td>LIST OF FIGURES</td>
<td>11</td>
</tr>
<tr>
<td>LIST OF ABBREVIATIONS</td>
<td>12</td>
</tr>
<tr>
<td>ABSTRACT</td>
<td>14</td>
</tr>
<tr>
<td>CHAPTER 1: INTRODUCTION</td>
<td>18</td>
</tr>
<tr>
<td>Overview of Hazardous Drinking</td>
<td>19</td>
</tr>
<tr>
<td>Rationale for a Focus on Women</td>
<td>19</td>
</tr>
<tr>
<td>Treatment Options for Hazardous Drinking</td>
<td>20</td>
</tr>
<tr>
<td>Choice of Pharmacologic Treatment for Alcohol Consumption</td>
<td>21</td>
</tr>
<tr>
<td>Biopsychosocial Model</td>
<td>22</td>
</tr>
<tr>
<td>Biological</td>
<td>22</td>
</tr>
<tr>
<td>Psychological</td>
<td>23</td>
</tr>
<tr>
<td>Sociological</td>
<td>24</td>
</tr>
<tr>
<td>Overview of Chapters</td>
<td>25</td>
</tr>
<tr>
<td>CHAPTER 2: A SYSTEMATIC REVIEW OF NALTREXONE FOR ATTENUATING ALCOHOL CONSUMPTION IN WOMEN WITH ALCOHOL USE DISORDERS (AUD)</td>
<td>27</td>
</tr>
<tr>
<td>Background</td>
<td>28</td>
</tr>
<tr>
<td>Methods</td>
<td>30</td>
</tr>
<tr>
<td>Results</td>
<td>31</td>
</tr>
<tr>
<td>Study Summaries</td>
<td>34</td>
</tr>
<tr>
<td>Study Outcomes</td>
<td>36</td>
</tr>
<tr>
<td>Discussion</td>
<td>37</td>
</tr>
<tr>
<td>CHAPTER 3: HOW DOES PARTICIPATION IN CLINICAL TRIALS INFLUENCE DRINKING BEHAVIOR AMONG WOMEN WITH HIV</td>
<td>42</td>
</tr>
<tr>
<td>Background</td>
<td>43</td>
</tr>
<tr>
<td>Methods</td>
<td>47</td>
</tr>
<tr>
<td>Study Design</td>
<td>47</td>
</tr>
<tr>
<td>Inclusion Criteria</td>
<td>48</td>
</tr>
<tr>
<td>Recruitment</td>
<td>48</td>
</tr>
<tr>
<td>Procedure</td>
<td>49</td>
</tr>
<tr>
<td>Study Instrument</td>
<td>51</td>
</tr>
</tbody>
</table>
Dissertation Findings .................................................................................................................. 98
  Chapter 2: Systematic Literature Review .............................................................................. 98
  Chapter 3: Qualitative Interviews ....................................................................................... 99
  Chapter 4: Analysis of the Brief Important Inventory Questionnaire ................................. 100
Strengths ................................................................................................................................. 101
Limitations ............................................................................................................................... 103
Recommendations for Future Research .................................................................................. 105
Clinical and Policy Implications ............................................................................................. 106

APPENDIX

A  PATIENT INFORMED CONSENT FORM (ICF) ................................................................. 108

B  IMPORTANT PEOPLE INVENTORY (IPI) ASSESSMENT .............................................. 118

LIST OF REFERENCES ........................................................................................................... 128

BIOGRAPHICAL SKETCH ........................................................................................................ 137
## LIST OF TABLES

<table>
<thead>
<tr>
<th>Table</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-1</td>
<td>The main characteristics of included studies.</td>
<td>40</td>
</tr>
<tr>
<td>3-1</td>
<td>Interview Question Guide</td>
<td>52</td>
</tr>
<tr>
<td>3-2</td>
<td>Demographic of Study Participants</td>
<td>56</td>
</tr>
<tr>
<td>3-3</td>
<td>Themes related to reasons for seeking treatment, clinical trial experience,</td>
<td>57</td>
</tr>
<tr>
<td></td>
<td>and specific aspects of the trial associated with reducing hazardous drinking</td>
<td></td>
</tr>
<tr>
<td>3-4</td>
<td>Drinking Outcome Variables</td>
<td>62</td>
</tr>
<tr>
<td>4-1</td>
<td>Brief Important People Inventory Questionnaire</td>
<td>76</td>
</tr>
<tr>
<td>4-2</td>
<td>Social Network Categories and Variables</td>
<td>78</td>
</tr>
<tr>
<td>4-3</td>
<td>Demographic characteristics of the women who completed the Brief</td>
<td>82</td>
</tr>
<tr>
<td></td>
<td>Important People Inventory Questionnaire</td>
<td></td>
</tr>
<tr>
<td>4-4</td>
<td>Description of the important people listed in the participant’s daily lives</td>
<td>83</td>
</tr>
<tr>
<td></td>
<td>as reported in the Brief IPI</td>
<td></td>
</tr>
<tr>
<td>4-5</td>
<td>Relationship of network members to social network variables</td>
<td>87</td>
</tr>
<tr>
<td>4-6</td>
<td>Social network variables that may influence hazardous drinking among</td>
<td>90</td>
</tr>
<tr>
<td></td>
<td>women with HIV infection</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Figure</td>
<td>Description</td>
<td>Page</td>
</tr>
<tr>
<td>--------</td>
<td>-------------------------------------------------</td>
<td>------</td>
</tr>
<tr>
<td>2-1</td>
<td>Flow chart of study selection process</td>
<td>33</td>
</tr>
<tr>
<td>Acronym</td>
<td>Description</td>
<td></td>
</tr>
<tr>
<td>---------</td>
<td>-------------</td>
<td></td>
</tr>
<tr>
<td>AIDS</td>
<td>Acquired Immunodeficiency Syndrome</td>
<td></td>
</tr>
<tr>
<td>ART</td>
<td>Antiretroviral Therapy</td>
<td></td>
</tr>
<tr>
<td>AU</td>
<td>Alcohol use</td>
<td></td>
</tr>
<tr>
<td>AUD</td>
<td>Alcohol use disorder</td>
<td></td>
</tr>
<tr>
<td>BCST</td>
<td>Brief Coping Skills Therapy</td>
<td></td>
</tr>
<tr>
<td>BRMC</td>
<td>Behavioral Medical Research Center</td>
<td></td>
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<td>Brief Skills Training</td>
<td></td>
</tr>
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<td>CBPR</td>
<td>Community-Based Participatory Research</td>
<td></td>
</tr>
<tr>
<td>CBST</td>
<td>Cognitive Behavioral Skills Therapy</td>
<td></td>
</tr>
<tr>
<td>CBT</td>
<td>Cognitive Behavioral Therapy</td>
<td></td>
</tr>
<tr>
<td>CINAHL</td>
<td>Cumulative Index to Nursing and Allied Health Literature</td>
<td></td>
</tr>
<tr>
<td>CRB</td>
<td>University of Miami’s Clinical Research Building</td>
<td></td>
</tr>
<tr>
<td>DD</td>
<td>Drinking days</td>
<td></td>
</tr>
<tr>
<td>DDD</td>
<td>Drinks per drinking day</td>
<td></td>
</tr>
<tr>
<td>DPD</td>
<td>Drinks per day</td>
<td></td>
</tr>
<tr>
<td>DSM-IV</td>
<td>American Psychiatric Association’s Diagnostic and Statistical Manual Fourth Edition</td>
<td></td>
</tr>
<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
<td></td>
</tr>
<tr>
<td>HD</td>
<td>Heavy drinking days</td>
<td></td>
</tr>
<tr>
<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
<td></td>
</tr>
<tr>
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<td></td>
</tr>
<tr>
<td>IRB</td>
<td>Institutional Review Board</td>
<td></td>
</tr>
</tbody>
</table>
MM Medical Management
NAL Naltrexone
NIAAA National Institute on Alcohol Abuse and Alcoholism
NIH National Institute of Health
PDA Percent days abstinent
PHDD Percent heavy drinking days
PL Placebo
PT Psychotherapy
RCT Randomized Controlled Trial
SST Standardized Supportive Therapy
TFD Time to first drink
THDD Time to first heavy drinking day
TLFB Timeline Follow Back
WHAT-IF Will Having Alcohol Treatment Improve Functioning?
Abstract of Dissertation Presented to the Graduate School of the University of Florida in Partial Fulfillment of the Requirements for the Degree of Doctor of Philosophy

BIOPSYCHOSOCIAL FACTORS ASSOCIATED WITH REDUCING HAZARDOUS DRINKING AMONG WOMEN WITH HIV INFECTION

By
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In the United States, HIV and hazardous drinking are two prevalent and costly public health issues that have been associated with negative health outcomes in women. Studies have shown the effects of hazardous drinking in women to include biological, psychological, and social repercussions, which may lead to an increased vulnerability of women. Thus, hazardous drinking among women with HIV infection can lead to more personal and public health consequences. Moreover, research focused on examining treatment efficacy, clinical trial participation and experience, and social networks variables influence on reducing hazardous drinking in women with HIV is scarce. This dissertation aimed to evaluate the complex social phenomenon of hazardous drinking among women with HIV infection by investigating biopsychosocial factors associated with reducing hazardous drinking.

In this project, a mixed methodological approach was undertaken. In study 1, we conducted a systematic literature review to review and summarize the evidence regarding the impact of naltrexone for attenuating alcohol consumption in women with an alcohol use disorder (AUD). This research sought out to answer the following research question: “Is naltrexone effective in treating substance use in women with an
alcohol use disorder?” Next, study 2 and 3 involved analyses of data from participants who completed the WHAT-IF clinical trial. Recruitment for the WHAT-IF study participants occurred from outpatient referral sites, associated centers, and surrounding community. The trial utilized the following inclusion criteria: 1) age 18 or over, 2) female, 3) hazardous drinking, on average, during the previous 4 weeks and/or high total weekly consumption, 4) HIV infection, and 5) able to understand and comply with study procedures and to provide written consent. In study 2, we conducted qualitative interviews (n = 20) to identify women with HIV reasons for enrolling in the WHAT-IF clinical trial for a reduction in hazardous drinking and to identify the reasons women with HIV were successful or unsuccessful in changing their drinking behavior. This study aimed to discuss the following research questions within the context of the biopsychosocial model: 1) “What are the attitudes among women with HIV toward participating in the WHAT-IF clinical trial for a reduction in hazardous drinking?” 2) “How did women with HIV describe their experience in the clinical trial experience?” 3) “What specific aspects of the trial, besides the study medication were associated with a reduction in hazardous drinking among the women with HIV?” In study 3, we analyzed the Brief Important People Inventory (IPI) questionnaire data collected in the WHAT-IF study at month 2 to describe the important people in the women with HIV daily lives, and to identify the social network variables associated with the important people and the likelihood that they support a reduction in hazardous drinking. This study aimed to answer the following research question, “What are the social network variables that may influence hazardous drinking in women with HIV infection?”
Henceforth, the results of the systematic literature review (n = 7 studies) in study 1 suggested naltrexone might lead to modest reductions in the quantity of drinking and time to relapse, but not on the frequency of drinking in women. Moreover, the results of the systematic literature review laid the foundation for the following study. In study 2, several themes within the context of the biopsychosocial model (reduction in drinking, the ability for self-reflection, and interactions with the study staff) emerged identifying the women with HIV reasons for enrolling in the WHAT-IF study for a reduction in hazardous drinking and the reasons why women with HIV were successful or unsuccessful in changing their drinking behavior. Findings provided a basis for understanding why hazardous drinking women with HIV enroll in clinical trials while also examining the women with HIV perceptions of clinical trial experience and its relationship to drinking outcomes. Likewise, the results from study 3 suggested social network variables such as the presence of at least one regular drinker in the network and at least one daily contact person in the network may influence a reduction or increase in hazardous drinking among women with HIV. Study limitations associated with this dissertation research include lack of generalizability given that all of the women in the three studies were women, potential recall bias, selection bias, and possible data collection challenges.

In summary, the findings of these three studies provided an understanding of the biopsychosocial factors associated with reducing hazardous drinking in women with HIV infection. These findings also add to the limited literature base examining treatment efficacy, clinical trial participation and overall clinical trial experience, and social network variables influence on reducing hazardous drinking comorbidities in women with HIV.
The information ascertained in this project will aid in the development of interventions for HIV-infected women with hazardous drinking.
CHAPTER 1
INTRODUCTION

HIV is a major global public health problem. Currently, one million people are living with HIV in the United States and 39 million people are living with the virus worldwide (WHO, 2016). In the US, nearly 240 new cases of HIV occur every hour and an estimated 50,000 people become infected with HIV each year (amfAR, 2016). Despite global actions made toward reducing HIV incidence, research has shown substance abuse contribution to the spread of HIV/AIDS, which can negatively affect treatment for infected people, primarily women with HIV (NIAAA, n.d.).

In the United States, alcoholism is a prevalent and costly public health issue with women representing the fastest-growing population of alcohol users (Krystal et al., 2001; NCADD, 2015). The National Institute on Alcohol Abuse and Alcoholism (2016) estimates that 5.3 million women over 18 years in the US have an alcohol use disorder (AUD); the term used to describe problem drinking and classified as mild, moderate or severe (NIAAA, 2016; SAMHSA, 2012; NIH, 2015). While severe problems associated with alcohol use disorders include alcohol abuse or dependence, less severe disorders are often called as heavy, hazardous, or harmful drinking (Carrington Reid et al., 1999). Consequently, alcohol use disorders are the fourth leading preventable cause of death in the US (Mokdak et al., 2004; Stahre et al., 2014).

In Chapter 1, we will offer an overview of hazardous drinking, a rationale for focusing on women, treatment options, and choice of pharmacologic treatment for hazardous drinking in women. We will also give a review of the biopsychosocial model and how we created three studies to investigate using this model to explore hazardous drinking in women with HIV.
Overview of Hazardous Drinking

Hazardous drinking defined as a quantity or pattern of drinking is associated with increased risk of physical and or psychological harm but does not necessarily involve alcohol abuse or dependence (NIAAA, 2016). The quantity or pattern of alcohol consumption associated with hazardous drinking is usually quantified by setting specific values of an individual’s average number of drinks consumed per week or occasion (Carrington, Fiellin, and O’Connor, 1999). The National Institute on Alcohol Abuse and Alcoholism (2005) defines hazardous drinking for women as consuming 7 drinks or more per week (or ≥3 drinks per occasion). Among HIV-infected people, hazardous drinking can lead to more personal and public health consequences (NIAAA, 2016).

Hazardous drinking presents unique health risks in women with HIV infection including increased HIV viral load, lower medication adherence, increased risky sexual behavior, more rapid disease progression and decreased survival (Cook et al., 2001; Chandler et al., 2008; Peretti-Watel et al., 2006; Baum et al., 2010). Moreover, hazardous drinking could be very harmful in women with liver diseases such as Hepatitis C virus (HCV) infection, which has become a leading cause of mortality in women with HIV infection (Elliot et al., 2016; Barve et al., 2010; Nunes et al., 2006; Schiff & Ozden, 2004). While hazardous drinking is more common in men, an estimated 6%-54% of women with HIV infection engage in hazardous drinking (Cook et al., 2001; Theall et al., 2007; Cook et al., 2009).

Rationale for a Focus on Women

For decades, clinical research has underrepresented women regardless of whether they have HIV infection. In the past, majority of the participants in substance abuse research were male or consisted of a mixed sample of men and women with little
regard to gender differences (Greenfield et al., 2006). Despite the gender bias in earlier research, substance abuse is increasing in women, warranting further exploration. Therefore, it is vital that clinical trials be powered sufficiently to make definitive conclusions in women.

Presently, 25% of people living with HIV in the U.S. are women (CDC, 2017). In 2015, women made up 19% of the new HIV diagnoses in the US (CDC, 2017). Although advancements in the fight against the HIV epidemic has resulted in improved health outcomes and survival rates, in the US HIV remains the 4th leading cause of death for Black women ages 35-44 (KFF, 2017). Specifically, among women with HIV infection, liver disease has emerged as the most common non-AIDS-related cause of death (Shiferaw et al., 2016; Deeks and Phillips, 2009). Moreover, consuming hazardous levels of alcohol can increase the risk of developing cirrhosis and hepatocellular carcinoma while worsening other live conditions especially in women with hepatitis C virus (Hu et al., 2016; Joshi et al., 2011; Cohen et al., 2002).

**Treatment Options for Hazardous Drinking**

Substantial research has demonstrated support for the use of brief interventions, lasting 15-60 minutes as effective tools used in clinical trials for addressing a range of drinking behaviors (Anderson et al., 2017; Derges et al., 2017; McCambridge and Saitz, 2017). Unfortunately, brief interventions are often met with mixed reviews about their use in everyday practice and often need clinicians and staff to undergo training (McCambridge and Saitz, 2017). On the contrary, multiple psychosocial, behavioral, and pharmacotherapy interventions are effective in treating hazardous drinking, however, little evidence exists about pharmacologic treatment to reduce hazardous drinking outside of substance-abuse treatment settings (Moos & Moos, 2006). The primary
treatment goals are abstinence from drinking or reduction in heavy drinking (Srisurapanont & Jarusuraisin, 2005; Maisel et al., 2012; Jonas et al., 2014). Thus, women present a special subset of drinkers as a result of physiologic status, psychosocial factors, and genetic considerations (Mann et al., 1992; Mann et al., 2005; Ponce et al., 2005; Diehl et al., 2007; Greenfield et al., 2010). To date, effective treatment options have not been evaluated in a sample of hazardous drinking women with HIV infection.

**Choice of Pharmacologic Treatment for Alcohol Consumption**

Several medications are effective in reducing heavy drinking and increasing days of alcohol abstinence in drinkers; however, the efficacy of these interventions varies considerably (Streeton & Whelan, 2001; Srisurapanont & Jarusuraisin, 2005; Carmen et al., 2004; Maisel et al., 2012; Jonas et al., 2014). As mentioned, naltrexone is a prescription medication approved by the U.S. Food and Drug Administration (FDA) and promoted for use in AUD populations (Garbutt et al., 2005; Hernandez-Avila et al., 2006; Roozen et al., 2007). Naltrexone acts to decrease alcohol cravings and reduce the reinforcing effects of alcohol consumption by blocking opioid-mediated increases in central dopamine release (Gianoulakis, 2001). Administration options include oral medication once per day or a once-a-month injectable (Garbutt et al., 2005; Hernandez-Avila et al., 2006; Roozen et al., 2007). While the ideal dose of naltrexone is not known, most studies used 50mg/day (range 50mg-150mg). Moreover, studies have reported that naltrexone is more effective than other pharmacotherapy particularly when combined with behavioral treatment (Anton et al., 2006; O'Malley et al., 2007). However, clinical trials evaluating combinations of naltrexone and behavioral interventions have demonstrated mixed results (Anton et al., 2006; Ponce et al., 2005;
Lovallo et al., 2012; Garbutt et al., 2014). While recent systematic reviews suggest slight benefit from naltrexone [Jonas et al., 2014; Donoghue et al., 2015], they do not specifically address variables specific to naltrexone treatment in women.

Biopsychosocial Model

For decades, the biopsychosocial (BPS) model has postulated that substance abuse is the result of multifaceted interactions between biological, psychological, and social factors (Lindstrom, 1992). Research investigating the causes of alcoholism has shown connections between biological and psychosocial factors instead of examining each separately (NIAAA, n.d.). By adopting a holistic approach, the biopsychosocial model guided this dissertation research. In this section, we will offer an overview and review of how the BPS model evaluated the effectiveness of treatment in women with an AUD. We will then review how the BPS identified reasons for enrolling in the clinical trial among hazardous drinking women with HIV while also identifying reasons women with HIV were successful or unsuccessful in reducing hazardous drinking. Finally, the biopsychosocial model will examine social network variables influence on reducing hazardous drinking in women with HIV infection.

Biological

Research has demonstrated the role of genetics and other biological factors as it relates to alcohol dependence. While men are generally more prone to drinking larger amounts of alcohol than women, gender variances in body makeup and chemistry cause women to absorb more alcohol quicker, which in turn delays the breakdown process of removing alcohol from their system (CDC, 2016). Women have also been reported to incur different heritability for alcoholism compared to men (Greenfield et al., 2007; Ponce et al., 2005) and this is important since family history is a noted factor in
treatment response. However, not all women who have a family history of alcoholism develop problems. Most importantly, gender differences (i.e., absorption, genetics, and vulnerability) underscore the need to evaluate the effectiveness of specific treatment options for AUDs in women. In a study by Lyon and Willott (2008), women were found redefining their gender identities in comparison to men by consuming alcohol. The authors identified seven themes related to gender and alcohol use including (1) amount of alcohol consumed, (2) frequency of drinking, (3) choice of drinks, (4) reasons for drinking, (5) negative aspects of drinking, (6) site of drinking, (7) alcohol and other drugs. Thus, some of these themes explored in the qualitative interviews that focus on identifying the treatment-seeking practices among hazardous drinking women with HIV infection and the reasons why women with HIV were successful or unsuccessful in changing their drinking behavior. On the other hand, research has shown that consuming an excessive amount of alcohol can lead to addiction disorder beyond AUD (Bushack, 2014). This in turn can lead to developing an alcohol use disorder (Bushack, 2014). While consuming too much alcohol can lead to many negative health consequences, understanding resolution of deliberate self-harm by identifying the role of alcohol as a precipitating and maintaining factor in self-harm is vital (Sinclair and Green, 2005).

**Psychological**

While the number of women diagnosed with an alcohol use disorder who seek treatment is relatively low, studies have shown that when compared to men, women have better overall treatment outcomes (CDC, 2016). This finding warranted further examination of literature to identify treatment-seeking practices among women with an AUD. By definition, treatment seeking for an alcohol problem is seeking care, support,
or help for alcohol problems at a treatment facility (Jakobsson et al., 2004). For example, Jakobsson et al. (2004) interviewed 12 participants within in a month of their first voluntary treatment for alcohol and were able to explore treatment-seeking processes in men and women with alcohol problems by focusing on promoting and hindering factors (Jakobsson et al., 2004). Likewise, Harris et al. (2005) was able to identify themes that supported recovery among women with substance abuse, which included connection, self-awareness, a sense of purpose and meaning, and spirituality. On the contrary, themes that served as barriers to recovery were battles with depression and despair, destructive habits and patterns, and lack of personal control (Redko et al., 2006).

