

3-25-2015

The Influence of Psychological Predictors and Cognitive Behavioral Stress Management Intervention on Antiretroviral Therapy (ART) Adherence Among HIV-Positive Female Haitian Alcohol Users

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DOI: 10.25148/etd.FI15032139

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FLORIDA INTERNATIONAL UNIVERSITY

Miami, Florida

THE INFLUENCE OF PSYCHOLOGICAL PREDICTORS AND COGNITIVE
BEHAVIORAL STRESS MANAGEMENT INTERVENTION ON
ANTIRETROVIRAL THERAPY (ART) ADHERENCE AMONG HIV-POSITIVE
FEMALE HAITIAN ALCOHOL USERS

A dissertation submitted in partial fulfillment of

the requirements for the degree of

DOCTOR OF PHILOSOPHY

in

PUBLIC HEALTH

by

Pascale Cecile Jean

2015

To: Interim Dean Mark Williams
Robert Stempel College of Public Health and Social Work

This dissertation, written by Pascale Cecile Jean, and entitled The Influence of Psychological Predictors and Cognitive Behavioral Stress Management Intervention on Antiretroviral Therapy (ART) Adherence Among HIV-Positive Female Haitian Alcohol Users, having been approved in respect to style and intellectual content, is referred to you for judgment.

We have read this dissertation and recommend that it be approved.

Consuelo Beck-Sague

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Jessy G. Dévieux, Major Professor

Date of Defense: March 25, 2015

The dissertation of Pascale Cecile Jean is approved.

Interim Dean Mark Williams, PhD
Robert Stempel College of Public Health and Social Work

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Florida International University, 2015

DEDICATION

This dissertation is dedicated to my parents Lionel and Maud Jean for all the sacrifices that they made so that my siblings and I could have all the opportunities in order to live a fulfilled life. This is also dedicated to my grandparents for teaching me about the role of family and about faith. Most importantly, this is dedicated to Haiti and the people of Haiti, for teaching me about perseverance and how to overcome adversities. I hope that with this PhD, I am able to make a difference for the people of Haiti and similar communities.

ACKNOWLEDGMENTS

First, I would like to thank my dissertation committee members, Dr. Jessy Dévieux, Dr. Virginia McCoy, Dr. Consuelo Beck-Sague and Dr. Hafiz Khan, for their time and guidance throughout the years and dissertation process. A special thank you to Dr. Michèle Jean-Gilles and Charlene Brown for providing me with a great deal of support and advice during this process. Thank you to all my professors, both in Dietetics and Nutrition and in Public Health, as well as the staff and fellow students at FIU who I have had the pleasure of meeting.

A million thanks to my family and support system. Manmie, Papi, Christine and Junior; no words could express my gratitude for the significant role that you play in my life; thank you for loving me and supporting me. Thank you to my wonderful niece and nephew, Leah and Karim for giving me pure joy; being your Tatie Pas is my greatest accomplishment. A special thank you to Myriam Duret, Gracie Gomez, Courtney Rivas, Stephanie Wade and Cetremia Roberts, for the calls, texts, encouraging quotes, emails and prayers which help me survived the dissertation writing process. Finally, I would like to thank Tania Rivera and Marie Sandra Severe for their friendship and unconditional support through the final stages of this dissertation process.

ABSTRACT OF THE DISSERTATION
THE INFLUENCE OF PSYCHOLOGICAL PREDICTORS AND COGNITIVE
BEHAVIORAL STRESS MANAGEMENT INTERVENTION ON
ANTIRETROVIRAL THERAPY (ART) ADHERENCE AMONG HIV-POSITIVE
FEMALE HAITIAN ALCOHOL USERS

by

Pascale Cecile Jean

Florida International University, 2015

Miami, Florida

Professor Jessy G. Dévieux, Major Professor

Purpose: Over half the HIV-infected persons in the Caribbean, the second most HIV-impacted region in the world, live in Haiti. Using secondary data from a parent study, this research assessed the effects of psychological and social factors on antiretroviral therapy (ART) adherence among Haitian, HIV-positive, female alcohol users.

Theoretical Foundation and Research Questions: Using the Theory of Planned Behavior/Reasoned Action and the Information, Motivation, Behavior skills model as guiding theoretical frameworks, the study examined the effectiveness of an adapted cognitive behavioral stress management (CBSM-A) intervention in improving ART adherence. The effect of psychological factors (depression, anxiety, beliefs about medicine, and social support), social factors (stigma, relationship status, and educational attainment), and alcohol on adherence to ART was assessed.

Methods: The sample consisted of 116 female ART patients who were randomly assigned to the CBSM-A intervention or the wait-list control group. Participants completed

intervention sessions as well as pre- and post-test assessments. Analyses of variance, t-tests, and point biserial correlations were used to test hypotheses.

Results: Surprisingly, ART adherence rates significantly decreased for both groups combined [$F(1, 108) = 8.79, p = .004$]; there was no significant difference between the intervention and control groups with regard to the magnitude of change between baseline and post assessment. On average, depression decreased significantly among participants in the CBSM-A group only [$t(62) = 5.54, p < .001$]. For both groups combined, alcohol use significantly decreased between baseline and post-assessment [$F(1, 78) = 34.70, p < .001$]; there was no significant difference between the intervention and control groups with regard to the magnitude of change between baseline and post-assessment. None of the variables were significantly correlated with ART adherence.

Discussion: Adherence to ART did not improve in this sample, nor were any of the variables significantly associated with adherence. The findings suggest that additional supportive and psychological services may be needed in order to promote higher adherence to ART among HIV-positive females. More research may be needed on this sample; a focus on mental health issues, partner conflict, family and sexual history may allow for better targeting and more successful interventions.

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CHAPTER I

INTRODUCTION

Haiti shares the island of Hispaniola with the Dominican Republic. Haiti is the third largest Caribbean nation, after Cuba and the Dominican Republic; it is known for being the first independent nation in the Americas, the only republic born of a successful slave revolt, and the first black-led republic in the world since 1804 (CIA World Fact Book, 2013; World Book Encyclopedia, 1996). Haiti is the poorest country in the Western Hemisphere and among the poorest in the world. Haiti ranks 161st of 187 countries in the Human Development Index (HDI) and has limited resources to meet its citizens' basic needs (UN Development Programme, 2013; World Bank- Haiti, 2014). Haiti is estimated to have a population of approximately 10 million inhabitants, just under a million of whom live in the capital city, Port-au-Prince; Haiti's large population coupled with its deficient infrastructure make the country particularly vulnerable to the effects of natural disasters (WHO, 2011). Over half of its population lives on less than U.S. \$1 per day, and approximately 80% live on less than U.S. \$2 per day (World Bank- Haiti, 2014).