**Sociological**

While social network variables influence on alcohol use has garnered attention in recent decades, research has supported the role of social networks on long-term recovery for people with alcohol addiction (Valente et al., 2010, Kelly et al., 2011). Several studies have demonstrated the relationship between social networks and social network’s approval toward participant drinking associated with negative health outcomes (Worley et al., 2015). According to Longabaugh and Beattie (1985, 1986), understanding the construct of social support and its relationship to drinking outcomes is vital. For this purpose of this dissertation, the categorization of social support categorized included: a) alcohol-specific support, specifically related to alcohol use, or b) general or global support, related to the overall well-being of an individual. According to the literature social network influences were mediators and predictors of drinking outcomes such as percent days abstinent (PDA) (Katskutas et al., 2002; Longabaugh et al. 2009).
Alcoholism is a prevalent and costly public health issue with women representing the fastest-growing population of alcohol users (Krystal et al., 2001; NCADD, 2015). The research focused on examining treatment efficacy, clinical trial participation and clinical trial experience, and social network variables influence on reducing hazardous drinking in women with HIV is scarce. Whilst alcohol affects men and women differently, little research exists on the most effective treatment options for hazardous drinking women with HIV infection. This project aimed to evaluate the complex social phenomenon of hazardous drinking among women with HIV infection by investigating biopsychosocial factors associated with reducing hazardous drinking.

**Overview of Chapters**

In Chapter 2, the biological mechanism of the biopsychosocial model examined response to pharmacological process. Chapter 2 reviewed quantitative studies that have evaluated the impact of naltrexone on drinking outcomes in women alone or distinct from men. The purpose of Chapter 2 was to review and summarize the evidence regarding the impact of naltrexone for attenuating alcohol consumption in women with an alcohol use disorder (AUD). In Chapter 3, the biopsychosocial model helped frame the initial line of questions for participants related to the multiple determinants of drinking behavior carried out in qualitative interviews. The purpose of this study was to identify women reasons for seeking treatment for hazardous drinking and to identify the reasons women were successful or unsuccessful in changing their drinking behavior. Specifically, this study aimed to discuss the following research questions within the context of the biopsychosocial model: 1) “What are the attitudes among women toward seeking treatment for hazardous drinking?” 2) “How did women describe their experience in the clinical trial experience?” 3) “What specific aspects of the trial, besides
the study medication associated with a reduction in hazardous drinking among the women?” Therefore, in Chapter 4, the biopsychosocial model helped explain linkages to broader health constructs while examining the role of social networks on drinking outcomes, thus enabling the interpretive theories to explain the relationships unearthed. The purpose of this study was to describe the important people in the participants’ daily life (as described in the Brief Important People Inventory questionnaire), and to identify the social network variables associated with the number of important people and the likelihood that the support hazardous drinking reduction. Specifically, this study aimed to answer the following research question, “What are the social network variables that may influence hazardous drinking in women with HIV infection?” Finally, Chapter 5 synthesizes the findings of this dissertation, discusses the strengths and limitations of this dissertation, and provides recommendations and implications for future research in this area.
CHAPTER 2
A SYSTEMATIC REVIEW OF NALTREXONE FOR ATTENUATING ALCOHOL CONSUMPTION IN WOMEN WITH ALCOHOL USE DISORDERS (AUD).

Several clinical trials have evaluated naltrexone as a treatment for alcohol use disorders, but few have focused on women. The aim of this review was to systematically review and summarize the evidence regarding the impact of naltrexone compared to placebo for attenuating alcohol consumption in women with an alcohol use disorder (AUD). A systematic review was conducted using PubMed, Cochrane, Web of Science, CINAHL, and Alcohol Studies Database to identify relevant peer-reviewed randomized controlled trials (RCTs) published between January 1990 and August 2016. Seven published trials have evaluated the impact of naltrexone on drinking outcomes in women distinct from men. 903 alcohol-dependent or heavy drinking women were randomized to receive once daily oral or depot (injectable) naltrexone or placebo with/without behavioral intervention. Two studies examining the quantity of drinks per day observed trends toward reduction in drinking quantity among women who received naltrexone vs. placebo. The 4 studies examining the frequency of drinking had mixed results, with one study showing a trend that favored naltrexone, two showing a trend that favored placebo, and one that showed no difference. Two of the three studies examining time to relapse observed trends that tended to favor naltrexone for time to any drinking and time to heavy drinking among women who received naltrexone vs. placebo. While the growing body of evidence suggests a variety of approaches to treat alcohol use disorders (AUD), the impact of naltrexone to combat AUD in women is understudied. Taken together, the results suggest that naltrexone may lead to modest reductions in quantity of drinking and time to relapse, but not on the frequency of drinking in women. Future research should incorporate sophisticated study designs that
examine gender differences and treatment effectiveness among those diagnosed with an AUD and present data separately for men and women.

**Background**

In the United States, alcoholism is a prevalent and costly public health issue with women representing the fastest-growing population of alcohol users (Krystal et al., 2001; NCADD, 2015). The National Institute on Alcohol Abuse and Alcoholism (2016) estimates that 5.7 million women over 18 years in the US have an alcohol use disorder (AUD); the term used to describe problem drinking and is classified as mild, moderate or severe (NIAAA, 2016; SAMHSA, 2012; NIH, 2015). Consequently, alcohol use disorders are the fourth leading preventable cause of death in the US (Mokdak et al., 2004; Stahre et al., 2014).

Multiple psychosocial, behavioral, and pharmacotherapy interventions have been shown to be effective in treating an AUD, however, the relapse rate approximates 70% [Moos & Moos, 2006]. The primary treatment goals for an AUD are abstinence from drinking or reduction in heavy drinking (Srisurapanont & Jarusuraisin, 2005; Maisel et al., 2012; Jonas et al., 2014). Thus, women present a special subset of an AUD as a result of physiologic status, psychosocial factors, and genetic considerations (Mann et al., 1992; Mann et al., 2005; Ponce et al., 2005; Diehl et al., 2007; Greenfield et al., 2010). Women who consume an extreme amount of alcohol can subject themselves to immediate effects that can increase their risk of harmful health conditions (CDC, 2015). Likewise, excessive alcohol consumption can lead to the development of chronic diseases and other serious problems such as developing alcohol dependence or alcoholism (CDC, 2015). While several medications (i.e., naltrexone, acamprosate, disulfiram) have been used to reduce heavy drinking and increase days of alcohol
abstinence in drinkers, the efficacy of these interventions varies considerably (Streeton & Whelan, 2001; Srisurapanont & Jarusuraisin, 2005; Carmen et al., 2004; Maisel et al., 2012; Jonas et al., 2014).

As previously mentioned, naltrexone is a prescription medication that has been approved by the U.S. Food and Drug Administration (FDA) and promoted for use in AUD populations (Garbutt et al., 2005; Hernandez-Avila et al., 2006; Roozen et al., 2007). Naltrexone acts to decrease alcohol cravings and reduce the reinforcing effects of alcohol consumption by blocking opioid-mediated increases in central dopamine release (Gianoulakis, 2001). Administration options include oral medication once per day or a once-a-month injectable (Garbutt et al., 2005; Hernandez-Avila et al., 2006; Roozen et al., 2007). While the optimal dose of naltrexone is not known, most studies used 50mg/day (range 50mg-150mg). Moreover, studies have reported that naltrexone is more effective than other pharmacotherapies particularly when combined with behavioral treatment (Anton et al., 2006; O'Malley et al., 2007). However, clinical trials evaluating combinations of naltrexone and behavioral interventions have demonstrated mixed results (Anton et al., 2006; Ponce et al., 2005; Lovallo et al., 2012; Garbutt et al., 2014). Most importantly, gender differences (i.e., absorption, genetics, vulnerability, etc.) underscore the need to evaluate the impact of specific treatment options for AUDs in women. While recent systematic reviews suggest slight benefit from naltrexone (Kranzler & Van kirk, 2006; Jonas et al., 2014; Donoghue et al., 2015), they do not specifically address variables specific to naltrexone treatment in women. Against this background, the objective of this paper is to systematically review and summarize the
evidence regarding the impact of naltrexone vs. placebo for attenuating alcohol consumption in women with an alcohol use disorder (AUD).

**Methods**

From January 1990 – August 2016, we queried online databases PubMed, Cochrane, Web of Science, CINAHL, and the Alcohol Studies Database for peer-reviewed original human research in Figure 2-1. A search was undertaken using the following search terms: naltrexone AND (alcohol; OR alcohol dependence; alcohol use disorders; hazardous drinking; heavy drinking; binge drinking; alcohol consumption) AND (women; OR female). Additional searches of Google Scholar and references of identified secondary literature were also carried out. This review included all relevant randomized controlled trials (RCT). All eligible articles were screened for relevance using titles and abstracts. Additionally, three researchers independently reviewed eligible papers.

This review included trials that evaluated the impact of naltrexone on drinking outcomes in women alone or distinct from men. This review used the following inclusion/exclusion criteria: (1) must include a RCT design, (2) published in English or capable of being translated, (3), published between 1990 to 2016, (4) intervention was oral or injectable naltrexone with or without behavioral intervention, (5) assessed a measurable drinking outcome, (6) study must present results for women alone or distinct from men, and (7) participants were 18 years of age or older. For the purposes of this review, we included only clinical trials as defined by the National Cancer Institute (2015) as, “a study in which participants are randomly assigned (by chance) to receive one of the several pharmacotherapies and/or behavioral interventions.”
For each eligible study, we abstracted information on the study population, intervention and comparison group, and main results. Because each study had different measures of alcohol use and slightly different combinations of treatments, we did not create a summary measure of risk; rather, we provided the results of each study. Drinking outcomes reported in the studies could be grouped into three general categories, including alcohol quantity (drinks per day, reduction in drinks/day, drinks per drinking day), frequency of drinking (days/month, percent drinking days (%), percent heavy drinking days (%), percent days abstinent (%)), and/or to time to relapse (time to any drinking, time to heavy drinking). Results were presented as significant differences if there was a statistically significant result (p<0.05); as trends if there was at least a 20% difference in outcomes, but the p-value was either not significant or not reported; and as “no difference” if the results were essentially the same or p-value was >0.5.

**Results**

The screening of relevant titles yielded a total of 2,765 articles. After reviewing the full-text articles (n=37) an additional thirty studies were eliminated. The 7 studies included in this review presented drinking outcomes for women distinct from men. Five studies were double-blind RCTs, one study was a factorial design RCT, and another study conducted an exploratory analysis post-hoc analysis from a double-blind RCT. Participants were randomized to a group treated with naltrexone (either oral once daily or targeted (drinking days only) 50mg-150mg or injectable naltrexone 380mg or 190mg, with or without a behavioral intervention or to a group receiving placebo with or without a behavioral intervention.

Six studies enrolled participants with alcohol dependence, diagnosed by the American Psychiatric Association’s Diagnostic and Statistical Manual Fourth Edition
(DSM-IV) (Kranzler et al., 2009; Greenfield et al., 2010; O'Malley et al., 2007; Garbutt et al., 2009; Kiefer, Jahn & Wiedemann, 2005; Pettinati et al., 2008). All of the studies except Pettinati et al. (2008) excluded persons who were dependent on substances other than alcohol or nicotine. The 7 studies included a total of 2,590 randomized participants, of whom 903 were women with a mean age range 39.2 to 49. In the four studies that reported race/ethnicity, the majority of women were Caucasian (n=576), followed by Hispanic (n=38), and then African American (n=37). Five studies reported the proportion of women who received naltrexone (daily or targeted) (n=271) or placebo (n=202) (Greenfield et al., 2010; O'Malley et al., 2007; Garbutt et al., 2009; Kiefer, Jahn & Wiedemann, 2005; Pettinati et al., 2008). All of the studies reported the timing of intervention application, ranging from 8 weeks to 16 weeks. Furthermore, the 7 studies utilized variable participant recruitment methods: advertisements (Greenfield et al., 2010; O'Malley et al., 2007; Hernandez-Avila et al., 2006), clinicians referrals (Kranzler et al., 2009; Hernandez-Avila et al., 2006), alcohol treatment study sites (Greenfield et al., 2010; O'Malley et al., 2007; Kiefer, Jahn, & Wiedemann, 2005; Pettinati et al., 2008), public hospitals, private and Veteran Administration clinics, or tertiary care settings (Garbutt et al., 2009).
Figure 2-1. Flow chart of study selection process.
Study Summaries

Detailed information about each study is in Table 2-1 and includes study summaries. Kranzler et al. (2009) conducted a 12-week factorial design study in the United States to determine the impact of targeted use of naltrexone to reduce heavy drinking. A total of 163 alcohol-dependent randomized participants (95 men and 68 women) received daily or targeted naltrexone (50mg/d) or daily or targeted placebo. The authors measured the drinking outcome drinks per day at multiple time points.

Greenfield et al. (2010) conducted a secondary analysis of the COMBINE Study (a national, multisite 16-week double-blind study in the US) to assess gender differences in treatment outcomes. A total of 1226 alcohol-dependent randomized participants (848 men and 378 women) assigned to one of eight groups received medical management with active naltrexone (100mg/d) or placebo, active acamprosate (3g/day) or placebo, with or without a behavioral intervention (CBI). The study assessed drinking outcomes percent days abstinent, percent heavy drinking days, and time to first heavy drinking day.

O’Malley et al. (2007) conducted a double-blind, 12-week study in the United States to investigate the safety and efficacy of oral naltrexone 50mg in a sample of 103 alcohol-dependent randomized women who received naltrexone or placebo. The study assessed drinking outcomes percent days abstinent, percent heavy drinking days, and time to first heavy drinking day.

Garbutt et al. (2009) conducted a 24-week double-blind study in the United States to determine the efficacy and tolerability of a long-acting intramuscular formulation of naltrexone. A total of 624 alcohol-dependent randomized participants (423 men and 201 women) received long-acting injectable naltrexone (380mg or
190mg) or placebo and standardized supportive therapy. The study measured the drinking outcome number of heavy drinking days at multiple time points.

Kiefer, Jahn & Wiedemann (2005) conducted an exploratory analysis post-hoc from Kiefer et al., (2003) (a 12-week double-blind study in Germany) to compare and combine naltrexone and acamprosate in relapse prevention in alcoholism. A total of 160 alcohol-dependent randomized participants (118 men and 42 women) assigned to one of four groups received active naltrexone (50mg/d), acamprosate (1998mg/d), naltrexone plus acamprosate, or placebo. The authors measured drinking outcomes mean time to first drink and mean time to relapse.

Hernandez-Avila et al. (2006) conducted a secondary analysis of a study by Kranzler et al. (2003) (an 8-week double-blind study in the US) to examine the effects of daily naltrexone and targeted scheduled administration on a continuous outcome of drinks/day. A total of 150 heavy-drinking randomized participants (87 men and 63 women) assigned to one of four-treatment groups received daily or targeted naltrexone (50mg/d) or daily or targeted placebo (50mg/day). The study measured the drinking outcome drinks per day at multiple time points.

Pettinati et al. (2008) conducted a 12-week double-blind study in the United States to determine the efficacy of a higher-than-normal daily dose of naltrexone among treatment-seeking participants with co-occurring cocaine and alcohol dependence. A total of 164 alcohol-dependent randomized participants (116 men and 48 women) received naltrexone (150mg/d) or placebo with cognitive behavioral therapy or medical management. The study measured drinking outcomes abstinence (yes/no), number of
drinks per drinking day, the percentage of drinking days, and the percentage of heavy drinking days at multiple time points.

**Study Outcomes**

Overall, study outcomes focused on alcohol quantity (drinks per day, reduction in drinks/day, drinks per drinking day), frequency of drinking (days/month, percent drinking days (%), percent heavy drinking days (%), percent days abstinent (%)), and/or time to relapse (time to any drinking, time to heavy drinking).

Three studies reported findings related to drinking quantity. Kranzler et al. (2009) reported no difference in women’s drinking across the four study conditions (e.g. daily naltrexone, daily placebo, targeted naltrexone, and targeted placebo). However, a trend toward reduced alcohol consumption was observed among women at study week 12 in the daily naltrexone group compared to the daily placebo group (Naltrexone group: 2.6 drinks per day vs. placebo group: 3.5 drinks per day) (no p-value reported) (Kranzler et al., 2009). Hernandez-Avila et al. (2005) reported no difference in mean drinks per day outcome among women at week 8 who received targeted naltrexone (2.75 drinks), targeted placebo group (2.5 drinks), daily naltrexone (2 drinks), or daily placebo (2 drinks) (no p-value reported). Pettinati et al. (2008) observed a trend toward reduced number of drinks per drinking day among women who received naltrexone (3.7 drinks (3.1)) versus placebo (6.4 drinks (6.7)) (no p-value reported).

Four studies considered the frequency of drinking as an outcome. Greenfield et al. (2010) observed a trend toward increased percentage of days abstinent among women who received naltrexone (78%) compared to placebo (71%) (p = 0.092); and a trend toward decreased percentage of heavy drinking days was observed among women receiving naltrexone (Naltrexone 14% of days vs. Placebo: 20.5% of days)) (no
p-value reported) (Greenfield et al., 2010). O’Malley et al. (2007) reported no difference in percent days abstinent (p = >.30) or percent heavy drinking days (p = >.30) among women who received naltrexone or placebo (actual results not provided). Pettinati et al. (2008) found a trend toward an increase in the percentage of any drinking days among women who received naltrexone (14.8% (16.6)) vs. placebo (9.8% (12.0)); but no difference in percentage of heavy drinking days among women (Naltrexone group: 6.9% (10.6) vs. Placebo group: 7.8% (12.2)) (no p-value reported). Garbutt et al. (2005) observed a trend toward greater percent drinking days among women who received 380mg injectable naltrexone vs. placebo, (HR, 1.23 (0.85-1.78), p = 0.28) or 190mg injectable naltrexone vs. placebo (HR, 1.07 (0.73-1.58), p = 0.72).

Three studies reported findings on the time to first drink outcome. Kiefer, Jahn, & Wiedemann (2005) observed a significantly longer time to first drink among women who received oral naltrexone (68.9 ± 8.7 days) vs. placebo (19.2 ± 6.1 days) (p < 0.001); and a significant increase in time to first heavy drinking day among women who received naltrexone (77.0 ± 8.0 days) vs. placebo (32.2 ± 8.0 days) (p < 0.05). Greenfield et al. (2010) observed a trend in longer time to relapse to first heavy drinking day (number of days in which 50% of the sample returned to drinking) among women who received naltrexone (42 days) vs. placebo (18 days)(p-value not reported). O’Malley et al. (2007) found no significant difference in time to return to drinking among women who received naltrexone (30 days) vs. placebo (40 days) (p = 0.88)

Discussion

This review systematically reviewed and summarized the evidence regarding the impact of naltrexone compared to placebo for attenuating alcohol consumption. To date, this is the first systematic literature review that focuses solely on women with an AUD.
Our review identified seven studies conducted between 1990-2016 that met the a priori inclusion criteria. Two of the three studies examining the quantity of drinks per day observed trends toward reduction in drinking quantity among women who received naltrexone vs. placebo. The 4 studies examining the frequency of drinking had mixed results, with one study showing a trend that favored naltrexone, two showing a trend that favored placebo, and one that showed no difference. Two of the three studies examining time to relapse observed trends that tended to favor naltrexone for time to any drinking and time to heavy drinking among women who received naltrexone vs. placebo. Taken together, the results suggest that naltrexone may lead to modest reductions in quantity of drinking and time to relapse, but not on the frequency of drinking in women. However, among 7 studies, only 1 reported a statistically significant improvement in drinking outcomes among women who received naltrexone vs. placebo.

Due to a limited amount of research examining gender difference regarding naltrexone’s effectiveness coupled with the variability in intervention prescription dosage/duration, it is not possible to identify the optimal approach for use of naltrexone to treat alcohol use disorders in women. Unlike previously conducted systematic reviews (Srisurapanont & Jarusuraisin, 2005; Maisel et al., 2012), our review focused on women with an AUD or other evidence of serious drinking. Thus, this review was imperative given that many studies have not explored gender differences in the efficacy of naltrexone for women distinct from men. Six studies reported results for both men and three of these observed trends that indicated the effect of naltrexone to reduce drinking was stronger in men than in women (Kranzler et al., 2009; Garbutt et al., 2009; Pettinati et al., 2008).
We note several potential limitations as context for interpreting our findings. Four studies included fewer than 100 women and were relatively underpowered to detect significant changes in drinking over time. (Kranzler et al., 2009; Kiefer, Jahn & Wiedemann, 2005; Hernandez-Avila et al., 2006; Pettinati et al., 2008). Due to the low representation of minority women in the 7 studies, results may not be generalizable to women of other ethnic/racial groups. Next, the intervention components varied across all of the studies with some women receiving more counseling interventions than others. Additionally, the measurement of alcohol consumption is limited to self-report, and our review only included one study using depot (injectable) naltrexone (Garbutt et al., 2005). Most notably, the review lacked studies with common intervention strategies or outcome measures to justify doing a statistical summary of effect using meta-analysis techniques as done in other reviews.

In summary, the limited existing evidence suggests that naltrexone may have a very modest effect on drinking quantity and time to relapse, but not on overall frequency of drinking among women. Over time, better interventions are needed that can demonstrate a greater magnitude of effect. While the growing body of evidence suggests a variety of pharmacotherapy and behavioral intervention approaches to treat alcohol use disorders (AUD), the impact of naltrexone on combatting AUD in women is understudied. Future research should incorporate sophisticated study designs that examine gender differences and treatment effectiveness among those diagnosed with an AUD and present data separately for men and women. This may lead to the development of better treatment options for women or the ability to identify the subset of women who might benefit most from naltrexone.
<table>
<thead>
<tr>
<th>Study ID</th>
<th>Methods</th>
<th>Participants</th>
<th>Recruitment</th>
<th>Interventions</th>
<th>Drinking Outcome Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kranzler et al., 2009</td>
<td>RCT, factorial study design, 12-week study</td>
<td>Alcohol dependence (DSM-IV); 18-70 years old, women and men</td>
<td>Advertisements in local media, patient referrals by primary care physician or other clinician</td>
<td>NAL: naltrexone 50mg, (N= 83) PL: placebo tablet identical to naltrexone once daily: (N=80) BST: biweekly counseling sessions</td>
<td>DPD: drinks per day</td>
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<tr>
<td>Greenfield et al., 2010</td>
<td>RCT, double blind, 16-week study</td>
<td>Alcohol dependence (DSM-IV) 18 years and older, women and men</td>
<td>Advertisements and from clinical referrals at 11 academic sites</td>
<td>NAL: naltrexone 25mg, 50mg, or two 50mg once daily: (N= 49) PL: placebo tablet identical to naltrexone once daily: (N=50) MM: nine sessions of medical management delivered over (0,1,2,4,6,8,10,16) weeks</td>
<td>PDA: percent days abstinent PHDD: percent heavy drinking days THDD: time to first heavy drinking day</td>
</tr>
<tr>
<td>O'Malley et al., 2007</td>
<td>RCT, double blind, 12-week study</td>
<td>Alcohol dependence (DSM-IV); 18 to 55 years old, women only</td>
<td>Newspaper advertisements and from patients seeking treatment at the Substance Abuse Treatment Unit of the Connecticut Mental Health Center</td>
<td>NAL: naltrexone 50mg: (N= 53) PL: placebo tablet identical to naltrexone once daily: (N=50) CBCST: weekly group sessions</td>
<td>PDA: percent days abstinent PHDD: percent heavy drinking days THDD: time to first heavy drinking day</td>
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<tr>
<td>Garbutt et al., 2009</td>
<td>RCT, double blind 24-week study</td>
<td>Alcohol dependence (DSM-IV); 18 years or older, women and men</td>
<td>Public hospitals, private and Veteran Administration clinics, or tertiary care settings</td>
<td>NAL: naltrexone 380mg injectable, (N= 67), NAL: naltrexone 190mg injectable (N=68) PL: placebo (N=66) SST: 12 sessions</td>
<td>HDD: number of heavy drinking days</td>
</tr>
<tr>
<td>Study</td>
<td>Design</td>
<td>Setting</td>
<td>Target Population</td>
<td>Interventions</td>
<td>Outcomes</td>
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<tr>
<td>Kiefer, Jahn and Wiedemann, 2005</td>
<td>RCT, double blind 12-week study</td>
<td>Alcohol dependence (DSM-IV); 18-65 years old, women and men</td>
<td>Alcohol treatment study sites</td>
<td>NAL: naltrexone 50mg oral, (N=9) PL: placebo tablet, 50 mg oral, (N=13) PT: biweekly group therapy</td>
<td>TFD: Time to first drink, THDD: Time to first heavy drinking day</td>
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<td>Hernandez-Avila et al., 2006</td>
<td>RCT, double blind 8-week study</td>
<td>Heavy drinkers; 18-60 years old, women and men</td>
<td>Newspaper advertisements and referrals from area clinicians</td>
<td>NAL: naltrexone 50mg/daily, (N=33) NAL: naltrexone, 50mg/targeted, (N=42) PL: placebo tablet identical to naltrexone once daily 50mg: (N=39) PL: placebo, 50mg/targeted, (N=36)</td>
<td>DPD: drinks per day</td>
</tr>
<tr>
<td>Pettinati et al., 2005</td>
<td>RCT, double blind 12-week study</td>
<td>Alcohol dependence (DSM-IV); 18-65 years old, women and men</td>
<td>Alcohol treatment study sites</td>
<td>NAL: naltrexone 150mg, (N=24) PL: placebo tablet identical to naltrexone once daily 150mg: (N=24)</td>
<td>AU: Alcohol use (measured in days) DD: drinking days (percent) DDD: drinks per drinking day HDD: Heavy drinking days</td>
</tr>
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</table>

*NAL: Naltrexone; BST: Brief Skills Training; PL: Placebo; MM: Medical Management; CBST: Cognitive Behavioral Coping Skills Therapy; AU: Alcohol use (measured in days); DD: Drinking days; DPD: Drinks per day; DDD: Drinks per drinking day; HDD: Heavy drinking days; PDA: Percent days abstinent; PHDD: Percent heavy drinking days; TFD: Time to first drink, THDD: Time to first heavy drinking day, SST: Standardized Supportive Therapy; PT: Psychotherapy; BCST: Brief Coping Skills Therapy; CBT: Cognitive Behavioral Therapy*
CHAPTER 3
HOW DOES PARTICIPATION IN CLINICAL TRIALS INFLUENCE DRINKING BEHAVIOR AMONG WOMEN WITH HIV

Considerable efforts have been made in the field of public health to reduce the incidence and prevalence of HIV. Of the 1.2 million individuals living with HIV in the U.S., 1 in 4 are women. Among women with HIV, an estimated 6-54% engage in hazardous drinking, a behavior that can lead to more personal and public health consequences. While the number of women diagnosed with an alcohol use disorder who seek treatment is relatively low, studies have shown that when compared to men, women have better overall treatment outcomes. Therefore, the purpose of this study is to identify women with HIV reasons for enrolling in the WHAT-IF clinical trial for a reduction in hazardous drinking and to identify the reasons women with HIV were successful or unsuccessful in changing their drinking behavior during study participation. Using thematic analysis, we conducted 20 qualitative interviews among hazardous drinking women with HIV infection who completed the WHAT-IF clinical trial. The biopsychosocial model helped frame the initial line of questions for participant interviews related to the multiple determinants of drinking behavior. Overall, findings from this study revealed several themes within the context of the biopsychosocial model associated with women with HIV reason for enrolling in to the clinical trial, their clinical experience, and the factors associated with the specific research questions. Women with HIV reasons for enrolling into the WHAT-IF clinical trial included: the ability to reduce their drinking to nonhazardous levels (biological), the opportunity for self-reflection or self-empowerment (psychological) and monetary compensation (social). Next, women with HIV described themes associated with their overall clinical trial experience including: the aspects of the study medication (and those could be positive
or negative) (biological), study procedures (i.e., lab work, survey assessment) (psychological), and their interactions with the research study staff (social). Lastly, women identified many themes associated with the perceived aspects of the trial that resulted in a reduction in drinking. While majority of the women were able to reduce their drinking to nonhazardous levels (biological), many of the women stated that the study provided them with the opportunity for self-reflection and change, while others cited fear of adverse events associated with drinking and taking the study medication (psychological) as primary reasons. Once more the study staff was very influential in providing encouragement to the participants that help result in a reduction in their drinking (social). Consistent with other studies, our findings highlight using qualitative methodologies to examine clinical trial participation among women with HIV who have been underrepresented in clinical research. In order to reduce hazardous drinking in women with HIV, studies should seek to adopt a mixed methodological approach to examine the biopsychosocial factors associated with treatment efficacy, clinical trial participation and clinical trial experience in women, as well as factors influencing drinking outcomes in women with HIV.

**Background**

HIV is a disease that affects millions of women worldwide. Of the 39 million people living with HIV around the world, 17.8 million are women (WHO, 2016). Furthermore, 1 in 4 women are living with HIV in the US (CDC, 2017). Despite global actions made toward reducing HIV incidence and prevalence, research has shown substance abuse contribution to the spread of HIV/AIDS, which can negatively affect treatment for infected people, primarily women with HIV (NIAAA, n.d.).
Alcohol abuse is a growing public health issue and women have become the fastest growing population of alcohol users (Krystal et al., 2001; NCADD, 2015). As of 2016, an estimated 5 million women aged 18 and older have an alcohol use disorder (NIAAA, 2016; SAMHSA, 2012; NIH, 2015). The term alcohol use disorder (AUD) describes problem drinking and is classified as mild, moderate, or severe (NIAAA, 2016; SAMHSA, 2012; NIH, 2015). While several problems associated with an alcohol use disorder including alcohol abuse or dependence, less severe disorders are often called hazardous or harmful drinking (Carrington Reid et al., 1999). For women, hazardous drinking for women is defined as consuming 7 or more drinks per week (or ≥3 drinks per occasion) (NIAAA, 2016). While hazardous drinking is more common in men, an estimated that 6-54% of women with HIV consume alcohol at hazardous levels each year (Cook et al., 2001; Theall et al., 2007; Cook et al., 2009). As a result, hazardous drinking presents unique health risks in these women that can include an increase in HIV viral load, risky sexual behavior, and a decrease in medication adherence (Cook et al., 2001; Chandler et al., 2008; Peretti-Watel et al., 2006; Baum et al., 2010). While behavioral and pharmacologic treatment options to reduce hazardous drinking are available, effective treatment options have not evaluated in a general sample of hazardous drinking women with HIV infection.

For decades, clinical research has underrepresented women regardless of whether or not they have HIV. In the past, majority of the participants in substance abuse research were male or consisted of a mixed sample of men and women with little regard to gender differences (Greenfield et al., 2006). Primary exclusion criteria among studies were women of childbearing potential (Greenfield et al., 2006). For this reason,
findings from studies examining the effectiveness of treating substance abuse were not
generalized to women (Greenfield et al., 2006; Tuchman, 2010). Ultimately in 1993, this
disparity prompted the National Institute of Health (NIH) to publish a clarion call to
enhance women and minorities’ participation in clinical research (Congress, 1993; FDA,
1994). Despite the regulatory efforts by the NIH, women are still underrepresented in
substance abuse research.

Several studies have evaluated gender disparities among research participants
in substance abuse treatment with reasons for entering treatment differing between
women and men. In a study by Weisner (1993), reasons for treatment entry among
women included: lifetime general treatment history, ethnicity, and employment rate.
Another study examining demographic characteristics associated with treatment entry
among women concluded age, positive family history of alcohol dependence, and daily
drinking as factors associated with treatment entry (Dawson, 1996). Moreover, specific
barriers to treatment entry for women have been well-documented and include
pregnancy, lack of services for pregnant women, preference of a form of intervention
over the other (Mostafa et al., 2013; Infanti et al., 2014; Martin et al., 2013; Melloni et
al., 2010; Ayyagari et al., 1999). Likewise, women and those with HIV may also
demonstrate certain attitudes toward treatment that may include a decreased likelihood
of higher levels of drinking, perceiving a need for substance abuse treatment, less
knowledge about the benefits of substance abuse treatment, or negative beliefs about
treatment (Kline, 1996; Kail and Ethbert, 2002; Wu and Ringwalt, 2004; Tuchman, 2010;
Hu et al., 2016). Besides, little is known about the clinical trial experiences of hazardous
drinking women. Our ability to understand these processes, from women’s own
perspectives, could enhance effective treatment programs (Slade et al., 2010). In a qualitative study by Slade et al. (2010), women perceptions of the personal qualities of the healthcare professional was associated with their willingness to discuss sensitive topics. Additional qualitative studies have demonstrated that the interpersonal skills of the healthcare professional are instrumental in enrolling, retaining, and intervention efficacy (Beal et al., 2009; Jackson et al., 2010). Conducting qualitative research (particularly in underserved, disadvantaged groups) could provide critical data on the perceptions, cultural relevancy, acceptability, and salience of specific aspects of intervention approaches of the randomized clinical trial. For example, the WHAT-IF clinical trial an outstanding follow-up rate (86%) but not all studies do, furthermore as we think about how to encourage persons to do research need to see if there is anything that might help us to understand whether persons trust researchers or feel misinformed, etc (Cook et al., unpublished).

Therefore, research geared toward studying issues specifically to women and evaluating drinking outcomes separately in men and women in substance abuse research is important. Additionally, gender differences (i.e., absorption, genetics, and vulnerability) underscore the need to evaluate the impact of specific treatment options for women. The conceptual framework of this research incorporates concepts from the biopsychosocial model. For decades, the biopsychosocial model has postulated that substance abuse is the result of multifaceted interactions between biological, psychological, and social factors (Lindstrom, 1992). Research investigating the causes of alcoholism has shown connections between biological and psychosocial factors instead of examining each separately (NIAAA, n.d.). Thus, the purpose of this study is
to identify women with HIV reasons for seeking treatment for hazardous drinking and to identify the reasons women with HIV were successful or unsuccessful in changing their drinking behavior. Most importantly, qualitative interviews will be conducted in order to answer the following research questions within the context of the biopsychosocial model: Research Question 1) “What are the attitudes among women with HIV toward participating in the WHAT-IF clinical trial for a reduction in hazardous drinking?”, Research Question 2) “How did women with HIV describe the clinical trial experience?”, Research Question 3) “What specific aspects of the trial, besides the study medication associated with a reduction in hazardous drinking among the women with HIV?”. **Methods**

**Study Design**

In order to answer the research questions, qualitative interviews (Creswell, 2013) were conducted among hazardous drinking women with HIV that completed a large, randomized clinical trial examining pharmacotherapy for the reduction of hazardous drinking. According to the research team, the primary goal of the WHAT-IF study was to reduce the participant’s drinking to nonhazardous levels (<7 drinks per week or <3 drinks in one setting). Reductions in hazardous drinking were then determined by comparing the baseline and 7-month follow-up data. During both time points, the participants reported the number of drinks/past 30 days and the number of drinking days in the past 30 days. This information was then linked to the qualitative data from the individual interviews. The analysis of the interviews involved thematic analysis, an appropriate qualitative descriptive approach that allowed the co-investigator to identify, analyze, and report themes that emerge from the data (Braun and Clarke, 2006).
The Institutional Review Boards (IRB) at the University of Florida (Gainesville, FL), the University of Miami (Miami, FL) and Florida International University (Miami, FL) approved this research.

Inclusion Criteria

Women were eligible for the interviews if they completed the WHAT-IF clinical trial and provided permission for contact in the future. Participants in the overall study was women, aged 18-100 years old, who have HIV infection and who exceeded the NIAAA recommended limits for alcohol consumption. Approximately 80% of the women were African-American, 10% were white, and 10% mixed race. A total of 222 women contributed to the database for the clinical trial. Of this number, 20 women were conveniently selected to participate in the qualitative interviews based on whether or not they completed the WHAT-IF clinical trial, provided permission to be contacted for future studies. Convenience and theoretical sampling ensured the diversity of the sample by including representation for age (18 years or older), race (white, black, Hispanic, etc.), and alcohol status upon study entry (alcohol dependence or not). Potential bias associated with recruiting the women included selected bias given that the women had previously completed the WHAT-IF study and the women chosen may not be truly representative of the sample. Full details on the recruitment of the women with HIV in the qualitative study are provided below. The overall characteristics of these women were similar to those in the WHAT-IF study (85% African American, 10% white, and 5% mixed race).

Recruitment

The research coordinator of the WHAT-IF Miami-based research study team who had contact information, but not access to the study data, contacted potential
participants who completed the WHAT-IF study and who agreed on the Informed Consent Form (ICF) for contact in the future. The goal was to recruit a range of women including some who quit drinking and some who did not. After the first 12 interviews, the data manager presented a demographic summary to the research team of the participants (n=4) for whom the number of drinks per week was extremely high. Upon review of the information, the data manager suggested the specific ID numbers based on the data provided in the clinical trial be given to the research coordinator with the contact information. In the WHAT-IF study, all participants provided written informed consent, where they agreed that their de-identified study data could be used for analyses.

Some of the women who participated in the qualitative study were recruited at the time of completion of the WHAT-IF study. At that time, participants determined if they would be interested in participating in a qualitative study. The research coordinator also contacted participants who completed the study within 2 years. If the participant agreed that they might be interested, a meeting occurred within a 1-month time period when the co-investigator became available to conduct the individual interviews.

Procedure

Before the scheduled interviews, the co-investigator received extensive training from members of her mentoring team. The co-investigator participated in mock consent training, one-on-one interview training, and received ongoing advice and support from the University of Florida’s Qualitative Research Colloquium. On the day of the scheduled interviews, the co-investigator reviewed the Informed Consent Form (ICF) with the potential participant, answered questions, and obtained written informed consent before data collection. The study PI was also available by phone to answer
questions. Each interview took place in Miami at the Behavioral Medical Research Center (BMRC) located at University of Miami’s Clinical Research Building (CRC). As a part of the interview, the co-investigator asked participants about their current drinking patterns, experiences associated with drinking, knowledge and awareness of health issues related to drinking behavior, and attitudes and perceptions of participation in the WHAT-IF study. On average, each interview lasted one hour and was digitally recorded. Interviews began with a semi-structured format; however, questions adapted specifically to each person after the participant’s lead and as theoretical coding dictated. Participants reflected upon factors influencing their continued drinking behavior and decisions related to WHAT-IF study outcomes.

The co-investigator did not collect any identifying health information from the participant such as name or contact information during the interview. However, the co-investigator was able to use an ID number provided from the WHAT-IF study that the participant already completed to link qualitative and quantitative data by the data manager. The information was in a limited data set that only included information that did not directly identify the participant. For example, the limited data set could not include the participants’ name, address, telephone number, social security number, photographs, or other codes that link the participant to the information in the limited data set. Due to the limited data set being created and used, agreements between the parties creating and receiving the limited data set were required to protect the participant’s identity, confidentiality, and privacy. The co-investigator detailed field notes at the end of each interview that included details about the setting, the participant’s reaction to the interview process, and non-verbal behaviors. At the end of each
interview, the participant received an incentive, a $25 gift card to compensate them for time, transportation, and parking. The research coordinator recruited 4-6 new women every 1 or 2 months and continued until theoretical saturation; about 20 women completed interviews and the recipient provided no new information.

**Study Instrument**

The biopsychosocial model helped frame the first line of questions for participant interviews related to the multiple determinants of drinking behavior and help explain linkages to broader health constructs, thus enabling interpretive theories to explain relationships unearthed. The following helped create the interview question guide: members from the dissertation committee, members from the Miami-based research study team, and members from the Qualitative Research Colloquium at the University of Florida. The interview guide consisted of five categories each with several open-ended questions about: 1) drinking history, 2) study participation, 3) changes as a result of participating in the randomized controlled trial, 4) support, and 5) next steps. For the purposes of this study, only the following questions were relevant: 1) “What was it about the study that motivated you to participate?” 2) “What were your likes/dislikes about the WHAT-IF study?” 3) Describe your relationship with the study staff and dislike your likes/dislikes (probe), 4) Tell me about your drinking now that you have completed the WHAT-IF study, 5) “What motivated you to change your drinking behavior?” 6) “Why do you believe that you were successful or unsuccessful in changing your drinking behavior?” The full interview question guide is in Table 3-1.
Table 3-1. Interview Question Guide

Sections

Drinking History:
1. Tell me about your experience with drinking alcohol
   a. At what age did you first start drinking?
   b. When you first started drinking, were you a light, moderate, or heavy drinker?
   c. Why did you decide to start drinking?
      a. Traumatic experience, social drinker, stress, anxiety, depression…
   d. What was it about alcohol that made you continue to drink?
   e. Have you tried to quit drinking?
      a. Tell me about your previous attempts to quit
         i. Successful or Unsuccessful
         ii. Time period that you were able to quit or reduce your drinking
         iii. Were there any barriers that stopped you from quitting or reducing drinking?

Study Participation:
1. How did you find out about the study?
   a. What was it about the study that motivated you to participate?
   b. Tell me about your participation in other research studies, if any?
   c. What benefits do you get out of participating in research?
2. Tell me about your experience in this study
   a. What were some things that you like about the study?
   b. What were some things that you did not like about the study?
      a. What was difficult? (Probe)
   c. Describe your relationship with the study staff
      a. What did you like about the study staff? (Probe)
      b. What did you not like about the study staff? (Probe)

Changes as a result of participating in the WHAT-IF study:
1. What changed in your life as a result of being in the study?
   a. How were you able to quit or reduce drinking?
      a. If so, why do you believe you were successful in doing so?
         i. Do you think that the study medication helped to reduce or not reduce your drinking?
            1. Do you know if you were taking naltrexone or the placebo?
      b. If not, why do you believe you were unsuccessful?
   b. Besides drinking, what else changed in your life as a result of being in the study?
2. What do you think are the barriers (things that keep you from doing something) or the facilitators (things that help you do something) to this treatment that would exist in the real world outside of a research setting?
Table 3-1. Continued.

Support:
1. Did you have any support from family, friends, etc.?
2. When you think of someone that is being supportive, what are they doing?
   a. Before being in the study, who did you receive support from?
      a. In what ways were they supportive or not supportive of you wanting to quit or reduce drinking?
   b. During the study, who did you receive support from?
      a. In what ways were they supportive or not supportive of you wanting to quit or reduce drinking?
   c. After completing the study, who did you receive support from?
      a. In what ways were they supportive or not supportive of you wanting to quit or reduce drinking?
3. How important do you think it is to have support?
   a. Who do you think are your best providers of support?
      a. Family, friends, healthcare providers, etc.?
   b. Do you think that support is needed in order to successfully quit or reduce drinking?
      a. Why or why not?

Next steps:
1. Now that you have completed the study, what would you recommend the research staff do next?
   a. What could be done differently in the study?
2. If you were going to give advice to women about quitting or reducing their drinking, what would you tell them?

Additional information:
1. Would you like to add anything else?

Data Analysis

As mentioned, each interview lasted about one hour, was digitally recorded, and transcribed by a professional Health Insurance Portability and Accountability Act of 1966 (HIPAA) approved transcription service. The transcription service was an approved vendor for the University of Florida. Individuals working on the transcription projects took HIPPA classes as part of several other rigorous requirements. The co-investigator sent the encrypted transcriptions using the Express File and also encrypted
the transcribed files when uploading. After delivery, the co-investigator encrypted and
destroyed once delivered to the co-investigator.

In qualitative research, there are several qualitative descriptive approaches such
as phenomenology (find and list statements of meanings for people, ground theory
(engage in axial, open, and selective coding) ethnography (analyze data for themes and
patterned regularities) (Creswell, 2013; Vaismoradi, Turunen, and Bondas, 2013).
Thematic analysis involved searching for and identifying common themes that emerge
across the 20 interviews and began with the first round of interviews (DeSantis & Noel
Ugarriza, 2000). Thus, the following steps in the thematic analysis process as described
by Braun & Clarke, 2006: 1) immersed self with data, 2) generated initial codes, 3)
searched for themes, 4) reviewed the themes, 5) defined and named the themes, and 6)
produced the report.