Haiti and HIV/AIDS. There are numerous health issues that affect the lives of people living in Haiti. These health issues are fueled by rampant poverty and high illiteracy rates, as high as 48.7% in 2008-2012 (UNICEF, 2009; WHO, 2013). Additionally, inadequate social services have deteriorated due to an unstable political government; a devastating earthquake and the first cholera epidemic in the Caribbean in over 100 years (Charles et al., 2014; Pape, Johnson, & Fitzgerald, 2010); high migration rates and high prevalence of sexually transmitted diseases have also contributed to

numerous health issues (WHO, 2013). Haiti has the highest rates of under-five, infant and maternal mortality in the Western Hemisphere (CIA World Fact Book, 2013; UNICEF, 2009). Diarrhea, malaria, tuberculosis and HIV/AIDS are the leading causes of death among the population (UNICEF, 2009; WHO, 2013; AIDS Healthcare Foundation, 2014). Haiti also has the second highest prevalence of HIV in Latin America and the Caribbean and the highest number of people living with HIV/AIDS in the region (UNAIDS Global Report, 2013; UNAIDS Fact Sheet, 2012). The epidemic, which began in the late 1970s, has spread widely across the country (AIDS Healthcare Foundation, 2014). Haiti not only faces the worst AIDS epidemic outside of Africa but also bears the greatest burden of HIV infection in the Western Hemisphere (AIDS Healthcare Foundation, 2014).

Women and HIV. Although data show a decrease in the proportion of women living with HIV over the last 10 years, the latest World Health Organization (WHO) and UNAIDS global estimates reveal that women comprise 50% of People Living with HIV (PLWH) worldwide (UNAIDS Global Report, 2013). The latest HIV and AIDS data from Haiti indicate that 74,000 women (aged 15 and older) are living with HIV, which represents 52% of the 130,000 adults (aged 15 and older) living with HIV (AIDS Healthcare Foundation, 2014; UNAIDS Fact Sheet, 2012; CDC HIV among Women, 2013). Worldwide, the WHO reports that there are a number of key drivers of HIV incidence and adherence to antiretroviral therapy (ART) in women associated with gender inequalities. Several of these key factors are gender norms, gender-related barriers in access to services, the far greater efficiency of HIV transmission from male to female partners during penile-vaginal sex, women assuming the major share of caregiving, and

lack of education and economic security (UNAIDS Global Report, 2013; WHO Department of Gender, Women and Health, 2013; Nicolosi et al, 1994). Additional information regarding women and HIV will be discussed in the literature review in the following chapter.

Treatment Adherence. There are several key components included in all successful HIV/AIDS treatment programs; one of the most important variables that influences the success of these programs is the level of adherence to ART. According to the WHO, standard ART consists of at least three antiretroviral drugs from at least two classes that not only maximally suppress the HIV virus but also stop the progression of the disease (WHO, 2014). Current WHO recommendations include using ART for HIV prevention, especially in pregnant women and other vulnerable populations (WHO, 2014). Some research indicates that, depending on the ART regimen, from 80% to as much as 95% adherence may be necessary to achieve optimal clinical, virologic, and immunologic outcomes (Lucas, 2005; Kobin & Sheth, 2011; Bangsberg et al., 2001).

Optimal ART adherence has multiple benefits, among them suppressing viral replication, rendering viral levels undetectable in blood, sexual fluids, and most importantly, reducing risk of progression to opportunistic infections and death HIV transmission (White House Office of National AIDS Policy, 2010; White House Office of National AIDS Policy, 2013; Cohen et al., 2011). ART has played a significant role not only in reducing mortality and improving the quality of life of persons living with HIV, but also in helping them achieve long-term optimal health and almost certainly in reducing HIV incidence (UN Development Programme, 2013; Donnell et al., 2010; Palombi et al., 2012; Paterson et al., 2000; Bangsberg, Moss, & Deeks, 2004; Carpenter

et al., 1997; UNAIDS HIV and AIDS Estimates, 2014). Conversely, inadequate ART adherence is associated with increased risk of progression to AIDS, mortality, emergence of viral resistance, and higher risk of transmission (Donnell et al., 2010; Palombi et al., 2012; Paterson et al., 2000; Bangsberg et al., 2004; Carpenter et al., 1997; UNAIDS HIV and AIDS Estimates, 2014).

Haiti and ART. In 2012, more than 9.7 million people living with HIV were receiving ART in low and middle-income countries (UNAIDS Global Report, 2013; CDC, 2013; CDC HIV among Women, 2013). In Haiti, it is estimated that the number of people with HIV is 130,000 adults. However, only 63% of those who needed it were receiving ART in 2012 (CIA World Fact Book, 2013; World Bank, 2014). The latest HIV and AIDS data from Haiti indicate that 74,000 of persons living with HIV/AIDS are women aged 15 and older; 13,000 children aged 0 – 14 years are living with HIV (World Bank, 2014), of whom 6,700 require ART, while only 34% receive it (UNAIDS Global Report, 2013). The number of deaths attributed to HIV declined from 15,000 in 2001 to 6,400 in 2014 (CIA World Fact Book, 2013; World Bank, 2014). The adult prevalence rate is estimated to be between 1.8% and 2.1% (UNAIDS Global Report, 2013; CDC, 2013; CDC HIV among Women, 2013; World Bank, 2014).

Recent studies have found varying adherence rates among individuals, reporting that between 18% - 73% of participants are non-adherent (Bangsberg et al., 2004; Cats et al., 2000; Tesoriero et al., 2003; Purcell et al., 2004; Castro 2005; Wood et al., 2009). Study findings further indicate that even lower adherence rates can be found in PLWH who are also dealing with substance abuse and/or environmental and psychological constraints, including the formidable challenges endured by Haitians with HIV infection

since the 2010 earthquake (Wood et al., 2009; Malow et al., 2010; Moatti, 2002; Safren et al., 2001; Koenig et al., 2010). Research has identified multiple barriers to ART adherence and response, including poor social support (Dévieux et al., 2009; Malow, Rosenberg, & Dévieux, 2009; Bryant, 2006), alcohol abuse (Samet et al., 2004; Baum et al., 2010; Malow et al., 2013; Nachega et al., 2005), negative beliefs about medicine (DiMatteo, Lepper, & Croghan, 2000; Starace et al., 2002), depression and anxiety (Dévieux et al., 2009; Starace et al., 2002; Weaver et al., 2005; Krain & Fitzgerald, 2005; Ghose et al., 2013), and stigma (Castro & Farmer, 2005; Dévieux et al., 2004; Vyavaharkar et al., 2007).

Psychological Factors Associated with ART Adherence.