After an outside source transcribed the interviews, the co-investigator uploaded
the documents into NViVo, a qualitative data analysis management program used to
manage transcripts, coding, and memos (QSR International, 2015). The data was
stored on a password protected, encrypted computer at the University of Florida. Data
analysis was continuous and began after the first interview. The transcripts were then
read several times in an attempt for the co-investigator to immerse herself in the data to
get a sense of the interview as a whole (Creswell, 2013). During this process, the co-
investigator recorded initial ideas, questions, and comments for future use. Next, began
the process of generating preliminary codes. Coding involved organizing the data into
categories and then labeling each category (Creswell, 2013). Using the interview script,
each question became its own separate code and the group of codes was used to
create a codebook in NVivo. Beginning with line-by-line coding, the text of the transcript identified pre-identified codes referred to as nodes in NVivo. Subcategories of the codes were also created. After the completion of a few interviews, we presented the codebook and examples of data to the Qualitative Data Analysis Colloquium at UF. The goal of this step was to test credibility and confirmability of the codes that were created. Furthermore, weekly meetings were held with a qualitative expert that served on the co-investigator’s dissertation committee to review the codes and coding schemes to allow for a different perspective. The analysis process ended when no new themes emerged from the ongoing analysis. After coding all interviews (n = 20) and verifying the codes with a second coder, themes were identified and refined. The last step involved writing up the findings while relating it back to the research questions and literature, thus producing a report of the analysis that is found below.

**Findings**

Among the participants (n=20) who participated in the study, 85% (n=17) were African-Americans; most had less than a high school diploma (n = 12), and were single (n = 12). The mean age of the participants were 49.3 (range 36-59 years) in Table 3-2.
<table>
<thead>
<tr>
<th>Characteristics</th>
<th>(N = 20)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographics, No. (%)</td>
<td></td>
</tr>
<tr>
<td>Age range, years</td>
<td>Mean 49.3</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Female</td>
<td>20 (100)</td>
</tr>
<tr>
<td>Race</td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td>17 (85)</td>
</tr>
<tr>
<td>White</td>
<td>2 (10)</td>
</tr>
<tr>
<td>Native American</td>
<td>1 (5)</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
</tr>
<tr>
<td>Hispanic/Latino</td>
<td>1 (5)</td>
</tr>
<tr>
<td>Not Hispanic/Latino</td>
<td>19 (95)</td>
</tr>
<tr>
<td>Education Level</td>
<td></td>
</tr>
<tr>
<td>Less than High School</td>
<td>12 (60)</td>
</tr>
<tr>
<td>High School Graduate</td>
<td>4 (20)</td>
</tr>
<tr>
<td>Some College</td>
<td>2 (10)</td>
</tr>
<tr>
<td>College Graduate</td>
<td>2 (10)</td>
</tr>
<tr>
<td>Marital Status</td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>12 (60)</td>
</tr>
<tr>
<td>Married</td>
<td>4 (20)</td>
</tr>
<tr>
<td>Separated</td>
<td>1 (5)</td>
</tr>
<tr>
<td>Divorced</td>
<td>3 (15)</td>
</tr>
</tbody>
</table>
Furthermore, themes that summarized the reasons why participants enrolled in the WHAT-IF study and the reasons why they were successful or unsuccessful in changing their drinking behavior in Table 3-3.

Table 3-3. Themes related to reasons for seeking treatment, clinical trial experience, and specific aspects of the trial associated with reducing hazardous drinking

<table>
<thead>
<tr>
<th>Biopsychosocial Factors</th>
<th>RQ 1: Reasons for seeking treatment</th>
<th>RQ 2: Clinical trial experience</th>
<th>RQ 3: Specific aspects of the trial associated with reducing hazardous drinking</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biological</td>
<td>To reduce hazardous drinking</td>
<td>Study medication (negative)</td>
<td>Reported changes in alcohol consumption level (quit, reduction, no change)</td>
</tr>
<tr>
<td>Psychological</td>
<td>Knowledge</td>
<td>Lab work (negative)</td>
<td>Reflection and reappraisal Opportunity for change</td>
</tr>
<tr>
<td></td>
<td>Self-reflection</td>
<td>Survey assessments (positive)</td>
<td>Fear of adverse events Study procedures (counseling)</td>
</tr>
<tr>
<td></td>
<td>Self-empowerment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Social</td>
<td>Monetary compensation</td>
<td>Interactions with the research study staff (positive)</td>
<td>Encouragement from the study staff</td>
</tr>
</tbody>
</table>

Reasons for Seeking Treatment

Biological

A biological reason for seeking treatment included reducing hazardous drinking.

As mentioned, a reduction in hazardous drinking defined as consuming <7 drinks per week (<3 in one sitting). For example, two participants stated their reasons for participating in the study was to reduce their drinking to nonhazardous levels or to quite
altogether given the negative role that alcohol played in their lives and believe that enrolling in the study would beneficial.

My alcoholism and my drinking. You know, it affects my life. It makes me – sometimes, I wouldn’t want to go anywhere. I just want to stay at home and drink. Who wants to go anywhere if you’re drunk? You’re not going to leave the house if you had three beers already. It just doesn’t work like that.

It’s supposed to help me to stop or at least slack up. It’s supposed to help me stop drinking. At the time, I was all for it, something that’s going to help me stop drinking. I was going through something at the time, so I was like okay, what the hell? Give it a try, and I’ve tried it. It helped a little bit. Like I say, I’m not doing it as much as I used to do it.

Psychological

Several of the women reported enrolling in the WHAT-IF study because of how they were living their lives. To the participants, the study provided an opportunity for self-reflection or self-empowerment. The co-investigator defined knowledge as the participant’s ability to gain new insight and information about the effects of hazardous drinking on HIV infection. Moreover, self-reflection defined as the ability of the participant to examine their life and recognize the areas that she would like to improve. The women in the trial also discussed self-empowerment, defined as taking control of one’s life and making positive decisions.

The way I was carrying my life, and I wanted my life to be better. That’s why I participated in the program.

I think it gave me a time to reflect on the way I had been, where I’ll wind up at, and where I am now. I wasn’t a drinker. I got into this relationship. He was a drinker, so just being a part… I started drinking. Then when things went sour in the relationship, I realized – I’m not going to say it was a problem, but I was drinking more heavily than I would normal do. Then once I got into the study, it kind of allowed me to look at myself.
Social

Many women reported enrolling into the trial for social reasons, which included enrolling because their peers were in the study and because they were receiving monetary compensation for their participation. Majority of the women in the study were of a lower socioeconomic status (SES) and were unable to work. Several of the women choose to participate in research because of the monetary incentives.

I was motivated because I saw a lot of people going. Do you know what I mean? Now I got paid to go. I found myself when I got paid to go I said, “God was doing for me what I couldn’t do for myself.”

I just get into all type of studies, whatever comes up. If I’m able to get in it I’ll get in it. I try because it’s more money in my pocket, and I’m just sitting there for a little time instead of nine dollars an hour.

Clinical Trial Experience

Biological

As a participant in the clinical trial, a biological component included being randomized to receive the study medication. In the WHAT-IF study, participants were randomized to receive either naltrexone or placebo. Despite being blinded to the study medication assignment, several participants discussed their dissatisfaction with taking an oral medication. Several other women spoke about the negative adverse health effects as a result of taking the study medication and still consuming alcohol.

Taking the medication, and then still going out and doing the same thing. Not only that you still have problems that you didn’t count on that makes you want to go back to drinking. That was the hardest part.

They gave me that pill. I didn't like that, but I don't like taking medication. So it wasn't just even though I'm positive, I don't like taking pills.

Psychological

During the course of the study, some of the study procedures included requiring participants to undergo laboratory testing as well as complete a series of survey
assessments via the computer. Numerous women discussed their dislike in having to get their blood drawn citing their small vein sizes as a challenging factor. On the contrary, several of the women cited the computer assessments as a positive aspect of the trial and found the assessments to be both informative and beneficial. The computer assessments included a range of questions about the participants drinking history.

I hate getting’ stuck because they can’t stick me one time they have to stick me more than once because I have these old baby veins. I have to always get stuck more than once twice mostly more than twice.

They had a heck of a time drawing my blood. I am a hard stick. I have little thin, spider webby veins. They’re so tiny– it was just terrible. I had to drink a lot of water and– they had a really hard time. One time they had to do me six times to get my blood.

I like answering the different questions on the computer. I like when they asked me how long I had been going before I had a drink you know different questions they were asking me. I can’t remember per say you had them in steps.

…You know, I like doing those kinds of things– keeps my brain alive you know, doing those kinds of things on the computer and answering questions.

Social

The research study staff’s interaction with the women was a reoccurring theme throughout the interviewers. Majority of the women credited the research team for the role they played in the recruitment and retention of the study participants. All of the women that participated in the qualitative interviews completed the WHAT-IF study.

There’s nothing not to like about them.

Well, I didn’t like when it was over because I liked the research coordinator and the whole team.

Everyone I encountered was nice. I had no problem with anyone, and they were very encouraging. They were very happy to see you whenever they saw you. It was great.
They actually knew you when you got there. At first, you used to have to tell them your name. By the time you walk in there, they know who you are. They just grab the chart and say, “Miss XYZ, he waiting on you down there in Room 3.

They welcomed me. I felt comfortable and safe. I could talk to them about what’s going on with me. They were more like my listeners, not just only an employee, and they allowed me to be myself, and they treated me with respect, regardless of what my past was. I felt comfortable.

It was the encouragement because I know what research is about. We’re going to get this data, and we’re going to pay you, but the staff members from the study I felt were actually caring. I noticed there were questions that were not written on the paper. So to me, that showed me there was some kind of feelings of care and they would listen to everything I had to say. It wasn’t a rush or anything like that.

When I first came in, they never change their respect for me. They always asked me the same questions, even if I felt a little nervous. A member of the study staff would always say, “Just take your time.” She’s a good listener. She’s one of those persons who you can go to and a shoulder to cry on. She’s that type of person.

She allowed me to come in. She’d laugh; she kicked it with me; she didn’t judge me. She didn’t make me feel uncomfortable. She welcomed me. The whole staff did, because I’d just come in and have fun with them and say, “How are you all doing?

Specific Aspects of the Trial, Besides the Study Medication Associated with a Reduction in Hazardous Drinking

Biological

The primary goal of the WHAT-IF study was a reduction in drinking to nonhazardous levels among the study participants. The research team defined this as consuming less than 7 drinks per week (<3 drinks in one setting). During the qualitative interviews, each participant discussed their current drinking status (reduction, quit, no change) since completing the trial (ranged from a few months to 2 years earlier). At the end of the interviews, the data manager provided the co-investigator with a de-identified data set with the participants Study ID and drinking history data (number of drinks/past
30 days and the number of drinking days in the past 30 days for baseline and month 7). The co-investigator was able to compare the quantitative data of the women with the information in the qualitative interviews.

During the qualitative interviews, all the women stated that they were able to successfully reduce or quit their drinking in Table 3-4.

### Table 3-4. Drinking Outcome Variables

<table>
<thead>
<tr>
<th>Drinking Outcomes</th>
<th>Baseline (Mean)</th>
<th>Month 7 Follow-up (Mean)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Drinks</td>
<td>417.8</td>
<td>65.6</td>
</tr>
<tr>
<td>Number of Drinking Days (30 days)</td>
<td>24.3</td>
<td>4</td>
</tr>
</tbody>
</table>

In particular, 50% (n = 10) stated a reduction in their drinking and the other 50% (n = 10) reportedly quit. According to the quantitative data provided by the WHAT-IF study data manager, at the completion of the study 40% (n = 8) reported a reduction in drinking where, 55% (n = 11) of the women reported quit drinking, and 5% (n = 1) reported an increase in drinks. Furthermore, the mean number of drinks reported at baseline among the women (in the last 30 days) was 417.8 drinks (ranging from 39 to 1640 drinks). The mean number of drinking days (in the last 30 days) reported at baseline among the women was 24.3 days (range from 13 to 30 days). Likewise, at the completion of the study (month 7), the mean number of drinks (in the last 30 days) reported among the women was 65.6 drinks and the mean number of drinking days (in the last 30 days) was 4 days. Overall, findings from both the qualitative interviews and the quantitative drinking data show that 85% (n=17) were able to reduce their drinking to nonhazardous levels.

I don’t drink, period. I’ve been noticing that when I get around my twin sister and family (who likes to drink), I go and get a Slurpee. I found that Slurpee’s decrease on alcohol, because I don’t buy alcohol.
I don't drink anymore. I'm going on a year.

I did stop drinking. I mean, completely stop probably for about a year. I could have parties at my house with alcohol and would not drink.

I don't make it a habit. I don't buy liquor anymore. Like I said, I've got a bottle sitting in my house, so it's just sitting there. I probably won't touch it. I probably won't touch it no time soon, mm-mm. Like I said, if I go to my sister and my nieces, “Oh, auntie, have a drink with me.” That's the only way. Me saying, hey, you all, let's get a bottle, or hey, go to the store and say I'm going to spend my money for it, uh-uh. I go buy me a bag of cookies or something. That's a good thing, though. [Participant 4112]

**Psychological**

Some women reported themes related to psychological factors as specific aspects of the study associated with a reduction in hazardous drinking. Many of the women stated the study provided them the opportunity to reflect on their life and to come to the realization the way that they were not beneficial to them. Other women mentioned the fear of adverse effects as a result of drinking alcohol and taking the study medication as a reason for changing their drinking behavior. Other themes mentioned by the women included the opportunity for change, and the study procedures as aspects of the study associated with changes in drinking behavior.

My life. I looked down on my grandchildren, the baby boys, and I didn't want to leave without getting to know them real good and finish college and be something and understand what happened. That's it. That's what really got me started. [Participant 4149]

The fear and the thought of getting some help for myself. The fear was there that the medicine would make me sick, but it also – I liked the idea that I felt somebody was trying to help me to get a little further than what I was.

Being HIV-positive and interfering with my medication, my eating, sleeping. I'm just to that point where I know I need to make some changes. I'm getting older, and I'm still doing things that I did when I was a teenager, and it's just time to make some changes.
If it wasn’t for certain people also reminding me, “Did you take that pill today that you were supposed to take?” A lot of times I wouldn’t have taken it, even by it sitting on the alcohol beverage, I still wouldn’t have taken it; just push it to the side and got whatever I’m going to do. I feel it’s more of someone showing me their love. That’s what it did for me.

Social

As identified in the previous section, the study staff was found to have a positive effect on majority of the participants. During the interviews, the women perceived the staff staff as very influential in motivating the participants to reduce their drinking to nonhazardous levels. Some women recalled conversations between themselves and the study staff that resulted in encouragement and the belief that they could change their lifestyle.

I don’t know, but [name of research coordinator] and her team did. They cared about me so much that, “Hey, your drinking is mixing up with your pills.” They didn’t say that, but it’s the advice. They didn’t say nothing about me drinking. They didn’t say nothing. They asked me how often. They didn’t say anything, but I felt it.

This program. It made me love me. I kept telling the study staff member I want to go. She kept asking me what I wanted to do…I want to go to school. She said, “Why don’t you?” That’s when [name of study staff] said the magic words. She said, “You can do it.”

Discussion

In this qualitative study, we were able to identify women with HIV reasons for seeking treatment for hazardous drinking and the reasons women with HIV were successful or unsuccessful in changing their drinking behavior. We conducted 20 individual interviews among hazardous drinking women with HIV infection in hopes of answering the following research questions: 1) “What are the attitudes among women with HIV toward participating in the WHAT-IF clinical trial for a reduction in hazardous drinking?” 2) “How did women with HIV describe the clinical trial experience?” 3) “What
specific aspects of the trial, besides study medication associated with a reduction in hazardous drinking among the women with HIV?"

During thematic analysis, themes within the context of the biopsychosocial model emerged pertaining to the women with HIV reasons for enrolling in the study and included: the ability to reduce their drinking to nonhazardous levels (biological), the opportunity for self-reflection or self-empowerment (psychological) and monetary compensation (social). Majority of the women with HIV who enrolled in the WHAT-IF study stated that a reduction in their drinking was a primary reason. Although women with substance abuse disorders are reportedly less likely to seek treatment during their lifetime as compared to males, research has demonstrated that women with substance use disorders are more likely to seek treatment in non-specialty settings (Grosso et al., 2013; Greenfield et al., 2006). Compared to other studies (Green et al., 2002; Grella and Joshi, 1999) that have examined women with HIV reasons for participating in clinical trials, our study reported similar findings among participants that stated reasons for seeking treatment included the opportunity for self-reflection or self-empowerment. Thus in both studies, the main reasons for seeking treatment among women believed that their “life was out of control” or that they needed services (Green et al., 2002; Grella and Joshi, 1999).

Majority of the women with HIV in the WHAT-IF study were African-American. Compared to other studies, the WHAT-IF trial was the first study to examine pharmacotherapy for reducing hazardous drinking in women (n=222) with HIV (Cook et al., unpublished). To date, African American women are disproportionately affected by HIV/AIDS. Thus, future research should seek to determine effective strategies for the
recruitment and retention of women and minorities in clinical research (Yancey et al., 2006; Vidaver et al., 2000). Despite regulatory guidelines published by the NIH to increase participation in clinical research among women and minorities, participation in substance abuse literature is still scarce (Yancey et al., 2006; Vidaver et al., 2000). In order to address this shortcoming, the successful recruitment of women and minorities requires additional planning, timelines, and budget requirements (Daunt, 2003; Vidaver et al., 2000; Yancey et al., 2006). As previously mentioned, specific barriers to treatment differ for men and women. Among women, reducing barriers related to economic expenses, individual challenges, and general reluctance could increase treatment-seeking practices (Daunt et al., 2003; Smith et al., 2007). Additionally, developing a rapport with the community and using community networks for advertisement can increase study participation particularly among African-Americans (Smith et al., 2007).

Considering reasons why women with HIV were successful or successful in changing their drinking behavior, we sought to describe the clinical trial experience reported among the women with HIV who completed the WHAT-IF study as well as identify the specific aspects of the study associated with a reduction in hazardous drinking among the women with HIV. Women with HIV identified themes within the context of the biopsychosocial model related to their clinical trial experience that included the effects of the study medication (biological), study procedures (i.e., lab work, survey assessment) (psychological), and the interactions with the research study staff (social). Compared to other studies that have examined women’s experiences in RCTs (Jackson et al., 2010, Slade et al., 2010, and Kneipp et al., 2013), our study
reported similar findings among study participants who credited some of their success to the positive interactions among the study staff members. For example, the study by Kneipp et al. (2013) explored study experiences among 31 disadvantaged women who participated in a Community-Based Participatory Research (CBPR)-drive RCT. The study concluded that the CBPR approach and the interpersonal communication styles shown by the research study staff resulted in positive experiences reported among the women in the RCT (Kneipp et al., 2013).

Additionally, women identified themes associated with the specific aspects of the trial, besides the study medication associated with a reduction in hazardous drinking also within the context of the biopsychosocial model. For example, a change in alcohol consumption level was considered a biological factor. As previously mentioned, a reduction in drinking to nonhazardous levels (<7 drinks per week or <3 in one setting) was a goal of the WHAT-IF study research team. Thus 85% (n=17) of the women who completed the interviews were able to reduce their drinking to nonhazardous levels.

Limited research exists about the treatment options reducing hazardous drinking is due to the widespread variability of interventions examining the effectiveness of medications aimed at reducing drinking. The results of a systematic literature review examining naltrexone for attenuating alcohol consumption in women with an alcohol use disorder suggest naltrexone could potentially lead to modest reductions in the quantity of drinks and time to relapse (Canidate et al., 2017).

Moreover, the knowledge of the associated medical risks of consuming hazardous levels of alcohol while infected with HIV was not reported as a factor associated with changes in drinking patterns (Elliot et al., 2014). Thus, women living
with HIV/AIDS have been found to drink more than other women in the general population (Cook et al., 2001; Theall et al., 2007; Cook et al., 2009). As previously mentioned, alcohol plays a debilitating role in the health outcomes of people living with HIV/AIDS (Cook et al., 2009; Chander et al., 2008; Peretti-Watel et al., 2006; Baum et al., 2010; Cook et al., 2016; Elliot et al., 2014). Designing interventions to reduce the negative effects of alcohol on HIV disease progression is important. Interventions should focus on reducing viral replication, increasing adherence to Antiretroviral therapy (ART) and decreasing morbidity and mortality (Cook et al., 2013; Neblett et al., 2011; Conen et al., 2009; Wu et al., 2009; Braithwaite et al., 2010; Samet et al., 2007). As evident in our findings, individuals who consume alcohol including many women with HIV generally change their drinking patterns from time to time (Cook et al., 2016). Findings from this study may highlight...

We note several potential limitations for context as interpreting our findings. Participants in this qualitative study were hazardous drinking women with HIV who previously completed the WHAT-IF study. The research coordinator for the WHAT-IF study recruited the women using convenience sampling. While all the women were HIV-positive and provided documentation for their HIV infection, self-report data was used to determine hazardous drinking status. Because of this, we are unable to determine if the information is completely accurate. Moreover, the time between the participants completing the clinical trial and the conducting of the individual interviews varied significantly. Some participants completed the qualitative interviews with a few months of completing the trial, whereas others had completed the WHAT-IF study two years earlier. Due to potential recall bias, the findings of this study are the participants’
narrative accounts of their reasons, experiences, and overall changes in hazardous drinking level as a result of participating in the WHAT-IF study.

Recruiting and retaining women who are most at-risk for adverse health effects into clinical research remains a challenge. Currently, women with HIV infection who consume hazardous levels of alcohol each year are subjected to adverse health effects. While men are generally prone to consuming larger quantities of alcohol, alcohol includes both social and community repercussions for women. As demonstrated by our study results, our findings highlight using qualitative methodologies to examine clinical trial participation among women with HIV. In order to reduce hazardous drinking in women, studies should seek to adopt a mixed methodological approach that seeks to examine the biopsychosocial factors associated with treatment efficacy, clinical trial participation and clinical trial experience, and as factors influencing drinking outcomes in women with HIV.
Several factors have attributed to the increase in alcohol consumption among women with HIV infection. In particular, literature exploring the social networks influence on alcohol use is increasing. While studies have suggested a simple change in a person’s social network from one that reinforces drinking to one that reinforces sobriety could result in improved treatment outcomes, limited research exists on the role of social network and their relationship to reducing hazardous drinking in women with HIV.

The purpose of this study was to describe the important people in the participants’ daily life, and to identify the social network variables associated with number of important people and the likelihood that the support hazardous drinking reduction. Participants enrolled in the WHAT-IF clinical trial were asked to complete the Important People Inventory (IPI) measure at month 2. Administration of the IPI, a structured interview occurred at month 2 by a trained member of the WHAT-IF study’s research team (Longabaugh et al., 2010). The Brief IPI involves seven questions about the participant’s perception of the individuals have been important to them and with whom she has had contact with (face to face or by phone) within the past 6 months. While the Brief IPI included seven variables, in this study we measured 4 of the variables that fell in to the following three categories: social investment (size of social network), alcohol-specific support (at least one regular drinker in the network and any network disapproval of drinking), and contact with the network (at least one daily contact person). A total of 183 women completed the IPI and the women reported a total of 375 people (missing n = 11) as being important individuals in their daily lives. The results of this study demonstrated among the women (n = 46) who reported at least one regular drinker in
their network (moderate/heavy drinker or at least weekly drinking) with whom they had at least daily contact (7 times a week) would be less likely to reduce their drinking. Findings suggest that social network variables such as the presence of at least one regular drinker \((p = 0.01)\) in the network and at least one daily contact person \((p = 0.02)\) in the network may influence a reduction or increase in hazardous drinking among women with HIV. Social networks may have a negative or positive effect on alcohol consumption. Due to the increase in hazardous drinking among women with HIV, influence of social networks on alcohol use has become a central focus. While alcoholism is an addition and considered a biopsychosocial condition, examining the social networks variables influence outside of family and friends, which could result in improved treatment outcomes among women with HIV. Future research should also seek to explore the role of gender and the relationship between social network variables and reducing drinking outcome, given that alcohol affects men and women differently.

**Background**

In recent years, social networks influence on alcohol use has become a central focus. In regards to long-term recovery, research has supported the role of social networks (Valente et al., 2010, Kelly et al., 2011). For years, studies have suggested that a change in a person’s social network from one that reinforces drinking to one that reinforces sobriety will result in a reduction in relapse and an increase in abstinence among alcoholics (Litt et al., 2007). While proposed, efforts to decrease the support of substance use among a person’s social network have not been widely adopted (Litt et al., 2007). Thus, people with social networks that support their drinking typically have poorer treatment outcomes (Worley et al., 2015).
According to Longabaugh and Beattie (1985, 1986), understanding the construct of social support and its relationship to drinking outcomes is vital. Social support is divided into two different constructs: a) alcohol-specific support, specifically related to alcohol use, and b) general or global support, related to the overall well-being of an individual. One way to measure social networks and their influence on drinking outcomes is through the Important People and Activities Instrument. Originally, the Important People and Activities (IPA) instrument measured structural and functional alcohol-specific support (Longabaugh et al., 1993a, 1995). However, a modified version of the instrument, Important People Inventory (IPI) (Longabaugh and Zywiak, 2002) was used in the COMBINE study, a large, multisite randomized controlled trial examining treatment for alcohol dependence (Anton et al., 2006).

Previous research has shown alcohol-specific support as a predictor of drinking (Falkin and Strauss, 2003, Wu and Witkiewitz, 2008, and Longabaugh et al, 2009). In this study, an analysis of the data collected from the Brief Important People Inventory in the WHAT-IF study occurred in order to describe the important people in the participants’ daily life, and to identify the social network variables associated with number of important people and the likelihood that the support hazardous drinking reduction in women with HIV. Specifically, this study aimed to answer the following research question, “What are the social network variables that may influence hazardous drinking in women with HIV infection?”. We hypothesized that women with HIV would reduce their drinking if all network members disapproved of their drinking. We also hypothesized that a reduction in drinking would be less for women with HIV with a large
network (>3+), or the women with HIV who have at least one regular drinker in their network, or the women with HIV with at least one daily contact person.

**Methods**

A pharmacotherapy for hazardous drinking in women with HIV infection—a large, randomized clinical trial supported by the National Institute on Alcohol Abuse and Alcoholism (NIAAA) and aimed to recruit 240 hazardous drinking women with HIV infection. Coined “WHAT-IF?” for the question, “Will Having Alcohol Treatment Improve Functioning?”, designed to determine whether naltrexone will be effective in reducing hazardous drinking in women with HIV infection, thus resulting in improved HIV-related outcomes including adherence to medication, CD4 count and viral load. Study enrollment began in December 2012 and participants completed their last follow-up visit in August 2016 in Miami, FL. All of the participants were randomized to receive either naltrexone (50mg) or placebo daily for 4 months. The WHAT-IF study assessed measurable outcomes at 2-months, 4-months, and 7-months and included alcohol consumption, HIV medication adherence, HIV disease control and progression, and risky sexual behavior. The goal of WHAT-IF study as defined by the research team was a reduction in drinking to nonhazardous levels among the study participants (<7 drinks per week or <3 in one setting).

Participants were recruited from outpatient referral sites, associated centers, and surrounding community. Inclusion criteria included (1) age 18 or over, (2) female, (3) hazardous drinking, on average, during the previous 4 weeks and/or high total weekly consumption, (4) HIV infection, and (5) able to understand and comply with study procedures and to provide written consent. The study utilized the following exclusion criteria: (1) contradictions to treatment with naltrexone, (2) baseline liver enzymes ≥ 5
times normal, evidence of acute hepatitis, or receiving hemodialysis for renal failure, (3) currently pregnant or breastfeeding, (4) taking an alcohol treatment medication, (5) currently unable to provide mailing address or reliable contact information or has plans to move from area within next 7 months, (6) unable to read study questionnaires in English, (7) research coordinator’s determination that participant cannot comprehend the study or consent procedure, (8) has current prognosis of less than one year to live, (9) currently taking antiviral treatment for hepatitis C, and (10) has other unique health condition.

Measures

Drinking outcome

A reduction in alcohol consumption (quantity and frequency) to none or less than hazardous amounts (<7 drinks per week) was the primary drinking outcome. The research study staff defined and assessed the drinking outcome using the Timeline Follow back (TLFB), a method that uses a calendar to help persons recall their drinking patterns (Sobell and Sobell, 1992). During the enrollment visit, the TLFB information for the past 90 days was also used to help determine study eligibility. During the 1-, 2-, 4-, and 7-month visits, the TLFB data was collected for all days since the previous TLFB data collection. However, this analysis only involved the TLFB data corresponding with month 2. A categorical variable “reduced drinking” was computed and denoted as (0) no reduction (>7 drinks/week) or (1) reduced drinking (<7 drinks/week).

Brief Important People Inventory

Administration of the IPI, a structured interview occurred at month 2 by a trained member of the WHAT-IF study’s research team (Longabaugh et al., 2010). The Brief IPI involves seven questions about the participant’s perception of the individuals have been
important to them and with whom she has had contact with (face to face or by phone) within the past 6 months. The individuals could be family members, friends, people from work, or anyone that the participant felt has had a significant impact of their life, whether or not they liked the individual. Participants could list up to 10 people in their network. The seven interview questions included: 1) network member’s first name and last initial, 2) relationship to the participant (i.e., partner, immediate family, friend), 3) specific relationship of the person to the participant (i.e., husband, mother, co-worker) 4) frequency of contact (“daily” to “once in the past 6 months”), 5) their drinking status (“heavy drinker” to “abstainer/recovering alcoholic”), 6) frequency of their drinking (“daily” to “not at all in the past 6 months”), and 7) how has this person (how would this person) react to the participant’s drinking (“encourage” or “left or made you leave when you’re drinking”) in Table 4-1.
<table>
<thead>
<tr>
<th>Item</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before we begin, are there any close people important to you?</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>No</td>
</tr>
<tr>
<td>1. 1st Person (first name and last initial)</td>
<td></td>
</tr>
</tbody>
</table>
| 2. Relationship                                                     | 1 = Partner  
|                                                                     | 2 = Immediate Family  
|                                                                     | 3 = Extended Family  
|                                                                     | 4 = Friend  
|                                                                     | 5 = From Work  
|                                                                     | 6 = Self-Help/Treatment  
|                                                                     | 7 = Other  |
| 3. Specify the Relationship                                         |          |
| 4. During the past 6 months on average, how frequency have you been in contact with this person? | 7 = Daily (7 Times a Week)  
|                                                                     | 6 = Three to 6 Times a Week  
|                                                                     | 5 = Once or Twice a Week  
|                                                                     | 4 = Every other Week  
|                                                                     | 3 = About Once a Week  
|                                                                     | 2 = Less than Monthly  
|                                                                     | 1 = Once in the Past 6 Months  |
| 5. What is this person’s drinking status?                           | 5 = Heavy Drinker  
|                                                                     | 4 = Moderate Drinker  
|                                                                     | 3 = Light Drinker  
|                                                                     | 2 = Abstainer  
|                                                                     | 1 = Recovering Alcoholic  
<p>|                                                                     | 8 = Don’t Know  |</p>
<table>
<thead>
<tr>
<th>Item</th>
<th>Response</th>
</tr>
</thead>
</table>
| 6. How often does this person drink alcohol? | 7 = Daily (7 Times a Week)  
6 = Three to 6 Times a Week  
5 = Once or Twice a Week  
4 = Every other Week  
3 = About Once a Week  
2 = Less than Monthly  
1 = Once in the Past 6 Months  
8 = Don’t Know |
| 7. How has this person (or how would this person) react to your drinking? | 5 = Encouraged  
4 = Accepted  
3 = Neutral  
2 = Didn’t Accept  
1 = Left, or made you leave when you’re drinking  
8 = Don’t Know |
| 8. Are there any other people you would like to add? | Yes  
No: We are ready to collect more details |

**Social Network Categories and Variables**

While the Brief IPI included seven variables, in this study we measured 4 of the variables that fell into the following three categories: social investment (size of social network), alcohol-specific support (at least one regular drinker in the network and all network members disapproved of the participants drinking), and contact with the network (at least one daily contact person). The categories and associated variables used in the present study are in Table 4-2.
Table 4-2. Social Network Categories and Variables

<table>
<thead>
<tr>
<th>Category</th>
<th>Variables</th>
</tr>
</thead>
<tbody>
<tr>
<td>Social investment category</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1. “Size of network” variable</td>
</tr>
<tr>
<td>Alcohol-specific support category</td>
<td>1. At least one regular drinker in the network variable (network drinking)</td>
</tr>
<tr>
<td></td>
<td>a. Heavy drinkers, %</td>
</tr>
<tr>
<td></td>
<td>b. Abstainers/recovering alcoholics, %</td>
</tr>
<tr>
<td></td>
<td>c. Total frequency of drinking in the network</td>
</tr>
<tr>
<td></td>
<td>2. All network members disapproved of the participants drinking</td>
</tr>
<tr>
<td></td>
<td>a. No. who accept/encourage participant drinking</td>
</tr>
<tr>
<td></td>
<td>b. No. who did not accept participant drinking</td>
</tr>
<tr>
<td></td>
<td>c. No. who had a neutral reaction to participant drinking</td>
</tr>
<tr>
<td>Contact with network</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1. Frequency of contact variable</td>
</tr>
</tbody>
</table>

*Roman numerals refer to social network categories. Numbers refer to social network variables associated with each category.*

**Social investment category**

Social investment defined as the participant’s dependence on others for reassurance or rewards and measured as: size of social network. As a part of the Brief IPI, study participants were able to list up to 10 people they perceived important to them. The number of important people reported among the participants ranged from 0 to 9 with majority of the women reporting 2 important people in their network. Therefore, the categorical variable “size of network” was computed and denoted as follows: (1) <3 (small network) or (2) >3+ (large network).

**Alcohol-specific support category**

As mentioned, alcohol-specific support has been found as a predictor of drinking (Longabaugh et al., 2009; Falkin and Strauss, 2003). Therefore, to keep consistent with other studies (Longabaugh et al., 2009, Hunter-Reel, McCrady, and Hildebrandt, 2009), alcohol-specific support includes: network drinking and network member’s reaction to participant’s drinking. The first, network drinking was a combination of the following three variables: a) percentage of heavy drinkers, b) percentage of abstainers, and c)
frequency of drinking in the network. The percentage of heavy drinkers calculated by as the number of moderate/heavy drinkers (numerator) and dividing this number but the total number of important people listed by the participants (denominator). Next, the percentage of abstainers calculated as the number of abstainers/recovering alcoholics (numerator) and dividing this number but the total number of important people listed by the participants (denominator). Lastly, the frequency of drinking in the network calculated as the values of those that reported drinking less than weekly, weekly drinking, and daily drinking and dividing each by the total number of important people listed. Thus, this resulted in a categorical variable that reflected whether participants had “at least one regular drinker in the network (moderate/heavy drinker or at least weekly drinking)”. Type of drinker computed as: (1) recovering alcoholic/abstainer, (2) light drinker, or (3) moderate to heavy drinker, or frequency of drinking: (1) less than weekly, (2) weekly drinking, or (3) daily drinking.

The second type of alcohol-specific support that was measured included the participant’s perception of the network member’s reaction to their drinking and included the following variables: a) all members’ approval of participant’s drinking, b) all members’ disapproval of participant’s drinking, or c) neutral. Each of the three variables were separately calculated by adding together the number of people that reportedly didn’t accept the participant’s drinking, were neutral, or those who encouraged/accepted and divided the values by the total number of important people listed by the participants (denominator). Furthermore, the categorical variable “all network members disapproved of the participant’s drinking” was computed and defined as: (1) all members did not accept, (2) neutral, or (3) all members accepted/encouraged.
Contact with network category

Contact with network defined as the frequency of contact with network members during the past 6 months, on average whether face-to-face or by phone. Responses to this variable ranged from (“daily” to “once in the past 6 months”). For the purposes of this study, a categorical variable “frequency of contact” was computed and measured (1) less than weekly contact, (2) weekly contact, and (3) daily contact.

Statistical Analysis

In order to test our hypotheses, chi-square test of independence were conducted using IBM SPSS Statistics 20. This test was an appropriate nonparametric statistical test given that the purpose of the study was to examine the relationship between the social network variables and the drinking outcome. Specifically, the test of independence determined whether the following variables: a large network size, at least one regular drinker in the network, all network members disapproved of the participant’s drinking, and frequency of contact and whether the participant experienced a reduction in hazardous drinking (yes/no) was related or independent. SPSS presented the date using bivariate tables and the p-value provided determined significance of the relationship. Among the relationships with a reported p-value of less than .05, the variables are not independent of each other and there is a statistical relationship between the social network variables and the drinking outcome (reduction in hazardous drinking). Additionally, SPSS calculated baseline demographic variables (age, race/ethnicity, marital status, employment, and education) each participant.

A total of 222 women completed the WHAT-IF clinical trial; however, the study excluded participants from the WHAT-IF sample who were missing responses to the
Brief Important People Inventory related to the study aforementioned study variables (n=39).

**Results**

**Demographic Characteristics**

Women who completed the Brief Important People Inventory (n = 183) were 18 to 66 years old (M = 48.37, SD = 8.54) and 82.5% were Black/African-American. Majority (83.1%) was single, unemployed (90.7%), and 43.2% had less than a high school education. All of the women provided documentation of HIV status and self-identified as hazardous drinkers in Table 4-3.
Table 4-3. Demographic characteristics of the women who completed the Brief Important People Inventory Questionnaire

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>N = 183</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographics, No. (%)</td>
<td></td>
</tr>
<tr>
<td>Age range, years</td>
<td>Mean 48.3</td>
</tr>
<tr>
<td>Age group</td>
<td></td>
</tr>
<tr>
<td>18-39</td>
<td>26 (14)</td>
</tr>
<tr>
<td>40-49</td>
<td>64 (35)</td>
</tr>
<tr>
<td>50-59</td>
<td>77 (42)</td>
</tr>
<tr>
<td>≥60</td>
<td>16 (9)</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>21 (11)</td>
</tr>
<tr>
<td>Black/African American</td>
<td>151 (83)</td>
</tr>
<tr>
<td>White</td>
<td>8 (4)</td>
</tr>
<tr>
<td>Other</td>
<td>3 (2)</td>
</tr>
<tr>
<td>Race</td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>14 (7)</td>
</tr>
<tr>
<td>Black/African American</td>
<td>157 (86)</td>
</tr>
<tr>
<td>American Indian</td>
<td>1 (&lt;1)</td>
</tr>
<tr>
<td>Multi-racial</td>
<td>4 (2)</td>
</tr>
<tr>
<td>Unknown</td>
<td>7 (4)</td>
</tr>
<tr>
<td>Marital Status</td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>152 (83)</td>
</tr>
<tr>
<td>In a relationship</td>
<td>31 (17)</td>
</tr>
<tr>
<td>Employment</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>166 (91)</td>
</tr>
<tr>
<td>Yes</td>
<td>17 (9)</td>
</tr>
<tr>
<td>Education Level</td>
<td></td>
</tr>
<tr>
<td>Less than High School</td>
<td>79 (43)</td>
</tr>
<tr>
<td>High School Graduate</td>
<td>61 (33)</td>
</tr>
<tr>
<td>Some College or college graduate</td>
<td>43 (24)</td>
</tr>
</tbody>
</table>

Description of the Important People Listed in the Participant’s Daily Lives

Before the interview began, each participant (n = 183) was asked the question, “Are there any close people important to you?” Approximately 94% (n = 172) of the women reported ‘yes’ compared to 6% (n = 11) that reported ‘no’. Altogether, 375 people were important to the participant (n = 183) in Table 4-4.
Table 4-4. Description of the important people listed in the participant’s daily lives as reported in the Brief IPI

<table>
<thead>
<tr>
<th>Important People Inventory Variables</th>
<th>N = 183 Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N= 375 Important people listed</td>
</tr>
</tbody>
</table>

Characteristics of the important people, No. (%)

Are there any close people important to you?

| No | 11 (6) |
| Yes | 172 (94) |

Number of reported important people

| 0     | 11 (6) |
| 1     | 52 (28) |
| 2     | 80 (44) |
| 3     | 18 (10) |
| 4     | 10 (5) |
| 5     | 6 (3) |
| 6     | 5 (3) |
| 9     | 1 (<1) |

Relationship

| Partner | 65 (17) |
| Immediate Family | 228 (61) |
| Extended Family | 17 (5) |
| Friend | 60 (16) |
| Self-Help/Treatment | 2 (<1) |
| Other | 3 (<1) |
| Single | 152 (83) |
| In a relationship | 31 (17) |

Frequency of contact

| Less than Monthly | 2 (<1) |
| About once a Month | 8 (2) |
| Every other Week | 15 (4) |
| Once or Twice a Week | 37 (10) |
| Three to 6 Times a Week | 33 (9) |
| Daily (7 Times a Week) | 280 (75) |

What is this person’s drinking status

| Recovering Alcohol | 40 (11) |
| Abstainer | 176 (47) |
| Light Drinker | 69 (18) |
| Moderate Drinker | 49 (13) |
| Heavy Drinker | 36 (10) |
| Don’t Know | 5 (1) |
Table 4-4. Continued.

<table>
<thead>
<tr>
<th>Important People Inventory Variables</th>
<th>N = 183</th>
</tr>
</thead>
<tbody>
<tr>
<td>How often does this person drink alcohol</td>
<td></td>
</tr>
<tr>
<td>Not in the Past 6 Months</td>
<td>202 (54)</td>
</tr>
<tr>
<td>Once in the Past 6 Months</td>
<td>7 (2)</td>
</tr>
<tr>
<td>Less than Monthly</td>
<td>14 (4)</td>
</tr>
<tr>
<td>About Once a Month</td>
<td>17 (5)</td>
</tr>
<tr>
<td>Every Other Week</td>
<td>6 (2)</td>
</tr>
<tr>
<td>Once or Twice a Week</td>
<td>50 (13)</td>
</tr>
<tr>
<td>Three to 6 Times a Week</td>
<td>42 (11)</td>
</tr>
<tr>
<td>Daily (7 Times a Week)</td>
<td>20 (5)</td>
</tr>
<tr>
<td>Don’t Know</td>
<td></td>
</tr>
<tr>
<td>How has this person reacted to your drinking</td>
<td></td>
</tr>
<tr>
<td>Didn’t Accept</td>
<td>160 (43)</td>
</tr>
<tr>
<td>Neutral</td>
<td>104 (28)</td>
</tr>
<tr>
<td>Accepted</td>
<td>91 (24)</td>
</tr>
<tr>
<td>Encouraged</td>
<td>10 (3)</td>
</tr>
<tr>
<td>Don’t Know</td>
<td>10 (3)</td>
</tr>
</tbody>
</table>

The breakdown of the number of people listed as important to the participant is as follows: 6% (n = 11) reported no one, 28% (n = 52) reported 1 person, 44% (n=80) reported 2 people, 10% (n = 18) reported 3 people, 5% (n = 10) reported 4 people, 3% (n=6) reported 5 people, 3% (n=5) reported 6 people, and <1% (n = 1) reported 9 people.

Next, participants (n = 183) listed their relationship to the person important to them (n = 375). An estimated 17% (n=65) people were listed as partners (e.g., husband, boyfriend), 61% (n=228) as immediate family members (e.g., mother, father, sister, son), 5% (n=17) as extended family (e.g., Godmother, stepdaughter, daughter-in-law), 16% (n = 60) was listed as a friend, and <1.5% (n = 5) as either self-help/treatment or other (e.g., therapists, ex-boyfriend).

Then, participants answered the following questions, “During the past 6 month on average, how often have you been in contact with this person?” Less than 1% of
participants (n = 2) reported less than monthly, 2% (n = 8) reported about once a month, 4% (n = 15) reported every other week, 10% (n = 37) reported once or twice a week, 9% (n = 330) three to six times a week, and 75% (n = 280) reported daily (7 times a week).

Study participants were then asked, “What is the important person’s drinking status?” An estimated 11% (n = 40) as recovering alcoholics, 47% (n = 176) as abstainer, 18% (n = 69) was listed as light drinker, 13% (n = 49) as a moderate drinker, 10% (n = 36) was listed as a heavy drinker, and 1% (n = 8) was listed as don’t know.