Psychological variables, such as social support, when at optimal levels, are conceptualized as tools that not only help deal with stress but also may contribute to positive health outcomes. It is suggested that HIV-infected women who have access to resources, such as social support, are more likely to effectively manage stressful situations and less likely to have poor outcomes (Hudson et al., 2001). Furthermore, researchers and experts in the field have indicated that social support from family, friends, and/or healthcare professionals has been found to diminish depressive symptoms among HIV positive individuals (Lazarus & Folman, 1984). Conversely, individuals with less social support are less able to cope with the challenges related to HIV and experience more negative outcomes (Cox, 2002). Numerous studies have examined the association between perceived social support and ART adherence and have found emotional support

to be a significant predictor of medication adherence and adherence treatment (Gordillo et al., 1999; Neame & Hammond, 2005; Riekert & Drotar, 2002).

Belief about Medicines. Belief and attitude about illness correlate strongly with treatment adherence in other chronic diseases (Reynolds et al., 2004; Dilorio et al., 2009; Tyler-Viola et al., 2014). According to the health belief model, two major factors influence the likelihood that individuals will adopt recommended regimens: 1) they must feel susceptible to the serious or severe consequences of the disease, and 2) they must believe that the benefits of taking the preventive action outweigh the perceived barriers (Johnson et al., 2006). Studies focusing on the factors influencing medication adherence beliefs and self-efficacy in persons naïve to ART deduced that a greater belief in one's ability to adhere to ART and higher confidence in its benefits were associated with higher quality of life (Johnson et al., 2006; Horne & Weinman, 1999). Other studies have found that adherence, self-efficacy, and depression symptoms predicted ART adherence (Horne & Weinman, 1999; Horne, Weinman, & Hankins, 1999; UNAIDS Report on Global AIDS Epidemic, 2010). People with weaker beliefs about the necessity to adhere to medication treatment and those with higher levels of concern about the medications are more likely non-adherent (Sowell & Phillips, 2010; Katz et al., 2013).

Depression and anxiety have been associated with non-adherence to ART (Bryant, 2006; Dévieux et al., 2009; Baum et al., 2010; Malow et al., 2013; Nachegea et al., 2005; Li et al., 2011). A study examining behavioral and social factors that predict medication adherence found that poor ART adherence was significantly predicted by avoidant coping, which is predicted by both lack of social support and negative mood states (DiMatteo, Lepper, & Croghan, 2000). Similar links between mood and adherence

have been found in other studies (Bryant, 2006; Nachega et al., 2005; Starace et al., 2002; Weaver et al., 2002). Thus, multivariable investigation of the correlation between psychological variables, such as depression and anxiety and ART adherence, may be needed, particularly among high-risk groups such as alcohol users (Donnell et al., 2010; Li et al., 2011).

Social Factors Associated with ART Adherence.

Perceived stigma can lead to discrimination, shame, and fear. Studies have found that the fear of negative social consequences frequently causes HIV-positive individuals to keep their status secret, often resulting in negative psychological and physical outcomes and continued HIV transmission (Sowell & Phillips, 2010; Katz et al., 2014; Ansari & Gaestel, 2010; Li et al., 2011; Malow et al., 2000). Thus, stigma is a challenge when treating and caring for persons with HIV infection. The fear associated with being stigmatized may cause individuals to avoid care and services (Cox, 2002; Fawzi et al., 2010; DeSantis, Thomas, & Sinnett, 1999; Arrivillaga et al., 2011; Do et al., 2010). This fear is also associated with the lack of protective behaviors such as adherence to ART (Fawzi et al., 2010; DeSantis et al., 1999; Arrivillaga et al., 2011; Do et al., 2010). Additional studies have found that stigma may be especially problematic for women, as it can limit their marital prospects, constrain their participation in community, household and family roles, and diminish their quality of life (Do et al., 2010; Mills et al., 2006; Lillard & Panis, 1996; Smith & Waitzman, 1994; Bourne, 2009; Waldron, Hughes, & Brooks, 1996; Ross, Mirowsky, & Golsteen, 1990).

Relationship Status. Studies have found that married individuals have a better self-reported health status and/or lower mortality than non-married people (Ross et al., 1990; Macintyre, 1992; McKenzie, 1993). In most studies, married adults also have lower morbidity and better physical health than unmarried adults (St. Bernard, 2003; AIDS Control and Prevention, 1996; Byakika-Tusiime et al., 2005). In the Caribbean sub-region, the percentage of formal marriage and common-law unions has remained constant (DeWalt et al., 2004). Although common law and visiting unions have been traditionally associated with individuals from a lower socio-economic status group, the prevalence of common-law unions has increased among women from middle and higher socio-economic groups in Caribbean societies (Kilian et al., 1990; Hargreaves & Glynn, 2002). Research found that the union status of women may be considered as a proxy for exposure to sexual intercourse and by extension, their risk of childbearing and prevalence of sexually transmitted infections (Hargreaves & Glynn, 2002; Nachega et al., 2004). Although marital status and/or companionship is related to lower mortality, marital status has been associated with low adherence to ART, especially in countries with high prevalence of HIV/AIDS (Nachega et al., 2004; Orrell et al., 2003).

Educational Attainment. Among the main methods to reduce the prevalence and transmission of HIV in heterosexual transmission is behavior change. Behavior change may be associated with educational level (Weidle et al., 2002). Increased educational attainment may improve the ability to understand and act on health promotion messages, though some studies call this into question (Weidle et al., 2002; Laurent et al., 2002). For example, in a study conducted in Soweto, South Africa, 66 participants were studied (71% were women and 79% had completed high school or some advanced educational

training) (Smith, El Obeid, & Jensen, 2000). The study concluded that despite the low socioeconomic status, and low-to-mid levels of educational attainment of the population, 88% reported 95% adherence to ART (Smith et al, 2000). The study concluded that the high adherence levels observed may be due to the increased motivation of South Africans who know that drugs are scarce and who have witnessed and have been exposed to the negative effects of untreated HIV/AIDS (Smith et al., 2000). Similar results regarding education attainment's role in ART adherence were also found from cohorts in South Africa, Senegal and Uganda (Orrell et al., 2003; Weidle et al., 2002; Laurent et al., 2002; Smith et al., 2000).

Value of the Research

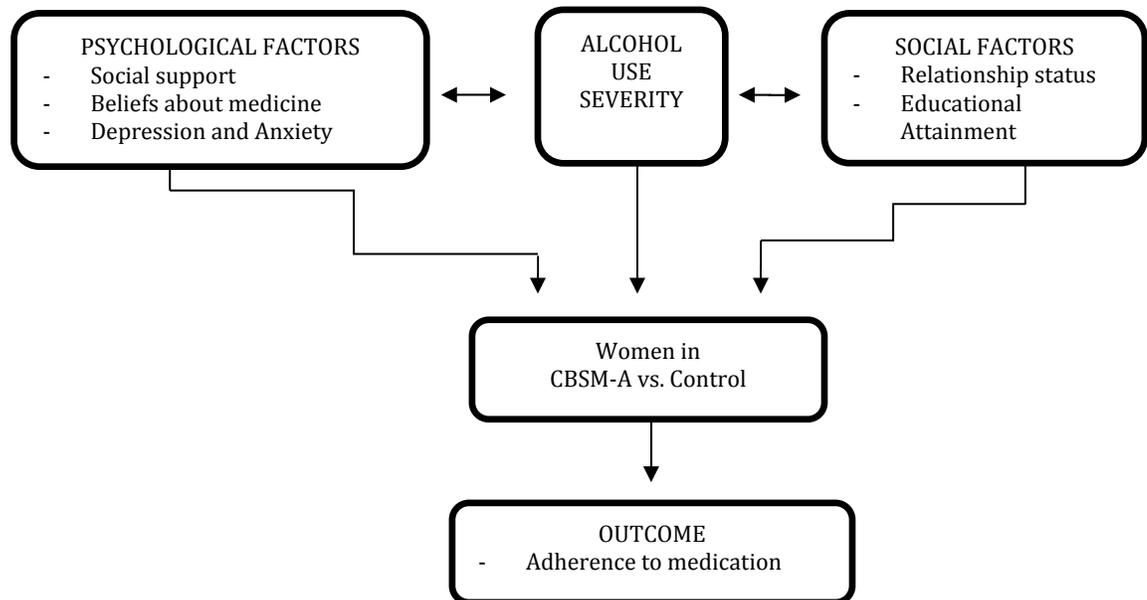
Findings on the impact of psychological and social factors on ART adherence among HIV-positive female Haitians may contribute to the direction of future research and practice. Outcomes from this study may be informative in guiding implementation of an effective intervention, such as CBSM-A, to improve adherence. The target population, HIV-positive female Haitians, has the second highest HIV prevalence and death rates from HIV/AIDS in the Caribbean (WHO, HIV/AIDS Fact Sheet, 2014; World Bank, 2014; UNAIDS Report on Global AIDS Epidemic, 2010). This research assessed the relationship between psychological factors (depression, anxiety, beliefs about medicine, and social support) and adherence to ART among Haitian HIV-positive female alcohol users. The present study also examined the role of stigma, relationship status and educational attainment on adherence to ART. Outcomes from this study may contribute

to the growing body of knowledge on this understudied group of Haitian HIV-positive female alcohol users.

Proposed Study

Using secondary data from the parent study, this dissertation examined the short-term effectiveness of the Cognitive Behavioral Stress Management – Adapted (CBSM-A) intervention on improving ART adherence in a female, HIV+ sample of alcohol users. This dissertation aims to identify relationships among measures of social support, beliefs about medicines, depression and anxiety, and alcohol use severity in predicting adherence to antiretroviral medications. In addition to examining the psychological predictors, this dissertation also examined the role of perceived stigma, relationship status, and educational attainment on adherence to ART. See Figure 1 below for a schematic conceptualization of the research.

Figure 1. Conceptual model of CBSM-A intervention effects moderated by psychological factors, alcohol use, and social factors



Research questions/hypotheses

Research Question 1: Is the Cognitive Behavioral Stress Management – Adapted (CBSM-A) intervention effective in improving ART adherence among HIV-positive Haitian female alcohol users?

Hypothesis #1: Female participants in the CBSM-A group will show better ART adherence than those in the wait-list control group.

Null Hypothesis #1: Female participants in the CBSM-A group will not show better ART adherence than those in the wait-list control group.

Research Question 2: Are the psychological factors —social support, depression, anxiety, and beliefs about medicine—associated with ART adherence at baseline and post-assessment among HIV-positive Haitian female alcohol users in the intervention group?

Research Question 3: Do psychological factors —social support, depression, anxiety, and beliefs about medicine— improve from baseline to post-assessment among HIV-positive Haitian female alcohol users at the end of the intervention?

Hypothesis #2a: Social support will be directly related to ART adherence among HIV-positive Haitian adult females.

Null Hypothesis #2a: Social support will not be related to ART adherence among HIV-positive Haitian adult females.

Hypothesis #2b: Social support will improve among HIV-positive Haitian adult females at the end of the intervention.

Null Hypothesis #2b: Social support will not improve among HIV-positive Haitian adult females at the end of the intervention.

Hypothesis #3a: Depression and anxiety will be inversely correlated with ART adherence among HIV-positive Haitian adult females.

Null Hypothesis #3a: Depression and anxiety will not be inversely correlated with ART adherence among HIV-positive Haitian adult females.

Hypothesis #3b: Depression and anxiety will improve among HIV-positive Haitian adult females at the end of the intervention.

Null Hypothesis #3b: Depression and anxiety will not improve among HIV-positive Haitian adult females at the end of the intervention.

Hypothesis #3c: Patients randomized to CBSM-A will have lower depression and anxiety scores at post-assessment than those assigned to wait-list control group.

Null Hypothesis #3c: Patients randomized to CBSM-A will not have lower depression and anxiety scores at post-assessment than those assigned to wait-list control group.

Hypothesis #4a: High beliefs in the value of medicines will be positively associated with ART adherence among HIV-positive Haitian adult females.

Null Hypothesis #4a: High beliefs in the value of medicines will not be positively associated with ART adherence among HIV-positive Haitian adult females.

Hypothesis #4b: Beliefs in the value of medicines will improve among HIV-positive Haitian adult females at the end of the intervention

Null Hypothesis # 4b: Beliefs in the value of medicines will not improve among HIV-positive Haitian adult females at the end of the intervention

Research Question 4: Do the social factors— perceived stigma, relationship status and educational attainment—affect ART adherence among HIV-positive Haitian female alcohol users?

Hypothesis #5: Perceived stigma will be inversely related to ART adherence among HIV-positive Haitian adult females.

Null Hypothesis #5: Perceived stigma will not be inversely related to ART adherence among HIV-positive Haitian adult females.

Hypothesis #6: Participants in a relationship will have higher adherence than those not in a relationship.

Null Hypothesis #6: Participants in a relationship will not have higher adherence than those not in a relationship.

Hypothesis #7: Participants with lower educational attainment will have lower ART adherence values.

Null Hypothesis #7: Participants with lower educational attainment will not have lower ART adherence values.

Research Question 5: Does the degree of alcohol abuse affect ART adherence among of HIV-positive Haitian female alcohol users?

Research Question 6: Does the degree of alcohol abuse change between baseline and post-assessment in response to the intervention among of HIV-positive Haitian female alcohol users?

Hypothesis #8a: Alcohol use will decrease among HIV-positive Haitian adult females at the end of the intervention.

Null Hypothesis #8a: Alcohol use will not decrease among HIV-positive Haitian adult females at the end of the intervention.