Following this, participants answered the question, “How often does this person drink alcohol?” Approximately 54% (n = 202) of the people listed as important to the participant did not consume any alcohol in the past 6 months, 2% (n = 7) consumed alcohol once in the past 6 months, 4% (n = 14) drank less than monthly, 5% (n = 17) reportedly drank about once a month, 2% (n = 6) drank every other week, 13% (n = 50) consumed alcohol once or twice a week, 5% (n = 17) drank three to 6 times a week, 11% (n = 42) drank daily (7 times a week), and 5% (n = 20) was listed as don’t know.

Lastly, each participant answered the question, “How does this person (or how this person would) react to your drinking? Majority (43%) of the important people (n = 160) did not accept the participant’s drinking, 28% (n = 104) were neutral to the participant’s drinking, 27% (n = 101) accepted/encouraged the participant to drink, and 3% (n = 10) was listed as don’t know.

**Relationship of network member to social network variables**

When examining the relationship of the network member to the social network variables, 6% (n = 11) reported no important person, 35% (n = 64) reported a partner,
76% (n = 139) reported a family member, followed by 23% (n = 42) who reported a friend, and 3% (n = 5) who reported other in Table 4-5.
Table 4-5. Relationship of network members to social network variables

<table>
<thead>
<tr>
<th>Social network variable</th>
<th>Important people reported by the participant</th>
<th>N = 375</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description, No. (%)</td>
<td>Partner</td>
<td>Family</td>
</tr>
<tr>
<td>At least one regular drinker in the network</td>
<td>34 (52)</td>
<td>146 (61)</td>
</tr>
<tr>
<td>Type of drinker</td>
<td>N = 370 (Missing N = 16)</td>
<td></td>
</tr>
<tr>
<td>Recovering alcoholic/abstainer</td>
<td>34 (52)</td>
<td>146 (61)</td>
</tr>
<tr>
<td>Light drinker</td>
<td>17 (26)</td>
<td>50 (21)</td>
</tr>
<tr>
<td>Moderate/heavy drinker</td>
<td>N = 355 (Missing N = 31)</td>
<td></td>
</tr>
<tr>
<td>Frequency of Drinking</td>
<td>N = 365 (Missing N = 21)</td>
<td></td>
</tr>
<tr>
<td>Less than weekly contact</td>
<td>39 (60)</td>
<td>165 (72)</td>
</tr>
<tr>
<td>Weekly contact</td>
<td>17 (26)</td>
<td>41 (18)</td>
</tr>
<tr>
<td>Daily contact</td>
<td>9 (14)</td>
<td>22 (10)</td>
</tr>
<tr>
<td>All network members disapproved of the participant’s drinking</td>
<td>30 (46)</td>
<td>105 (44)</td>
</tr>
<tr>
<td>Did not accept</td>
<td>21 (32)</td>
<td>69 (29)</td>
</tr>
<tr>
<td>Neutral</td>
<td>14 (22)</td>
<td>62 (26)</td>
</tr>
<tr>
<td>Accepted/Encouraged</td>
<td>N = 375 (Missing N = 16)</td>
<td></td>
</tr>
</tbody>
</table>
Table 4-5. Continued.

<table>
<thead>
<tr>
<th>Social network variable</th>
<th>Important people reported by the participant</th>
<th>N = 375</th>
</tr>
</thead>
<tbody>
<tr>
<td>At least one daily</td>
<td></td>
<td>N = 375</td>
</tr>
<tr>
<td>daily contact person</td>
<td></td>
<td>(Missing N = 11)</td>
</tr>
<tr>
<td>Less than weekly contact</td>
<td>0 (0)</td>
<td>22 (9)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3 (5)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0 (0)</td>
</tr>
<tr>
<td>Weekly contact</td>
<td>4 (6)</td>
<td>48 (20)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>16 (4)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2 (40)</td>
</tr>
<tr>
<td>Daily contact</td>
<td>61 (94)</td>
<td>175 (71)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>41 (11)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3 (60)</td>
</tr>
</tbody>
</table>

At least one regular drinker in their network

Network drinking computed as "at least one regular drinker in their network (moderate/heavy drinker or at least weekly drinking)" variable and defined as either type of drinker: (1) recovering alcoholic/abstainer, (2) light drinker, or (3) moderate to heavy drinker, or frequency of drinking: (1) less than weekly, (2) weekly drinking, or (3) daily drinking. When examining the relationship of the network member (n = 370; missing 16) to network drinking variable, in regards to type of drinker, 58% (n = 216) of the people listed as recovering alcoholic/abstainer, 19% (n = 69) were light drinkers, and 23% (n = 85) were moderate/heavy drinkers. Among the reported types of drinkers, 18% (n = 65) were partners, 65% (n = 240) as family members, 16% (n = 60) were friends, and 1.4% (n = 5) as other.

In regards to the frequency of drinking among the network members (n = 355; missing 31), 69% (n = 246) reportedly drank less than weekly, 19% (n = 67) were weekly drinkers, and 12% (n = 42) were daily drinkers. Among the drinkers specifically,
18% (n = 65) were partners, 64% (n = 228) were family members, 16% (n = 57) were listed as a friend, and 1.4% (n = 5) was listed as other.

**All network members disapproved of the participant’s drinking**

Additionally, the participants’ perception of the network member’s reaction to their drinking variable computed as the “network’s reaction to participant’s drinking” and defined as (1) did not accept, (2) neutral, or (3) accepted/encouraged. When examining the relationship of the network member (n = 370; missing 16) to network drinking variable, in regards to type of drinker, 58% (n = 216) of the people listed as recovering alcoholic/abstainer, 19% (n = 69) were light drinkers, and 23% (n = 85) were moderate/heavy drinkers. Among the drinkers specifically, 18% (n = 65) were partners, 65% (n = 240) as family members, 16% (n = 60) were friends, and 1.4% (n = 5) as other. When investigating the relationship of the network member (n = 365; missing 21) and their reaction to the participant’s drinking, 44% (n = 160) did not accept the participant drinking, 28% (n = 104) were neutral to the participant drinking, and 28% (n = 101) accepted the participant’s drinking. Among the network member’s that reacted to the participant’s drinking, 18% (n = 65) were partners, 65% (n = 236) were family members, 16% (n = 59) were friends, and 1.4% (n = 5) as other.

**At least one daily contact person**

The frequency of contact variable computed as (1) less than weekly contact, (2) weekly contact, and (3) daily contact. When examining the relationship of the network member (n = 375; missing 11) and their frequency of contact with the participant, 7% (n = 25) of the contacted less than weekly by the participant, 19% (n = 70) as weekly contacts, and 75% (n = 280) as daily contacts. Among the reported network members with who the participant had contact with, 17% (n = 65) were partners, 65% (n = 245)
were listed as family members, 16% (n = 60) were friends, and 1.4% (n = 5) was listed as other.

**What are the social network variables that may influence hazardous drinking in women with HIV infection?**

As mentioned, to test our hypotheses, a chi-square test of independence, was to examine the relationship between the social network variables and the drinking outcome, a reduction in drinking to nonhazardous levels defined as consuming <7 drinks/week in Table 4-6.

**Table 4-6. Social network variables that may influence hazardous drinking among women with HIV infection**

<table>
<thead>
<tr>
<th>Social network variable</th>
<th>Drinking Outcome (&lt;7 drinks/week)</th>
<th>N = 183</th>
<th>P-value</th>
<th>χ²</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description, No. (%)</td>
<td>No reduction</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Size of network</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;3 (small)</td>
<td>75 (85)</td>
<td>86 (91)</td>
<td>0.2708</td>
<td>1.2128</td>
</tr>
<tr>
<td>&gt;3+ (large)</td>
<td>13 (15)</td>
<td>9 (9)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>At least one regular drinker in the network (moderate/heavy or at least weekly drinking)</td>
<td>No</td>
<td>39 (44)</td>
<td>60 (63)</td>
<td>0.01</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>49 (56)</td>
<td>35 (37)</td>
<td></td>
</tr>
<tr>
<td>All network members disapproved of the participant's drinking</td>
<td>No</td>
<td>63 (72)</td>
<td>61 (64)</td>
<td>0.29</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>25 (28)</td>
<td>34 (36)</td>
<td></td>
</tr>
<tr>
<td>At least one daily contact person</td>
<td>No</td>
<td>6 (7)</td>
<td>17 (18)</td>
<td>0.02</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>82 (93)</td>
<td>78 (82)</td>
<td></td>
</tr>
</tbody>
</table>
Size of network

When examining the “size of network” variable, 88% (n = 161) of the women (n = 183) reported a small network size (<3 important people) compared to 12% (n = 22) that reported a large network size (>3+). Among the women with a large network, 9% (n = 9) reported a reduction in hazardous drinking compared to 91% (n = 86) of those with a smaller network (p = 0.2708).

At least one regular drinker in the network

An estimated 46% (n = 84) of the women reported having at least one important person in their network that was a regular drinker (moderate/heavy drinker or at least weekly drinking) compared to 54% (n = 99) that did not have at least one regular drinker in their network. Among the participants who reported a reduction in drinking, 37% (n = 35) reported at least one regular drinker in their network compared to 63% (n = 60) of those who did not have at least one regular drinker in their network (p = 0.01).

All network members disapproved of the participant’s drinking

Approximately 32% (n = 59) of the women reported all of the important people disapproved of their drinking compared to 68% (n = 124) that did not disapprove. Among the participants that reported a reduction in drinking, 36% (n = 34) reported all network members disapproved of their drinking compared to 64% (n = 61) of the participants that reported no disapproval among network members (p = 0.29).

At least one daily contact person in the network

Roughly 87% (n = 160) of the women reported having at least one daily contact person in their network compared to 13% (n = 23) of those who did not have at least one daily contact. Among the participants who reported a reduction in drinking, 82% (n
= 78) reported having at least one daily contact person compared to 18% (n = 17) of those who did not any one daily contact (p-value = 0.02).

Discussion

In this analysis of the Brief Important People Inventory questionnaire collected during month 2 as part of WHAT-IF study, we sought to describe the important people in the participants’ daily life, and to identify the social network variables associated with number of important people and the likelihood that the support hazardous drinking reduction. Specifically, this study aimed to answer the following research question, “What are the social network variables that may influence hazardous drinking in women with HIV infection?”. We hypothesized that women with at least one regular drinker in their network with whom they had daily contact with would be less likely to reduce their drinking. We also hypothesized that among women with large network sizes (>3+) in which all members in the network approved of their drinking would be less likely to reduce their drinking.

As mentioned, a total of 183 women completed the Brief IPI and among the women a total of 375 people (missing n = 11) were reported as being important people in their daily lives. Approximately, 88% (n = 161) of the women (n = 183) reported a small network size (<3 important people) with most 44% (n=80) reporting on average 2 people in their network. When examining the relationship of the participant to the important person, 61% (n=228) as immediate family members (e.g., mother, father, sister, son). On average, 75% (n = 280) reported daily (7 times a week) with the important person. In regards to the drinking status of the important person, 58% (n = 216) were abstainers/recovering alcoholics and estimated 54% (n = 202) of the people listed as important to the participant stated to not have consumed any alcohol in the
past 6 months. Moreover, 43% (n = 160) of the important people did not accept the participant’s drinking.

First, we hypothesized more women with HIV would reduce their drinking if all network members disapproved of their drinking, while true, this finding was not significant (p = 0.29). Next, we hypothesized a reduction in drinking would be less for women with HIV who had a large network size, or at least one regular drinker in the network, or at least one daily contact person. Findings demonstrated a large network size associated with women with HIV being less likely to reduce their drinking, though this variable was not significant (p = .27). Furthermore, Longabaugh et al. (2009), found that the two types alcohol-specific support was a predictor of percent days abstinent (PDA). In particular, network support for drinking, frequency of network drinking, and opposition to participant drinking associated with poorer treatment outcomes among patients. Moreover, many studies have examined the role of gender and the relationship between drinking variables and social support (Hunter-Reel, McCrady, and Hildebrandt, 2009). On the contrary, among the women with large network sizes (n = 22) and/or those who reported that all network members did not disapprove of their drinking (n = 124) were less likely to report a reduction in drinking. Study results have highlighted social network variables influence on women as compared to men (Hunter-Reel, McCrady, and Hildebrandt, 2009). This is particularly important given that the WHAT-IF trial included only hazardous drinking women with HIV infection. On the contrary, two variables were significant including having at least one regular drinker in the network (p = 0.01) and/or at least one daily contact person (p = .02). The results of this study suggests social network variables such as having at least one regular drinker in the
network (n = 35) and/or having at least one daily contact person in the network (n = 78) may influence a reduction or increase in hazardous drinking among women with HIV.

The primary goal of the WHAT-IF clinical trial was a reduction in alcohol consumption (quantity and frequency) to none or less than hazardous amounts (<7 drinks per week hazardous. Once again, the WHAT-IF study research team developed this definition. Taken together, the results highlight social network variables influence on the drinking outcome (reduction in hazardous drinking) with an overall 48% (n = 88) of the women reporting no reduction in alcohol consumption compared to 52% (n = 95) who did report a reduction across all the variables. Majority of the people listed as important to the participant was an immediate family member (e.g., mother, father, sister) and the women reported having at least one daily contact person. While women have also been reported to incur different heritability for alcoholism compared to men (Greenfield et al., 2007; Ponce et al., 2005) family history has been shown to be a factor in treatment response. However, not all women who have a family history of alcoholism develop problems. As evident in this study, 47% (n = 176) was reportedly abstinent and 43% (n = 160) of the important people did not accept the participant’s drinking.

Pursuing this further, a prime example of an existing social network that supports abstinence is Alcohol Anonymous (AA) (Litt et al., 2007). AA, a sobriety support network, provides alternatives to drinking and reinforces sober behavior (Litt et al., 2007). A study by Katskutas et al. (2002) concluded that social networks influences were mediators of abstinence. In particular, the larger social network and the greater network support for abstinence moderately explained the relationship between an increased involvement in Alcohol Anonymous (AA) related activities and better
outcomes. On the contrary, Bond et al. (2013) found that after treatment, the only mediator of abstinence was AA-specific network support.

This study has some limitations that are worth discussing. First, all the participants that enrolled in the WHAT-IF study were women with HIV infection, who self-identified as hazardous drinker. Moreover most of the women were African-American where participants were randomized to either naltrexone or placebo medication. While 42% of women living with HIV are African Americans and women have become the fastest growing population of alcohol user, at this time we are unable to determine the extent to which these findings are generalizable to other groups. Specifically, a larger percentage of people who are diagnosed with an alcohol use disorder do not seek treatment for various reasons, therefore the results of this study are not applicable to non-treatment-seeking populations. Additionally, the study’s exclusion criteria resulted in a reduction in heterogeneity of drug use and more concurrent conditions. Furthermore, participants enrolled in the clinical trial received medical management (MM) and combine behavioral interventions (CBI), which are not practical in real-world settings. As noted, the Brief IPI has limitations, the primary being is that the structured interview relies on self-reported information from the participant and is subjected to recall bias and information bias. As reported in the study results, participants (n = 31) excluded from study analysis due to the missing demographic and IPI data. Another limitation of the questionnaire is the administration time, which could variable considerably depending on a number of factors (e.g., number of important people listed by the participant, differences in the administration of the tool to the participant by the research staff member).
The results of this study suggest social network variables such as having at least one regular drinker in the network (n = 35) and/or having at least one daily contact person in the network (n = 78) may influence a reduction or increase in hazardous drinking among women with HIV. While alcoholism is an addition and considered to be a biopsychosocial condition, examining the influence of family and friends social networks could result in improved treatment outcomes among women with HIV. Future research should also seek to explore the role of gender and the relationship between social network variables and reducing drinking hazardous drinking, given that alcohol affects men and women differently.
CHAPTER 5
CONCLUSIONS

The field of public health has made relentless efforts to reduce the incidence and prevalence of HIV. Moreover, an estimated that 6-54% of women with HIV infection engage in hazardous drinking, a behavior that can lead to additional individual and public health consequences (Cook et al., 2001; Chandler et al., 2008; Peretti-Watel et al., 2006; Baum et al., 2010). Hazardous drinking presents unique health risks in women with HIV infection including lower medication adherence, increased risky sexual behavior, and more rapid disease progression (Cook et al., 2001; Chandler et al., 2008; Peretti-Watel et al., 2006; Baum et al., 2010). For women, hazardous drinking is defined as consuming 7 drinks or more per week (or ≥3 drinks per occasion) (NIAAA, 2005).

While behavioral and pharmacologic treatment options are available, few have evaluated the effectiveness, acceptability, and tolerability in women with HIV infection. In the past, majority of the participants in substance abuse research were male or consisted of a mixed sample of men and women with little regard to gender differences (Greenfield et al., 2006). Despite the gender bias in earlier research, substance abuse is increasing in women, warranting further exploration.

In summary, the field of public health challenges scholars to confront complex health issues surrounding the effects of alcohol on HIV infection in women. This required looking beyond individuals’ problems and identifying the underlying biological, psychological, and social factors that contribute to alcohol disparities in women. Thus, this dissertation aimed evaluate the complex social phenomenon of hazardous drinking among women with HIV infection by investigating biopsychosocial factors associated with reducing hazardous drinking. In Chapter 5, we will provide a summary of the
findings pertaining to the three studies that conduct as part of this dissertation. We will then provide an in-depth discussion of the strengths and limitations of this research while providing recommendations for future research and clinical implications.

Dissertation Findings

Chapter 2: Systematic Literature Review

In Chapter 2, we conducted a systematic literature review to review and summarize the evidence regarding the impact of naltrexone for attenuating alcohol consumption in women with an alcohol use disorder (AUD). To date, this is the first systematic literature review that focuses solely on women with an AUD. This review sought out to answer the following question: “Is naltrexone effective in treating substance use in women with an alcohol use disorder?” Our review yielded seven published trials that have evaluated the impact of naltrexone on drinking outcomes in women alone or distinct from men. A total of 903 alcohol-dependent women randomized to receive once daily naltrexone or depot (injectable) naltrexone or placebo with/without behavioral intervention. Two studies examining quantity of drinks per day observed trends toward reduction in drinking quantity among women who received naltrexone vs. placebo. The four studies examining the frequency of drinking had mixed results, with one study showing a trend that favored naltrexone, two showing a trend that favored placebo, and one that showed no difference. Two of the three studies examining time to relapse observed trends that tended to favor naltrexone for time to any drinking and time to heavy drinking among women who received naltrexone vs. placebo. While the growing body of evidence suggests different approaches to treat alcohol use disorders (AUD), the impact of naltrexone to combat AUD in women is understudied. Taken
together, the results suggest that naltrexone may lead to modest reductions in the quantity of drinking and time to relapse, but not on the frequency of drinking in women.

**Chapter 3: Qualitative Interviews**

In Chapter 3, 20 hazardous drinking women with HIV infection completed qualitative interviews. The purpose of this study was to identify women with HIV reasons for enrolling in the WHAT-IF clinical trial for a reduction in hazardous drinking and to identify the reasons women were successful or unsuccessful in changing their drinking behavior. This study aimed to address the following research questions: 1) “What are the attitudes among women with HIV toward seeking treatment for hazardous drinking?” 2) “How did women with HIV describe their experience in the clinical trial?” 3) “What specific aspects of the trial, besides the study medication associated with a reduction in hazardous drinking among the women with HIV?” Overall, findings from this study revealed several themes within the context of the biopsychosocial model and the factors associated with the specific research questions. For example, women cited reasons for enrolling in the WHAT-IF study that included: the ability to reduce their drinking to nonhazardous levels (biological), the opportunity for self-reflection or self-empowerment (psychological) and monetary compensation (social). Moreover, examining women with HIV overall clinical trial experience and the specific aspects of the trial associated with a reduction in hazardous drinking helped identify reasons why women with HIV were successful or unsuccessful in the clinical trial. In regards to the women with HIV overall clinical trial experience, themes associated with women likes and dislikes included the following: the participants did not like the negative effects of the study medication (biological) or the lab work that required drawing blood (psychological). Most participants liked the completing the survey assessment as a part of the study procedures.
(psychological), and many reported having positive interactions with the research study staff (social). Lastly, women identified many themes within the context of the biopsychosocial model that were associated with the perceived aspects of the trial that resulted in a reduction in drinking. While majority of the women were able to reduce their drinking to nonhazardous levels (biological), many of the women stated that the study provided them with the opportunity for self-reflection and change, while others cited fear of adverse events associated with drinking and taking the study medication (psychological) as primary reasons. Once more the study staff was very influential in providing encouragement to the participants that help result in a reduction in their drinking (social). These findings were consistent with other studies that have examined treatment-seeking practices among women and their overall experiences in randomized clinical trials. Thus, similar findings reported among study participants who credited some of their study success to the positive interactions among the study staff members (Jackson et al., 2010, Slade et al., 2010, and Kneipp et al., 2013).

Chapter 4: Analysis of the Brief Important Inventory Questionnaire

In Chapter 4, we conducted an analysis of the Brief Important Inventory completed by the participants in the WHAT-IF clinical trial. The purpose of the study was to describe the important people in the participants’ daily life, and to identify the social network variables associated with the number of important people and the likelihood that the support hazardous drinking reduction. Specifically, this study aimed to answer the following research question, “What are the social network variables that may influence hazardous drinking in women with HIV infection?” We hypothesized that women with HIV would reduce their drinking if all network members disapproved of their drinking. We also hypothesized that a reduction in drinking would be less for women
with HIV with a large network (>3+), or the women with HIV who have at least one regular drinker in their network, or the women with HIV with at least one daily contact person. Among the seven variables examined as a part of the Brief IPI, in this study we measured 4 of the variables that fell in to the following three categories: social investment (size of social network), alcohol-specific support (at least one regular drinker in the network and all network members disapproved of the participant’s drinking) and contact with the network (at least one daily contact person).