Hypothesis #8b: Greater alcohol use severity will be associated with lower ART adherence among HIV-positive Haitian adult females.

Null Hypothesis #8b: Greater alcohol use severity will not be associated with lower ART adherence among HIV-positive Haitian adult females.

The next chapter will review past and current literature on the subjects relevant to the research questions mentioned above, the psychological

factors, such as depression and anxiety, beliefs about medicine, and social support as they relate to adherence to ART. In addition, the role of perceived stigma, relationship status, and educational attainment will be reviewed.

CHAPTER II

LITERATURE REVIEW

The following literature review is organized into three distinct sections that focus on the scope of the problem and the major research questions. The three sections are theoretical foundations, Cognitive Behavior Stress Management, and psychological and social factors affecting adherence to ART. These three sections are presented in a logical approach to demonstrate the context, process, and content of the research study. A detailed review of the literature has been completed in each area, and trends are discussed.

Theoretical Foundations

This study examined the psychological factors associated with ART adherence among HIV-positive adult female Haitian alcohol users as well as the effectiveness of the adapted Cognitive Behavioral Stress Management Intervention in improving ART adherence. Multiple theoretical foundations were considered for the theoretical framework. Since the focus is on individual behavior and effectiveness of the intervention, the Theory of Planned Behavior/Reasoned Action and the Information Motivation Behavioral (IMB) Skills Model were selected. The parent study's adapted intervention was based on a National Institutes of Health (NIH) funded pilot study in Haiti, which was guided by the IMB skills model.

Theory of Planned Behavior/Reasoned Action- This theory is an individual-oriented theory which initially was named the Theory of Reasoned Action and later revised to the Theory of Planned Behavior. The Theory of Planned Behavior/Reasoned

Action (TPB/TRA) represents a theoretical framework which identifies the relationship between attitude and behavior (Ajzen, 1991; Ajzen, 1980; Edberg, 2007). This theory focuses on rational, cognitive decision-making processes, which include:

1) Attitude –

a. an individual's beliefs about what will happen if they perform the behavior;

b. an individual's judgment of whether the expected outcome is positive or negative.

2) Subjective Norms –

a. an individual's beliefs about what other people in their social group will think about the behavior;

b. an individual's motivation to conform to the perceived norms.

3) Behavioral Intention –

a. an individual's intention to perform a behavior.

4) Perceived Behavior Control – separated in two parts:

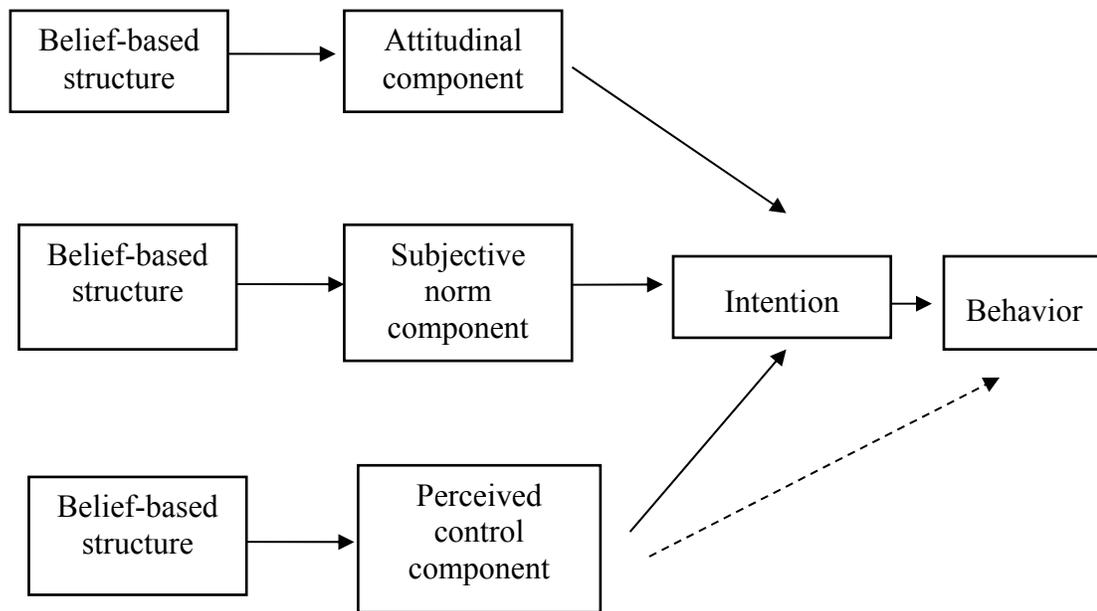
a. Control beliefs – an individual's beliefs about factors that will make it easier or more difficult to perform the behavior

b. Perceived Power – the amount of power an individual believes they have over performing the behavior (Ajzen, 1991; Ajzen, 1980; Edberg, 2007; Montana & Kasprzyk, 2002; Armitage & Conner, 1999; Hausmann-Muela, Muela & Nyamongo, 2003).

The fourth process, perceived behavior control, mentioned above was added to TRA, which led to the name change of the TPB. One of the most important aspects of the TPB

is the focus placed on the role of social support and feelings of self-control and self-efficacy (MacKian, 2003). Illustration of the TPB/TRA theory is outlined in Figure 2 (Edberg, 2007).

Figure 2. Schematic representation of Theory of Planned Behavior/Reasoned Action



Theory of Planned Behavior/Reasoned Action and Adherence. The TPB has been applied to multiple studies focusing on health-related behaviors and medication adherence (MacKian, 2003; Vissman, et al., 2011) and used extensively in HIV/AIDS research and programs (Kagee, 2008). Several researchers, including Hausmann-Muela et al. and Armitage and Corner (Hausmann-Muela, Muela, & Nyamongo, 2003; MacKian, 2003), have hailed the TPB for taking into consideration not only the motivational aspects of personal control, but also the role of social networks and peer pressure in health behavior. Other studies' findings applied the theoretical concepts of TPB in

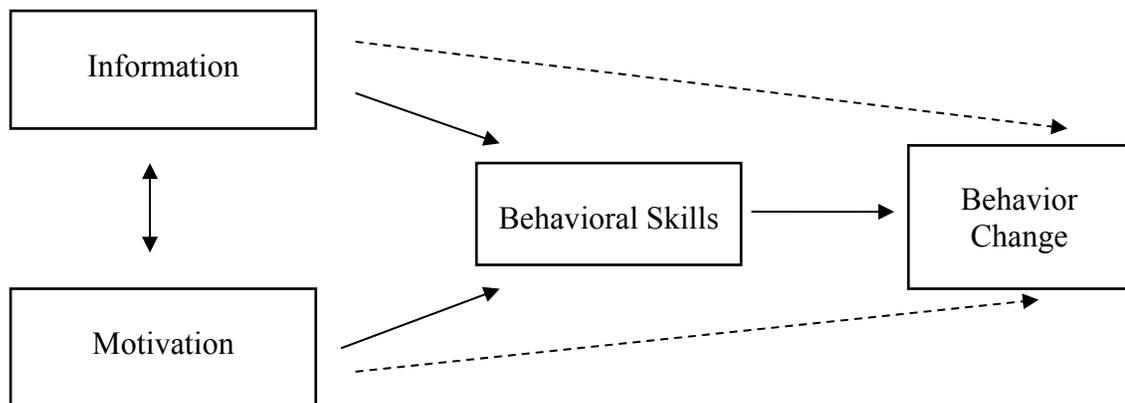
identifying factors to enhance adherence in underprivileged populations (Kagee, 2008; Harderman et al., 2002). While TPB has been found to have had promising (but not conclusive) results regarding the effectiveness of the theory's components (Armitage & Conner, 2001; Godin & Kok, 1996; Munro et al., 2007), it has been criticized by some researchers for not placing emphasis on structural and social factors, such as religious beliefs, stigma associated with diseases like HIV/AIDS, and availability of resources (Sutton, 1997; Noar & Zimmerman, 2005). By examining many psychological and social factors and attempting to determine which have a significant impact on ART adherence, this study hopes to add to the literature to clarify which variables have an effect on outcomes.

Cognitive processes are presumed to guide health behaviors, such as adherence to medication, and have been extensively associated with research focused on health behavior. TRA/TPB is one of the theories that has been utilized due to its focus on attitudinal beliefs, self-efficacy, and normative and norm-related beliefs and activities (Parsons, Rosof, & Mustanski, 2008; Parsons, Rosof, & Mustanski, 2007). There are multiple studies that have shown some connections between effective medication adherence and self-efficacy (Parsons et al., 2007; Ammassari et al., 2002). Similar studies have found that patients who believe they are capable of taking their medications (self-efficacy) are more likely to be adherent (Ickovics et al., 2002; Molassiotis et al., 2002; Wagner et al., 2002). Other studies have found that those who also believe in the effectiveness of the ART medication were more likely to be adherent (Fisher & Fisher, 1992). Therefore in the current study, perceived behavioral control will refer to specific

psychological and social factors that individuals may or may not have control over and the effects of perceived behavioral control on adherence to ART.

Information Motivation Behavioral Skills (IMB) Model. There are multiple models of health behavior change that have been developed to understand the factors that influence HIV transmission, prevention, and treatment. The IMB Model is one theoretical framework that has effectively predicted HIV risk and preventive behavior in diverse populations and conditions (Amico, Toro-Alfonso, & Fisher, 2005; Fisher et al., 2006). This model, although constructed to be malleable and simple (Sutton, 1997; Fisher & Fisher, 2006), has been tailored specifically to designing interventions that promote adherence to ART (WHO, 2003). The IMB model focuses on three components that result in behavior change: 1) information – relates to the basic knowledge about the conditions and associated recommendations; 2) motivation – personal attitudes towards adherence, perceived social support, and the individual’s subjective norm; and 3) behavioral skills (including factors such as tools and self-efficacy) – the belief that they can achieve the behavior (Fisher et al., 2006). An illustration of the IMB model is outlined in Figure 3 (Amico et al., 2005; Fisher et al., 2006; Fisher et al., 2008).

Figure 3. Information Motivation Behavioral Skills Model



Information Motivation Behavioral Skills (IMB) Model and Adherence. The IMB model proposes that ART regimen and its side effects, including attitudes and beliefs about adherence and non-adherence, will eventually influence adherence-related health behavior (WHO, 2003). Although several empirical studies have established the strength of the IMB model's three major components in predicting ART adherence (Fisher et al., 2006; Starace et al., 2006; Kalichman et al., 2002), it is suggested that the components of the model are usually generalizable when applied to a well-defined population (Kalichman et al., 2005) and require more specific measurable variables (Amico et al., 2009). Other reviews have concluded that the IMB model has not consistently resulted in an accurate prediction of adherence, especially when it comes to defining and measuring the motivation portion of the model (Rongkavilit et al., 2010; Schneidermna, Antoni, & Ironson, 2014). The results of this study will add further clarification when the IMB model is associated to ART adherence, especially in an understudied population.

The use of the IMB model along with the TPB/TRA will offer valuable input into the scope and use within this particular population: Haitian, HIV-positive, female alcohol users, who have low socioeconomic status, have low-to-middle education level and also reside in and receive care in Haiti. The fact that both TPB/TRA and IMB models have been used in such varied populations to improve adherence demonstrates their versatility and appropriateness for the current study. In this study, the adherence to ART was examined in conjunction with perceived stigma, belief about medicine, social support, level of depression and anxiety, and level of alcohol abuse.

Cognitive Behavioral Stress Management (CBSM)

Due to the recent advances in treatments and therapies, HIV/AIDS which was once viewed as a universally terminal disease, has become a chronic disease for ART patients, in which adherence to ART is a key component. Based on the theoretical foundation outlined in the previous section, the use of a psychological intervention technique, such as Cognitive Behavioral Stress Management (CBSM), is a good fit for use in this study. CBSM is a short-term therapeutic approach that concentrates on how people's emotions and behaviors are affected by their thoughts (Kelly & Kalichman, 2002). CBSM protocols provide opportunity to build individuals' emotional and interpersonal skills (Kelly & Kalichman, 2002). According to research, since patient self-management is so important, psychological interventions focusing on stress management have become effective components of successful HIV management and treatment (Kelly & Kalichman, 2002; Crepaz et al., 2008). CBSM's goals are to influence irrational thoughts while focusing on finding and shifting behaviors and thought patterns. CBSM protocols provide opportunities for psychologists to provide information, build emotional and interpersonal skills, and also provide support throughout the process. During CBSM therapy, individuals learn recovery skills that are useful throughout their lifetimes (Brown & Vanable, 2008; Berger et al., 2008; Linden, 2004). An outline of the CBSM training sessions is presented in Figure 4 (Ironson & Hayward, 2008).