The results of this study suggests social network variables such as having at least one regular drinker in the network (n = 35) and/or having at least one daily contact person in the network (n = 78) may influence a reduction or increase in hazardous drinking among women with HIV. Findings demonstrated a large network size associated with women with HIV being less likely to reduce their drinking, though this variable was not significant (p = .27). On the contrary, two variables were significant including having at least one regular drinker in the network (p = 0.01) and/or at least one daily contact person (p = .02). These findings were similar to other studies that highlighted social network variables influence on women with HIV as compared to men (Hunter-Reel, McCrady, and Hildebrandt, 2009).

**Strengths**

There were several strengths of this dissertation research. To date, Chapter 2 was the first study to systematically review the literature examining treatment options for attenuating alcohol consumption in women specifically with an AUD. Previous systematic reviews (Srisurapanont & Jarusuraisin, 2005; Maisel et al., 2012) have not explored gender differences in the efficacy of naltrexone for women alone or distinct from men. Additionally, previous systematic reviews suggest slight benefits from
naltrexone (Kranzler & Van kirk, 2006; Jonas et al., 2014; Donoghue et al., 2015), but do not specifically address variables specific to naltrexone treatment in women. Results of this systematic review suggest that naltrexone may lead to modest reductions in the quantity of drinking and time to relapse, but not on the frequency of drinking in women.

In Chapter 3, 20 hazardous drinking women with HIV infection completed qualitative interviews. Specifically, the WHAT-IF study is the first trial that evaluated pharmacotherapy for a reduction in hazardous drinking in women with HIV. This study was able use the biopsychosocial model to identify the reasons for enrolling in the WHAT-IF clinical trial for a reduction in hazardous drinking among women with HIV while identifying the reasons why women with HIV were successful or unsuccessful in changing their drinking behavior. The inclusion of a qualitative methodology (particularly in underserved, disadvantaged groups) provided critical data on the perceptions, cultural relevancy, acceptability, and salience of specific aspects of intervention approaches of the randomized clinical trial. For decades, women and minorities have been underrepresented in clinical research. However, in Chapters 3 and 4, majority of the sample were African-American who reported a positive clinical trial experience and reported a reduction in their drinking behavior.

To date, Chapter 4 was the first study to provide evidence of social network variables influences on reducing hazardous drinking in women with HIV infection. As with the previous study, the individuals in the WHAT-IF study were women who enrolled in the clinical trial for a reduction in hazardous drinking. As a part of the trial, participants discussed questions about the participant’s perception of the individuals have been important to them and with whom she has had contact with (face-to-face or by phone)
within the past 6 months. The results of this study demonstrated social network variables influence on reducing or increasing hazardous drinking in women with HIV. This study builds on previous research that has concluded social network variables as predictors of poorer treatment outcomes among participants (Longabaugh et al., 2009). Additionally, there is literature to support social network variables influence on women in relationship to between gender, drinking variables and social support (Hunter-Reel, McCrady, and Hildebrandt, 2009).

**Limitations**

We note several potential limitations as context for interpreting our findings in this dissertation. In Chapter 2, four studies included fewer than 100 women and were relatively underpowered to detect significant changes in drinking over time (Kranzler et al., 2009; Kiefer, Jahn & Wiedemann, 2005; Hernandez-Avila et al., 2006; Pettinati et al., 2008). Due to the low representation of minority women in the 7 studies, results may not be generalizable to women of other ethnic/racial groups. Next, the intervention components varied across all the studies with some women receiving more counseling interventions than others. Additionally, we measured alcohol consumption using self-report data, and the review only included one study using depot (injectable) naltrexone (Garbutt et al., 2005). Most notably, the review lacked studies with common intervention strategies or outcome measures to justify doing a statistical summary of effect using meta-analysis techniques as done in other reviews.

In Chapter 3, the characterizations of reasons for enrolling in the WHAT-IF clinical trial for a reduction in hazardous drinking, discussion of the clinical experience, and the specific aspects of the clinical trial associated with a reduction in hazardous drinking were the women with HIV narrative accounts of being enrolled in to the clinical
Therefore, due to the self-reported nature of the information provided in the qualitative interviews, there is no way to determine if the information is accurate. Furthermore, participants in this qualitative study were women who previously completed the WHAT-IF study, recruited by the research coordinator using convenience sampling. While all the women were HIV positive and provided documentation for their HIV infection, self-report data determined hazardous drinking status. Because of this, we are unable to determine if the information is completely accurate. Moreover, the time frame that the participant’s completed the clinical trial and when the individual interviews occurred varied significantly. Some participants completed the qualitative interviews with a few months of completing the trial, whereas others had completed the WHAT-IF study two years prior. Due to potential recall bias, the findings of this study are the participants’ narrative accounts of their reasons, experiences, and overall changes in hazardous drinking level as a result of participating in the WHAT-IF study.

In chapter 4, all the participants that enrolled in the WHAT-IF study were women with HIV infection, who self-identified as hazardous drinkers. Moreover, most of the women were African-American, randomized to receive either naltrexone or placebo medication. While 42% of women living with HIV are African Americans and women have become the fastest growing population of alcohol user, at this time we are unable to determine the extent to which these findings are generalizable to other groups. Specifically, a larger percentage of people diagnosed with an alcohol use disorder do not seek treatment for various reasons, therefore the results of this study are not applicable to non-treatment-seeking populations. Additionally, the study’s exclusion criteria reduced the heterogeneity of drug use and other concurrent conditions.
Furthermore, participants enrolled in the clinical trial received medical management (MM) and combine behavioral interventions (CBI), which are be practical in real-world settings. As noted, the Brief IPI has limitations, the primary being is that the structured interview relies on self-reported information from the participant and may be subjected to recall bias and information bias. As reported in the study results, we excluded participants \( n = 31 \) from study analysis due to the missing demographic and IPI data. Another limitation of the questionnaire is the administration time, which could variable considerably depending on a number of factors (e.g., number of important people listed by the participant, differences in the administration of the tool to the participant by the research staff member).

**Recommendations for Future Research**

As noted in the limitations of this dissertation research, there are several areas based upon the findings of this study that future research can build upon. Initially, future research should seek to incorporate the biopsychosocial model that postulates that substance abuse is the result of multifaceted interactions between biological, psychological, and social factors (Lindstrom, 1992). By adopting a holistic approach, the Biopsychosocial model can guide research seeking to examine relationship between factors associated with hazardous drinking and HIV outcomes in women. Specifically, future research should incorporate more sophisticated study designs that examine gender differences and treatment effectiveness among those diagnosed with an AUD and present data separately for men and women. For example, designing RCTs that seek to recruit a large sample of women and men and report the results separately for women alone or distinct from men. This may lead to developing better treatment options for women or the ability to identify the subset of women who might benefit most from
naltrexone. Though generalizability of findings is not a goal of qualitative research, recruiting a more diverse sample of participants could allow for the generalizability of the study findings to other populations of interest. Furthermore, a large sample would allow for the appropriate statically analyses needed in order to detect significant differences and provide evidence of treatment efficacy, acceptability, and tolerability in hazardous drinking women with HIV infection. Next, research should seek to design qualitative studies geared toward understanding clinical trial participation among a diverse sample of women with substance abuse issues while examining their attitudes toward clinical trial participation. As mentioned, there has been a widespread underrepresentation of women in clinical research, particularly in substance abuse research. In order to address this shortcoming, the success of future studies will need more planning, timelines and budget requirements (Yancey et al., 2006; Vidaver et al., 2000; Daunt, 2003). Furthermore, developing a rapport with the community and using community networks for advertisement can increase study participation particularly among African-Americans (Smith et al., 2007).

**Clinical and Policy Implications**

Health care providers play a critical role in delivering substance abuse treatment and understanding the complexities that surround treatment-seeking practices in women with an AUD needed. By exploring factors related to women’s relapse, Sun (2007) was able to identify practitioners can better understand the nature of women’s relapse and more effectively help them. In order to help health care providers understand relapse among women, four themes emerged: low self-worth and men, (2) interpersonal conflicts and/or negative emotion (anger, loss, depression, powerlessness, boredom), (3) less ability to sever the tie with the using network and to
establish a tie with the non-using network, (4) a lack of AUD-related knowledge (poor judgment on the nature of addiction) and relapse prevention coping skills (Sun, 2007). Limited research surrounding substance abuse among women exists, growing evidence and an increase in alcohol consumption by women supports the need for research examining problem drinking in women. Understanding the biopsychosocial factors that elucidates treatment efficacy, the reasons why women with problem drinking participates in clinical trials and their experiences, and the additional factors besides study medication that may contribute a reduction in alcohol consumption is essential to the development of interventions as well as informing of policy.

This dissertation project examined to evaluate the complex social phenomenon of hazardous drinking among women with HIV infection by investigating biopsychosocial factors associated with reducing hazardous drinking. By using a mixed methodological approach, we conducted three studies which allowed for the examination of treatment efficacy, clinical trial participation and clinical trial experience, as well as social networks influence on reducing hazardous drinking in women with HIV. The information ascertained in the dissertation may help develop interventions for HIV-infected women with hazardous drinking. There is a critical need to understand the reasons why many persons benefit from participating in randomized clinical trials, even those who receive the placebo intervention. Furthermore, future research should seek to better understand how social networks influence persons’ drinking behavior. Thus, this dissertation assisted in these goals along with the expanding the current knowledge base in this area.
APPENDIX A
PATIENT INFORMED CONSENT FORM (ICF)

INFORMED CONSENT FORM

to Participate in Research, and

AUTHORIZATION

to Collect, Use, and Disclose Protected
Health Information (PHI)

INTRODUCTION

Name of person seeking your consent: ____________________________________________

Place of employment & position: ________________________________________________

Please read this form which describes the study in some detail. A member of the research
team will describe this study to you and answer all of your questions. Your participation is
entirely voluntary. If you choose to participate you can change your mind at any time and
withdraw from the study. You will not be penalized in any way or lose any benefits to which
you would otherwise be entitled if you choose not to participate in this study or to with-
draw. If you have questions about your rights as a research subject, please call the University of
Florida Institutional Review Board (IRB) office at (352) 273-9600.

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

______________________________________________________________________________

2. What is the Title of this research study?

What about WHAT-IF: Qualitative assessment of drinking behaviors in women
diagnosed with HIV.
3. **Who do you call if you have questions about this research study?**

   Principal Investigator: Robert Cook, MD, MPH
   Other research staff:  Shantrel Canidate, MPH
   Christa Cook, MSN, RN, APHN-BC
   Giselle Carnaby, MPH, PhD, SLP/CCC
   Zhi Zhou, MPH

4. **Who is paying for this research study?**

   The sponsor of this study is The National Institute on Alcohol Abuse and Alcoholism. Grant #U01AA020797-04S1.

5. **Why is this research study being done?**

   The purpose of this research study is to identify the reasons that participants enroll in a clinical trial and the reasons that women are successful or unsuccessful in changing drinking behaviors as a part of a clinical trial research study.

   You are being asked to be in this research study because you have participated in the WHAT-IF clinical trial research study.

---

**WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?**

6. **What will be done as part of your normal clinical care (even if you did not participate in this research study)?**

   This is not a clinical study and no clinical care is provided. Your clinical care will be the same whether or not you choose to participate in this study.

7. **What will be done only because you are in this research study?**

   In this research, you will be asked to meet with one of the co-investigators, Shantrel Canidate, for a 1-2 hour interview. One of the investigators may also be at your interview to help take notes. The interview will take place in a private setting that is comfortable and convenient to you. During the interview, Ms. Canidate will ask you to provide information about participation in the WHAT-IF clinical trial and whether you had any change in your drinking. The interview will be audio-recorded and the audio recording will be stored on a password protected, encrypted computer at the University of Florida, College of Public Health and Health Professions. The recordings will be destroyed 6 years after the research has been completed. During the typing and validation process, any references to your personal health information or any other identifiers of persons and places will be removed. Any names mentioned during
the interviews will be transcribed as participant 1, participant 2, sibling of participant, etc.

You may also be contacted again, within a year after completing the interview, to see if you would be willing to participate in an additional one-hour interview to clarify any information from the original interview. You will have the option to accept or to decline the additional interview if it is offered.

If you have any questions now or at any time during the study, please contact, Robert Cook, MD, MPH, (386-273-5869) or one of the research team members listed in question 3 of this form or the IRB.

8. **How long will you be in this research study?**

You will spend approximately 1-2 hours for the interview. You do not have to answer any question that you do not feel comfortable answering. At some point in time, within the next year, one of our research team may contact you again for an additional 1-hour interview to clarify any information from the original interview.

9. **How many people are expected to take part in this research study?**

Up to forty (40) people are expected to take part in this study.

10. **What are the possible discomforts and risks from taking part in this research study?**

1) Risk of your private health information being revealed by accident.

2) Discomfort with interview process or questions asked.

Researchers will take appropriate steps to protect any information they collect about you. However, there is a very slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information, such a release could upset or embarrass you, or possibly affect your insurability or employability. Questions 17-21 in this form discuss what information about you will be collected, used, protected, and shared.

This study may include risks that are unknown at this time.

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or contact Robert Cook, MD, MPH, (386-273-5869) or one of the research team members listed in question 3 in this form.
11a. What are the potential benefits to you for taking part in this research study?

There are no direct benefits for participation in this research. However, participation may help some persons become more knowledgeable about issues related to HIV and changes in drinking.

11b. How could others possibly benefit from this study?

Participation in this research may help some persons become more knowledgeable about issues related to HIV and hazardous drinking. Knowledge gained from this study may help other women who have any problems with drinking.

11c. How could the researchers benefit from this study?

In general, presenting research results helps the career of a scientist. Therefore, the investigators listed in question 3 of this form may benefit if the results of this study are presented at scientific meetings or in scientific journals.

12. What other choices do you have if you do not want to be in this study?

The option to taking part in this study is doing nothing. If you do not want to take part in this study, just tell me and do not sign this Informed Consent Form.

13a. Can you withdraw from this study?

You are free to withdraw your consent and to stop participating in this study at any time. If you do withdraw your consent, you will not be penalized in any way and you will not lose any benefits to which you are entitled.

If you have any questions regarding your rights as a research subject, please call the Institutional Review Board (IRB) office at (352) 273-9600.

13b. If you withdraw, can information about you still be used and/or collected?

If you withdraw from this study, no more new information from you will be collected. However, any information obtained prior to your withdrawal will still be used.

13c. Can the Principal Investigator withdraw you from this study?

Yes, although this is extremely unlikely to happen. Very rarely, an interview does not go well and the participant is unable to answer the questions or the participant becomes distracted and can no longer participate. If for any reason you can’t complete the majority of the interview, we will withdraw you from the study and we will delete all of the recordings and other information about you.
14. If you choose to take part in this research study, will it cost you anything?

No, you do not have to pay anything to participate.

15. Will you be paid for taking part in this study?

You will receive a $25 VISA gift card at the completion of the first interview. The card will need to be activated and will be ready to use within 48 hours of completing the interview. If you are contacted for a second interview, and complete a second interview, you will receive an additional $25 gift card (or gift as described above) at that time.

Your payment for participation in this research study is handled through the University of Florida’s Human Subject Payment (HSP) Program. Access to the (HSP) Program site is limited to certain staff with the assigned security role. You will be randomly assigned a specific identification (ID) number to protect your identity.

If you are unable to access the money from the gift card within 48 hours, please contact Clery Quiros, the WHAT-IF project coordinator, and she will contact the study team to find out how to fix the gift card so that it works. Note that the gift card should be used within 6 months or it will start to lose money.

16. What if you are injured because of the study?

If emergency care is needed, area rescue services will be contacted. Assistance making referrals will be made if any other care is needed as a result of injury from the study.

Hospital expenses will be billed to you or your insurance provider. You will be responsible for any deductible, co-insurance, or co-payments. Some insurance companies may not cover costs associated with research studies. Please contact your insurance company for additional information.

No additional compensation is offered. The Principal Investigator and others involved in this study may be University of Florida employees. As employees of the University, they are protected under state law, which limits financial recovery for negligence.
Please contact one of the research team members listed in question 3 of this form, Robert Cook (352-273-5869) if you experience an injury or have questions about any discomforts that you experience while participating in this study.

17. How will your health information be collected, used and shared?

If you agree to participate in this study, the Principal Investigator will create, collect, and use private information about you and your health. This information is called protected health information or PHI. In order to do this, the Principal Investigator needs your authorization. The following section describes what PHI will be collected, used and shared, how it will be collected, used, and shared, who will collect, use or share it, who will have access to it, how it will be secured, and what your rights are to revoke this authorization.

Your protected health information may be collected, used, and shared with others to determine if you can participate in the study, and then as part of your participation in the study. This information can be gathered from you or your past, current or future health records, from procedures such as physical examinations, x-rays, blood or urine tests or from other procedures or tests. This information will be created by receiving study treatments or participating in study procedures, or from your study visits and telephone calls. More specifically, the following information may be collected, used, and shared with others:

- The health information we have about you is information you give during the interview; information provided from the clinical trial that you already completed. Our research team will not keep any identifying information about you such as your name or phone number. However, we will have your voice recording from the interview, and that could include some confidential information about your health. After the interview is completed today, we will securely transfer the recording from the voice recorder onto a private and secure file location managed by the University of Florida. The original recording will remain here in Miami, in a locked cabinet with your consent form. Then, we will use another secure transfer to send the file to a professional transcriptionist company called Alpha Translation Services based in Melbourne, Florida. This company has completed training in privacy of data and has signed a formal agreement to keep all information confidential. The transcriptionist will be transcribing the interview onto paper by writing down the words and answers you provide in the interview. During this time, the transcriptionist will remove any information that could directly identify you or any other specific person. Therefore, anyone who reads the written interview will not be able to identify you.
We will keep a study ID number that is attached to this interview. Later, we will use the study ID number to join the words from your interview with information that you provided as part of the WHAT-IF clinical trial. The only information we will use from the clinical trial includes characteristics about you, such as your age and race, and information about your alcohol consumption that you provided when you were a participant in that trial.

This information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices.

Some of the information collected could be included in a "limited data set" to be used for other research purposes. If so, the limited data set will only include information that does not directly identify you. For example, the limited data set cannot include your name, address, telephone number, social security number, photographs, or other codes that link you to the information in the limited data set. If limited data sets are created and used, agreements between the parties creating and receiving the limited data set are required in order to protect your identity and confidentiality and privacy.

18. For what study-related purposes will your protected health information be collected, used, and shared with others?

Your PHI may be collected, used, and shared with others to make sure you can participate in the research, through your participation in the research, and to evaluate the results of the research study. More specifically, your PHI may be collected, used, and shared with others for the following study-related purpose(s):

1) To analyze the information from the interviews and from the main clinical trial.

Once this information is collected, it becomes part of the research record for this study.

19. Who will be allowed to collect, use, and share your protected health information?

Only certain people have the legal right to collect, use and share your research records, and they will protect the privacy and security of these records to the extent the law allows. These people include:

- The co-investigator, Ms. Canidate, and research staff associated with this project.
- The University of Florida Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research).
20. Once collected or used, who may your protected health information be shared with?

Your PHI may be shared with:

- The study sponsor (listed in Question 4 of this form).
- United States and foreign governmental agencies who are responsible for overseeing research, such as the Food and Drug Administration, the Department of Health and Human Services, and the Office of Human Research Protections.
- Government agencies who are responsible for overseeing public health concerns such as the Centers for Disease Control and federal, state and local health departments.

Otherwise, your research records will not be released without your permission unless required by law or a court order. It is possible that once this information is shared with authorized persons, it could be shared by the persons or agencies who receive it and it would no longer be protected by the federal medical privacy law.

21. If you agree to take part in this research study, how long will your protected health information be used and shared with others?

Your PHI could be used and shared with others until the end of the study.

You are not required to sign this consent and authorization or allow researchers to collect, use and share your PHI. Your refusal to sign will not affect your treatment, payment, enrollment, or eligibility for any benefits outside this research study. However, you cannot participate in this research unless you allow the collection, use and sharing of your protected health information by signing this consent and authorization.

You have the right to review and copy your protected health information. However, we can make this available only after the study is finished.

You can revoke your authorization at any time before, during, or after your participation in this study. If you revoke it, no new information will be collected about you. However, information that was already collected may still be used and shared with others if the researchers have relied on it to complete the research. You can revoke your authorization by giving a written request with your signature on it to the Principal Investigator.
As an investigator or the investigator’s representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this research study; the alternative to being in the study; and how the participant’s protected health information will be collected, used, and shared with others:

Signature of Person Obtaining Consent and Authorization

Date

You have been informed about this study’s purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared with others. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask questions at any time.

You voluntarily agree to participate in this study. You hereby authorize the collection, use and sharing of your protected health information as described in sections 17-21 above. By signing this form, you are not waiving any of your legal rights.

Signature of Person Consenting and Authorizing

Date
Consent to be Photographed, Video and/or Audio Recorded

With your permission, you will have the following done during this research (check all that apply):

☐ photographed   ☐ video recorded   ☑ audio recorded

Your name or personal information will not be identified on the photograph(s), video or audio recordings, and confidentiality will be strictly maintained. However, when these photograph(s), video and/or audio recordings are shown or heard, others may be able to identify you.

The Principal Investigator (PI) of this study, Robert Cook, or his successor, will keep audio recordings in a locked cabinet, in a folder on a password protected computer server drive, or as an encrypted electronic file. These audio recordings will be shown under her direction to her faculty mentor and Co-Investigator, Dr. Robert Cook and research staff.

Please indicate under what conditions Ms. Canidate has your permission to use the photograph(s), video and/or audio recordings, and sign and date below.

☐ The following will be destroyed 6 years after study closes. (initial next to all that apply):

   _____ photograph(s)       _____ video recording(s)       _____ audio recording(s)

☐ As described in the Informed Consent Form, and for the purposes of education at the University of Florida Health Science Center. The PI may keep the following for an indefinite period of time in a locked file, in a password protected computer server drive, or as an encrypted electronic file (initial next to all that apply):

   _____ photograph(s)       _____ video recording(s)       _____ audio recording(s)

☐ As described in the Informed Consent Form; for the purposes of education at the University of Florida Health Science Center; and for presentations at scientific meetings outside the University. The PI may keep the following for an indefinite period of time in a locked file, in a password protected computer server drive, or as an encrypted electronic file (initial next to all that apply):

   _____ photograph(s)       _____ video recording(s)       _____ audio recording(s)

_________________________________________   ____________________________
Signature                                               Date
APPENDIX B
IMPORTANT PEOPLE INVENTORY (IPI) ASSESSMENT

Confidential

Brief Important Person

**Data entry and file uploads to be completed by Gainesville staff**
For missing lab values, leave the field blank; for values that are below detection, enter ‘0’.