Figure 4. Subject and outlines of Cognitive Behavioral Stress Management training sessions

| Session | Outline |
|----------------|---|
| First | Introduction, group member greeting, explaining group rules, time and |

| | |
|---------|--|
| | number of sessions, concept of stress, conducting pre-tests, giving homework |
| Second | Reviewing the previous session homework, educating the group about the causes and outcomes of stress, how to manage stress, teaching relaxation techniques with practical exercise, homework |
| Third | Reviewing the previous session's homework, introduction to automatic thought, role of thought in causing stress, association of thoughts with emotions and behavior, how to manage thoughts |
| Fourth | Challenging participants with thoughts and illogical beliefs |
| Fifth | Teaching communication skills, self-expression and self-confidence |
| Sixth | Practicing the already learned skills from past sessions, implications of these skills in stressful situations, conducting post-tests |
| Seventh | Teaching time management and planning activities |
| Eighth | Reviewing of already learned skills, answering the questions, conducting post-tests |

Cognitive Behavioral Stress Management (CBSM) and Adherence. Multiple studies, which have conceptualized HIV as a chronic disease, have utilized group-based CBSM to improve quality of life and slow symptom onset for those infected with HIV. Findings from multiple research studies (Dévieux et al., 2009; Kelly & Kalichman, 2002; Crepaz et al., 2008; Brown & Venable, 2008) showed that CBSM can improve the individual's quality of life by decreasing the distress and depressed affect associated with having a chronic and likely terminal disease. Additionally, by utilizing CBSM

techniques, the use of acceptance and positive reframing strategies would inherently lead to increased, or maintained, social support. The studies also show that psychological intervention facilitates adherence to good health practices and appropriate utilization of the health care system. This transpires by decreasing the use of maladaptive coping strategies, such as avoidance and denial, and instead using more problem-focused strategies. Additionally, the studies suggest that CBSM intervention, including relaxation training, is able to attenuate the impact of stressors upon an already compromised immune system and in doing so, might slow the course of immune decline that is detected in PLWH (Dévieux et al., 2009; Kelly & Kalichman, 2002; Crepaz et al., 2008; Brown & Vanable, 2008).

As indicated by the IMB model, these techniques and skills learned throughout the CBSM process help improve quality of life by facilitating adherence to medication, decreasing isolation and depressive symptoms as well as improving immune function (Rosenberg et al., 2009; Kelly & Kalichman, 2002; Crepaz et al., 2008; Brown & Vanable, 2008; Berger et al., 2008; Ironson & Hayward, 2008). The CBSM process targets the individual's relationship between attitude and behavior, as theorized by the TPB/TRA as well as the motivation and behavior skills' components of the IMB model. Collective research has shown that the use of CBSM therapy has had a significant role in the management of HIV. CBSM therapy includes reducing distress, improving adherence to ART, and facilitating the efforts of HIV-infected individuals in improving quality and quantity of life. Inversely, poor coping strategies were associated with increased morbidity and mortality risks, which contributed to adherence issues and missed medical appointments (Catz, Gore-Felton, & McClure, 2002; Talam et al., 2008).

Cognitive Behavioral Stress Management-Adapted (CBSM-A). In the parent study, CBSM-A was based on an NIH funded pilot study in Haiti that was guided by the IMB model. The population was a small group of HIV positive individuals, who were also alcohol users. CBSM-A focused on their cognitive/self-management and coping barriers that impeded dependable outcomes. The purposes of the treatment program were to a) provide participants with information on HIV disease and its treatment, including anti-retroviral medications, negative effects of substance abuse, and high-risk sexual behavior on the immune system and health in HIV; and b) teach anxiety reduction skills, such as progressive muscle relaxation, relaxing imagery, and autogenic exercise (Dévieux et al., 2009). The final phase of CBSM-A integrates cognitive appraisals of stressors within the context of interpersonal stressors. The primary goals were to improve contact with their social network and decrease conflict by enhancing communication skills through anger management and assertion skills. Figure 5 illustrates the training sessions implemented in the parent study.

Figure 5. Subject and Outlines of Cognitive Behavioral Stress Management (CBSM-A) Intervention Session

| Session | Outline |
|---------|--|
| 1 – 3 | <ul style="list-style-type: none"> • Focus on risk reduction strategies and information (HIV transmission, ART medications and adherence issues, impact of alcohol on sexual risk and maintaining physical health) • Stress management techniques focus on cognitive restructuring to introduce the notion that cognitions precede behavioral, affective (e.g. |

| | |
|-------|---|
| | <p>depressed mood), social (e.g. withdrawal), physical (e.g. muscle tension) and physiological (e.g. hormonal) responses to stressors.</p> <ul style="list-style-type: none"> • Special emphasis on how alcohol may influence this process in life or interaction with a sexual partner • As participants learn about identifying automatic thoughts (including cognitive distortions), they also learn how to use rational thought replacement to substitute cognitive reappraisals and thereby reduce distress responses. • Behavioral role-play. Participants receive supportive group feedback as they rehearse their newly acquired skills. |
| 4 – 5 | Focus of the stress management segment of each session shifts to coping skills training |
| 6 | Focus of the stress management segment of each session shifts to social support network building and help-seeking/communication |
| 7 | Focus of the stress management segment of each session shifts to anger management |
| 8 | Focus of the stress management segment of each session shifts to refusal skills and assertiveness training |

ART Adherence

Treatment Adherence. Recent studies have found varying adherence rates among individuals, reporting that between 18% - 73% of participants are non-adherent (Bangsberg, Moss, & Deeks, 2004; Catz et al., 2000; Tesoriero, et al., 2003; Purcell et al., 2004; Castro, 2005; Wood et al., 2009). Study findings further indicate that even lower adherence rates can be found in PLWH coping with substance abuse and/or environmental and psychosocial constraints (Wood et al., 2009; Malow et al., 2010; Moatti, 2002; Safren et al., 2001).

Research has identified multiple barriers to ART adherence and response, including poor social support (Dévieux et al., 2009; Malow et al., 2009; Bryant, 2006), alcohol abuse (Samet et al., 2004; Baum et al., 2010; Malow et al., 2013; Nachega et al., 2005), negative beliefs about medicine (DiMatteo et al., 2000; Starace et al., 2002), depression and anxiety (Dévieux et al., 2009; Malow et al., 2013; Weaver et al., 2005; Krain & Fitzgerald, 2005; Ghose et al., 2013) and stigma (Castro & Famer, 2005; Dévieux et al., 2004; Vyavaharkar et al., 2007).

Adherence in the Caribbean. In recent years, the increase in access to ART among PLWH in the Caribbean has had a significant positive impact on life expectancy (UNAIDS Global Report, 2013), reducing morbidity and reducing AIDS incidence (UNAIDS Global Report, 2013; Allen, Simon, Edwards & Simeon, 2011). However, concerns related to ART adherence still remain (Williams et al., 2007; Adomakoh et al., 2004; Armstrong, Thompson, & Persaud, 2004; Mukherjee et al., 2006).

In two different studies (Beng et al., 2011; Rivero-Mendez, Dawson-Rose, & Solis-Baez, 2010), in Haiti and Cuba, it was determined that some of the factors linked to

high adherence to ART were associated with communication with support staff (community health-workers, specialist physician) and self-efficacy. A study conducted in three Caribbean countries (Antigua and Barbuda, Grenada, and Trinidad and Tobago) assessed 274 individuals who were taking ART, in order to identify factors affecting adherence (UNAIDS, 2004). It was determined that improvements in ART adherence in the Caribbean may be achieved by improving counseling, reducing side effects of medications, and most importantly, focusing attention on alcohol users (UNAIDS, 2004).