Patient ID

Staff initial

Date (YYYY-MM-DD)

Read: “Hi, my name is ________, and now I’d like to ask you a few questions about the people that have been important to you and with whom you’ve had contact (face to face or by phone) during the past six months. These people may be family members, friends, people from work, or anyone that you see as having had a significant impact on your life, whether or not you liked them. Should you have any questions during the interview please don’t hesitate to ask. Now before we begin, do you have any questions?”

Before we begin, are there any close people important to you?

☐ Yes  ☐ No

1. 1st Person (first name and last initial)

2. Relationship

☐ 1 = Partner
☐ 2 = Immediate Family
☐ 3 = Extended Family
☐ 4 = Friend
☐ 5 = From Work
☐ 6 = Self-Help/Treatment
☐ 7 = Other

3. Specify the Relationship

4. During the past 6 months on average, how frequently have you been in contact with this person?

☐ 7 = Daily (7 Times a Week)
☐ 6 = Three to 6 Times a Week
☐ 5 = Once or Twice a Week
☐ 4 = Every Other Week
☐ 3 = About Once a Month
☐ 2 = Less Than Monthly
☐ 1 = Once in Past 6 Months

5. What is this person’s drinking status?

☐ 5 = Heavy Drinker
☐ 4 = Moderate Drinker
☐ 3 = Light Drinker
☐ 2 = Abstainer
☐ 1 = Recovering Alcoholic
☐ 8 = Don’t Know
6. How often does this person drink alcohol?
   - 7 = Daily (7 Times a Week)
   - 6 = Three to 6 Times a Week
   - 5 = Once or Twice a Week
   - 4 = Every Other Week
   - 3 = About Once a Month
   - 2 = Less Than Monthly
   - 1 = Once in Past 6 Months
   - 0 = Not in Past 6 Months
   - 8 = Don't Know

7. How has this person (or how would this person) react to your drinking?
   - 5 = Encouraged
   - 4 = Accepted
   - 3 = Neutral
   - 2 = Didn't Accept
   - 1 = Left, or made you leave when you're drinking
   - 0 = Don't know

8. Are there any other people you would like to add?
   - Yes
   - No: We are ready to collect more details

1. 2nd Person (first name and last initial)

2. Relationship
   - 1 = Partner
   - 2 = Immediate Family
   - 3 = Extended Family
   - 4 = Friend
   - 5 = From Work
   - 6 = Self-Help/Treatment
   - 7 = Other

3. Specify the Relationship

4. During the past 6 months on average, how frequently have you been in contact with this person?
   - 7 = Daily (7 Times a Week)
   - 6 = Three to 6 Times a Week
   - 5 = Once or Twice a Week
   - 4 = Every Other Week
   - 3 = About Once a Month
   - 2 = Less Than Monthly
   - 1 = Once in Past 6 Months

5. What is this person's drinking status?
   - 5 = Heavy Drinker
   - 4 = Moderate Drinker
   - 3 = Light Drinker
   - 2 = Abstainer
   - 1 = Recovering Alcoholic
   - 0 = Not in Past 6 Months
   - 8 = Don't Know

6. How often does this person drink alcohol?
   - 7 = Daily (7 Times a Week)
   - 6 = Three to 6 Times a Week
   - 5 = Once or Twice a Week
   - 4 = Every Other Week
   - 3 = About Once a Month
   - 2 = Less Than Monthly
   - 1 = Once in Past 6 Months
   - 0 = Not in Past 6 Months
   - 8 = Don't Know

7. How has this person (or how would this person) react to your drinking?
   - 5 = Encouraged
   - 4 = Accepted
   - 3 = Neutral
   - 2 = Didn't Accept
   - 1 = Left, or made you leave when you're drinking
   - 0 = Don't know
8. Are there any other people you would like to add?  
☐ Yes
☐ No: We are ready to collect more details

1. 3rd Person (first name and last initial)

2. Relationship

☐ 1 = Partner
☐ 2 = Immediate Family
☐ 3 = Extended Family
☐ 4 = Friend
☐ 5 = From Work
☐ 6 = Self-Help/Treatment
☐ 7 = Other

3. Specify the Relationship

4. During the past 6 months on average, how frequently have you been in contact with this person?

☐ 1 = Once in Past 6 Months
☐ 2 = Less Than Monthly
☐ 3 = About Once a Month
☐ 4 = Every Other Week
☐ 5 = Once or Twice a Week
☐ 6 = Three to 6 Times a Week
☐ 7 = Daily (7 Times a Week)

5. What is this person's drinking status?

☐ 1 = Recovering Alcoholic
☐ 2 = Abstainer
☐ 3 = Light Drinker
☐ 4 = Moderate Drinker
☐ 5 = Heavy Drinker
☐ 6 = Don't Know

6. How often does this person drink alcohol?

☐ 1 = Not in Past 6 Months
☐ 2 = Less Than Monthly
☐ 3 = About Once a Month
☐ 4 = Every Other Week
☐ 5 = Once or Twice a Week
☐ 6 = Three to 6 Times a Week
☐ 7 = Daily (7 Times a Week)

7. How has this person (or how would this person) react to your drinking?

☐ 1 = Left, or made you leave when you're drinking
☐ 2 = Didn’t Accept
☐ 3 = Neutral
☐ 4 = Accepted
☐ 5 = Encouraged
☐ 6 = Don’t Know

8. Are there any other people you would like to add?

☐ Yes
☐ No: We are ready to collect more details

1. 4th Person (first name and last initial)

2. Relationship

☐ 1 = Partner
☐ 2 = Immediate Family
☐ 3 = Extended Family
☐ 4 = Friend
☐ 5 = From Work
☐ 6 = Self-Help/Treatment
☐ 7 = Other

3. Specify the Relationship
4. During the past 6 months on average, how frequently have you been in contact with this person?
   - 7 = Daily (7 Times a Week)
   - 6 = Three to 6 Times a Week
   - 5 = Once or Twice a Week
   - 4 = Every Other Week
   - 3 = About Once a Month
   - 2 = Less Than Monthly
   - 1 = Once in Past 6 Months

5. What is this person's drinking status?
   - 5 = Heavy Drinker
   - 4 = Moderate Drinker
   - 3 = Light Drinker
   - 2 = Abstainer
   - 1 = Recovering Alcoholic
   - 0 = Not in Past 6 Months
   - 8 = Don't Know

6. How often does this person drink alcohol?
   - 7 = Daily (7 Times a Week)
   - 6 = Three to 6 Times a Week
   - 5 = Once or Twice a Week
   - 4 = Every Other Week
   - 3 = About Once a Month
   - 2 = Less Than Monthly
   - 1 = Once in Past 6 Months
   - 0 = Not in Past 6 Months
   - 8 = Don't Know

7. How has this person (or how would this person) react to your drinking?
   - 5 = Encouraged
   - 4 = Accepted
   - 3 = Neutral
   - 2 = Didn't Accept
   - 1 = Left, or made you leave when you're drinking
   - 0 = Not in Past 6 Months
   - 8 = Don't Know

8. Are there any other people you would like to add?
   - Yes
   - No: We are ready to collect more details

1. 5th Person (first name and last Initial)

2. Relationship
   - 1 = Partner
   - 2 = Immediate Family
   - 3 = Extended Family
   - 4 = Friend
   - 5 = From Work
   - 6 = Self-Help/Treatment
   - 7 = Other

3. Specify the Relationship

4. During the past 6 months on average, how frequently have you been in contact with this person?
   - 7 = Daily (7 Times a Week)
   - 6 = Three to 6 Times a Week
   - 5 = Once or Twice a Week
   - 4 = Every Other Week
   - 3 = About Once a Month
   - 2 = Less Than Monthly
   - 1 = Once in Past 6 Months

5. What is this person's drinking status?
   - 5 = Heavy Drinker
   - 4 = Moderate Drinker
   - 3 = Light Drinker
   - 2 = Abstainer
   - 1 = Recovering Alcoholic
   - 0 = Not in Past 6 Months
   - 8 = Don't Know
6. How often does this person drink alcohol?

○ 7 = Daily (7 Times a Week)
○ 6 = Three to 6 Times a Week
○ 5 = Once or Twice a Week
○ 4 = Every Other Week
○ 3 = About Once a Month
○ 2 = Less Than Monthly
○ 1 = Once in Past 6 Months
○ 0 = Not in Past 6 Months
○ 8 = Don't Know

7. How has this person (or how would this person) react to your drinking?

○ 5 = Encouraged
○ 4 = Accepted
○ 3 = Neutral
○ 2 = Didn't Accept
○ 1 = Left, or made you leave when you're drinking
○ Don't know

8. Are there any other people you would like to add?

○ Yes
○ No: We are ready to collect more details

1. 6th Person (first name and last initial)

2. Relationship

○ 1 = Partner
○ 2 = Immediate Family
○ 3 = Extended Family
○ 4 = Friend
○ 5 = From Work
○ 6 = Self-Help/Treatment
○ 7 = Other

3. Specify the Relationship

4. During the past 6 months on average, how frequently have you been in contact with this person?

○ 7 = Daily (7 Times a Week)
○ 6 = Three to 6 Times a Week
○ 5 = Once or Twice a Week
○ 4 = Every Other Week
○ 3 = About Once a Month
○ 2 = Less Than Monthly
○ 1 = Once in Past 6 Months

5. What is this person’s drinking status?

○ 5 = Heavy Drinker
○ 4 = Moderate Drinker
○ 3 = Light Drinker
○ 2 = Abstainer
○ 1 = Recovering Alcoholic
○ 8 = Don't Know

6. How often does this person drink alcohol?

○ 7 = Daily (7 Times a Week)
○ 6 = Three to 6 Times a Week
○ 5 = Once or Twice a Week
○ 4 = Every Other Week
○ 3 = About Once a Month
○ 2 = Less Than Monthly
○ 1 = Once in Past 6 Months
○ 0 = Not in Past 6 Months
○ 8 = Don’t Know

7. How has this person (or how would this person) react to your drinking?

○ 5 = Encouraged
○ 4 = Accepted
○ 3 = Neutral
○ 2 = Didn’t Accept
○ 1 = Left, or made you leave when you're drinking
○ Don’t know
8. Are there any other people you would like to add?  
○ Yes  
○ No: We are ready to collect more details

1. 7th Person (first name and last initial)

2. Relationship
○ 1 = Partner  
○ 2 = Immediate Family  
○ 3 = Extended Family  
○ 4 = Friend  
○ 5 = From Work  
○ 6 = Self-Help/Treatment  
○ 7 = Other

3. Specify the Relationship

4. During the past 6 months on average, how frequently have you been in contact with this person?
○ 7 = Daily (7 Times a Week)  
○ 6 = Three to 6 Times a Week  
○ 5 = Once or Twice a Week  
○ 4 = Every Other Week  
○ 3 = About Once a Month  
○ 2 = Less Than Monthly  
○ 1 = Once in Past 6 Months

5. What is this person’s drinking status?
○ 5 = Heavy Drinker  
○ 4 = Moderate Drinker  
○ 3 = Light Drinker  
○ 2 = Abstainer  
○ 1 = Recovering Alcoholic  
○ 8 = Don’t Know

6. How often does this person drink alcohol?
○ 7 = Daily (7 Times a Week)  
○ 6 = Three to 6 Times a Week  
○ 5 = Once or Twice a Week  
○ 4 = Every Other Week  
○ 3 = About Once a Month  
○ 2 = Less Than Monthly  
○ 1 = Once in Past 6 Months  
○ 0 = Not in Past 6 Months  
○ 8 = Don’t Know

7. How has this person (or how would this person) react to your drinking?
○ 5 = Encouraged  
○ 4 = Accepted  
○ 3 = Neutral  
○ 2 = Didn’t Accept  
○ 1 = Left, or made you leave when you’re drinking  
○ 8 = Don’t know

8. Are there any other people you would like to add?  
○ Yes  
○ No: We are ready to collect more details

1. 8th Person (first name and last initial)

2. Relationship
○ 1 = Partner  
○ 2 = Immediate Family  
○ 3 = Extended Family  
○ 4 = Friend  
○ 5 = From Work  
○ 6 = Self-Help/Treatment  
○ 7 = Other

3. Specify the Relationship
4. During the past 6 months on average, how frequently have you been in contact with this person?
   - 7 = Daily (7 Times a Week)
   - 6 = Three to 6 Times a Week
   - 5 = Once or Twice a Week
   - 4 = Every Other Week
   - 3 = About Once a Month
   - 2 = Less Than Monthly
   - 1 = Once in Past 6 Months

5. What is this person's drinking status?
   - 5 = Heavy Drinker
   - 4 = Moderate Drinker
   - 3 = Light Drinker
   - 2 = Abstainer
   - 1 = Recovering Alcoholic
   - 8 = Don't Know

6. How often does this person drink alcohol?
   - 7 = Daily (7 Times a Week)
   - 6 = Three to 6 Times a Week
   - 5 = Once or Twice a Week
   - 4 = Every Other Week
   - 3 = About Once a Month
   - 2 = Less Than Monthly
   - 1 = Once in Past 6 Months
   - 8 = Don't Know

7. How has this person (or how would this person) react to your drinking?
   - 5 = Encouraged
   - 4 = Accepted
   - 3 = Neutral
   - 2 = Didn't Accept
   - 1 = Left, or made you leave when you're drinking
   - 8 = Don't know

8. Are there any other people you would like to add?
   - Yes
   - No: We are ready to collect more details

1. 9th Person (first name and last initial)

2. Relationship
   - 1 = Partner
   - 2 = Immediate Family
   - 3 = Extended Family
   - 4 = Friend
   - 5 = From Work
   - 6 = Self-Help/Treatment
   - 7 = Other

3. Specify the Relationship

4. During the past 6 months on average, how frequently have you been in contact with this person?
   - 7 = Daily (7 Times a Week)
   - 6 = Three to 6 Times a Week
   - 5 = Once or Twice a Week
   - 4 = Every Other Week
   - 3 = About Once a Month
   - 2 = Less Than Monthly
   - 1 = Once in Past 6 Months

5. What is this person's drinking status?
   - 5 = Heavy Drinker
   - 4 = Moderate Drinker
   - 3 = Light Drinker
   - 2 = Abstainer
   - 1 = Recovering Alcoholic
   - 8 = Don't Know
6. How often does this person drink alcohol?
   - 7 = Daily (7 Times a Week)
   - 6 = Three to 6 Times a Week
   - 5 = Once or Twice a Week
   - 4 = Every Other Week
   - 3 = About Once a Month
   - 2 = Less Than Monthly
   - 1 = Once in Past 6 Months
   - 0 = Not in Past 6 Months
   - 8 = Don't Know

7. How has this person (or how would this person) react to your drinking?
   - 5 = Encouraged
   - 4 = Accepted
   - 3 = Neutral
   - 2 Didn't Accept
   - 1 = Left, or made you leave when you're drinking
   - 0 = Don't know

8. Are there any other people you would like to add?
   - Yes
   - No: We are ready to collect more details

1. 10th Person (first name and last initial)

2. Relationship
   - 1 = Partner
   - 2 = Immediate Family
   - 3 = Extended Family
   - 4 = Friend
   - 5 = From Work
   - 6 = Self-Help/Treatment
   - 7 = Other

3. Specify the Relationship

4. During the past 6 months on average, how frequently have you been in contact with this person?
   - 7 = Daily (7 Times a Week)
   - 6 = Three to 6 Times a Week
   - 5 = Once or Twice a Week
   - 4 = Every Other Week
   - 3 = About Once a Month
   - 2 = Less Than Monthly
   - 1 = Once in Past 6 Months

5. What is this person's drinking status?
   - 5 = Heavy Drinker
   - 4 = Moderate Drinker
   - 3 = Light Drinker
   - 2 = Abstainer
   - 1 = Recovering Alcoholic
   - 0 = Don't Know

6. How often does this person drink alcohol?
   - 7 = Daily (7 Times a Week)
   - 6 = Three to 6 Times a Week
   - 5 = Once or Twice a Week
   - 4 = Every Other Week
   - 3 = About Once a Month
   - 2 = Less Than Monthly
   - 1 = Once in Past 6 Months
   - 0 = Not in Past 6 Months
   - 8 = Don't Know

7. How has this person (or how would this person) react to your drinking?
   - 5 = Encouraged
   - 4 = Accepted
   - 3 = Neutral
   - 2 Didn't Accept
   - 1 = Left, or made you leave when you're drinking
   - 0 = Don't know
8. Are there any other people you would like to add?  
   ○ Yes  
   ○ No: We are ready to collect more details

1. 11th Person (first name and last initial)

2. Relationship
   ○ 1 = Partner  
   ○ 2 = Immediate Family  
   ○ 3 = Extended Family  
   ○ 4 = Friend  
   ○ 5 = From Work  
   ○ 6 = Self-Help/Treatment  
   ○ 7 = Other

3. Specify the Relationship

4. During the past 6 months on average, how frequently have you been in contact with this person?  
   ○ 7 = Daily (7 Times a Week)  
   ○ 6 = Three to 6 Times a Week  
   ○ 5 = Once or Twice a Week  
   ○ 4 = Every Other Week  
   ○ 3 = About Once a Month  
   ○ 2 = Less Than Monthly  
   ○ 1 = Once in Past 6 Months

5. What is this person's drinking status?  
   ○ 5 = Heavy Drinker  
   ○ 4 = Moderate Drinker  
   ○ 3 = Light Drinker  
   ○ 2 = Abstainer  
   ○ 1 = Recovering Alcoholic  
   ○ 8 = Don't Know

6. How often does this person drink alcohol?  
   ○ 7 = Daily (7 Times a Week)  
   ○ 6 = Three to 6 Times a Week  
   ○ 5 = Once or Twice a Week  
   ○ 4 = Every Other Week  
   ○ 3 = About Once a Month  
   ○ 2 = Less Than Monthly  
   ○ 1 = Once in Past 6 Months  
   ○ 0 = Not in Past 6 Months  
   ○ 8 = Don't Know

7. How has this person (or how would this person) react to your drinking?  
   ○ 5 = Encouraged  
   ○ 4 = Accepted  
   ○ 3 = Neutral  
   ○ 2 = Didn't Accept  
   ○ 1 = Left, or made you leave when you're drinking  
   ○ 8 = Don't know

8. Are there any other people you would like to add?  
   ○ Yes  
   ○ No: We are ready to collect more details

1. 12th Person (first name and last initial)

2. Relationship
   ○ 1 = Partner  
   ○ 2 = Immediate Family  
   ○ 3 = Extended Family  
   ○ 4 = Friend  
   ○ 5 = From Work  
   ○ 6 = Self-Help/Treatment  
   ○ 7 = Other

3. Specify the Relationship
4. During the past 6 months on average, how frequently have you been in contact with this person?

- 7 = Daily (7 Times a Week)
- 6 = Three to 6 Times a Week
- 5 = Once or Twice a Week
- 4 = Every Other Week
- 3 = About Once a Month
- 2 = Less Than Monthly
- 1 = Once in Past 6 Months

5. What is this person's drinking status?

- 5 = Heavy Drinker
- 4 = Moderate Drinker
- 3 = Light Drinker
- 2 = Abstainer
- 1 = Recovering Alcoholic
- 0 = Don't Know

6. How often does this person drink alcohol?

- 7 = Daily (7 Times a Week)
- 6 = Three to 6 Times a Week
- 5 = Once or Twice a Week
- 4 = Every Other Week
- 3 = About Once a Month
- 2 = Less Than Monthly
- 1 = Once in Past 6 Months
- 0 = Not in Past 6 Months
- 8 = Don't Know

7. How has this person (or how would this person) react to your drinking?

- 5 = Encouraged
- 4 = Accepted
- 3 = Neutral
- 2 Didn't Accept
- 1 = Left, or made you leave when you're drinking
- 0 = Don't know
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BIOGRAPHICAL SKETCH

Shantrel S. Canidate was born in Daytona Beach, FL to the parents of Willie C. Perry, Jr. and Pamela R. Canidate. Shantrel received a Bachelor of Science in health services administration from the University of Central Florida in 2010. Following the completion of her BS, she continued on to receive a Master of Public Health (MPH) in social and behavioral science (SBS) from the University of Florida (2012). During her master’s, Shantrel gave a presentation on Female Genital Mutilation to not only colleagues but to the Minister of Health from the Republic of Honduras and his high-ranking officials. At the completion of her presentation, she received a standing ovation. After graduating with her master’s degree, Shantrel worked at the Alachua County Health Department in Gainesville, FL where she served as the HIV Outreach Coordinator. In this position, where she was responsible for supervising over 50 volunteers, and she has helped to coordinate community events, such as the annual MLK day event that was a partnership with the Gainesville Police Dept. Shantrel is also 500/501 Certified to offer HIV testing and counseling services.

Under the supervision of Dr. Giselle Carnaby, Shantrel earned a Doctorate of Philosophy in public health with a concentration in social and behavioral sciences from the College of Public Health and Health Professions at the University of Florida. During her doctoral career, Shantrel was involved in service to the community, including participating in HIV testing and counseling services in the community, volunteering as part of my research team’s booth at the annual Gainesville Pride Festival, and mentoring students of all ages. During Shantrel’s second year in the doctoral program and under the mentorship of Drs. Cook and Carnaby, she was able to apply for and receive a NIH/NIAAA diversity supplement. This supplement guided her dissertation.
research by assisting in the translation of study results from the RCT by using the biopsychosocial model to examine biopsychosocial factors associated with reducing hazardous drinking in women with HIV. Furthermore, Shantrel has been accepted to three distinguished graduate honor societies during her doctoral career, one of which she is of the first cohort of minority students to be inducted at the University of Florida chapter. After graduation, Shantrel will be seeking a post-doctoral position that will allow her to implement culturally relevant and acceptable alcohol interventions in prevention and care at the individual and provider level that reduce the burden of substance use and HIV infection in men who have sex with men (MSM).