Adherence in women. Research focusing on gender differences in treatment adherence highlighted the following among HIV-positive women. In Columbia, women prioritized the needs of their HIV-positive children over their own adherence needs, and some women sold their ART to survive financially (Harris et al., 2011). In Botswana, nondisclosure of positive HIV status contributed to reduced adherence among women (Bing et al., 2001). In Sub-Saharan Africa and North America, restrictive diets and side effects were some of the reasons women abstained from adhering to treatment plans (Lucas et al., 2002).

ART adherence among Caribbean women. There is limited research on adherence among women in the Caribbean. Most studies in the Caribbean focused on ART adherence among both men and women (Williams et al., 2007; Beng et al., 2011; Rivero-Mendez et al., 2010; Harris et al., 2011; Koenig et al., 2012). A study conducted in Puerto Rico which focused on providers' perception of barriers to adherence in women with HIV/AIDS, concluded that factors that influence non-adherence behaviors were: gender related demands, fear of disclosure, and complexity of the treatment (Conigliaro et al., 2003).

Alcohol Abuse

Alcohol and adherence. Alcohol influences actions and behaviors that increase the risks for both acquiring and transmitting HIV and other sexually transmitted infections (STI) (Samet et al., 2004). Studies have found a correlation between both the degree of alcohol intoxication and history of alcohol abuse and higher risk-taking behaviors (Bryant, 2006; Samet et al., 2004). Studies focused on a sample of PLWH found that over half had reported alcohol abuse in the previous month (Talam et al., 2008; Lucas et al., 2002). Other research has reported similar outcomes, finding an association between alcohol abuse and poor adherence to health care recommendations, especially with respect to adherence to medication (Samet et al. 2004; Nachega et al., 2005; Lucas et al., 2002; Conigliaro et al., 2003; Justice et al., 2004). Research also shows that the severity of alcohol use is correlated with levels of non-adherence (Lucas et al., 2002; Conigliaro et al., 2003; Justice et al, 2004). Some negative effects of alcohol use on ART adherence among PLWH include associations with poor social support and mistrust of the medical establishment (Chesney, 2000), and unstable lifestyles that significantly affect the ability to adhere to ART (Shere, 1998; Lucas, Chaisson & Moore, 1999; Cook et al., 2001).

Although intervention programs targeting cognitions and adherence have played a significant role in improving adherence of ART among PLWH, some studies have shown that these interventions may not be sufficient to address other behavioral factors, such as alcohol use (Samet, et al., 2004). Studies also found that better adherence had a strong correlation with current abstinence from alcohol compared to those with moderate and at-risk level of alcohol use (Golin et al., 2001; Miguez et al., 2003). Alcohol consumption

has also been related to HIV disease progression, such as higher level of HIV viral load and lower CD4 counts (Golin et al., 2001; Miguez et al., 2003).

Alcohol abuse in the Caribbean. In the Caribbean, significant differences have been reported in alcohol abuse from island to island. This difference occurs in part because alcohol dependence rates are linked to environmental factors, such as ethnic differences in drinking culture (Hasin & Grant, 2002; Beaubrun, 1975). In Caribbean countries like Haiti, habitants are known to consume more spirit drinks (hard liquors) than beer and wine (Global Status Report on Alcohol and Health- Haiti, 2014). The 2014 Global Status report on Alcohol and Health states that in Haiti, the prevalence of heavy episodic drinking was higher amongst males than females. Studies have found alcohol dependence to also be associated with anxiety and other psychiatric disorders (Hasin & Grant, 2002; Beaubrun, 1975; Hasin & Nunes, 1997; Shafe et al., 2009).

Substance dependence, such as alcohol, contributes significantly to social problems, for instance domestic violence, that are common in many Caribbean countries (Gage & Suzuki, 2006; Converse et al., 2014). In a national survey conducted in Haiti, 16% of the women who either were married or in a common law relationship, reported experiencing sexual violence (Gage & Suzuki, 2006). Women in the study also claimed that alcohol use by male partners was a risk factor for partner sexual abuse. There are limited studies in Haiti that focus on the impact of alcohol abuse and adherence. The results of this study will add to the body of knowledge necessary to continue to improve HIV care and management in poor resource settings.

Gender differences in alcohol abuse. Compared to women, men are more likely to consume higher amounts of alcohol. This finding is more globalized and affects all

areas of the world differently; it is driven by a country's region and culture (Almeida-Filho et al., 2004; McKee et al., 2000; Siery et al., 2002). In recent decades, there has been increased concern about similar drinking behavior extending to both genders since some society's gender differences have minimized. It is more acceptable for women to drink alcoholic beverages in some cultures now than it was previously. Research has concluded that this is due to the fact that there are increased opportunities for women to perform traditional male roles, especially in the workforce, which often encourages women to incorporate drinking into their daily lives (Bermark, 2004; Bloomfield et al., 2001).

Alcohol abuse among Caribbean females. The continued prevalence and increase in alcohol consumption has become a public health issues especially in the Latin America and Caribbean (LAC) region (Pyne, Claeson, & Correia, 2002). The proportion of all deaths worldwide that can be attributed to alcohol use is 1.5%, compared to 4.5% for the LAC nations (Pyne et al., 2002; Montane Jaime et al., 2014). Studies have shown that women drink less, and are more likely to abstain from alcohol than are men in LAC nations (Bloomfield et al., 2001; Pyne et al., 2002). There are very limited studies in the Caribbean that focus on the impact of alcohol abuse and women. Most of the studies focused on the role of alcohol and domestic violence.

Psychological Factors

Social support and adherence among females. Prevalence and incidence of HIV/AIDS is increasing among women (WHO, 2014; Sambisa, Curtis, & Mishra, 2010), and a supportive social support environment is critical for those with HIV/AIDS.

Numerous studies have indicated that adherence to ART may be related to social support (Sowell & Phillips, 2010; Katz et al., 2013; Ansari & Gaestel, 2010). The following studies outlined below highlight some of the common findings in social support and ART adherence among women.

Studies focusing on women investigated their perceptions of social support and how it affected their medication adherence. Findings from the studies concluded that facilitators of adherence to HIV care also included the need for supportive family members, (Pyne et al., 2002; Sambisa et al., 2010) desiring emotional support, and instrumental support (Pyne et al., 2002). This is noteworthy, given that researchers have demonstrated that severe life stress is a predictor of early disease progression and poor health outcomes (Dilorio et al., 2009; Tyler-Viola et al., 2014; Sowell & Phillips, 2010; Katz et al., 2013; Ansari & Gaestel, 2010; Li et al., 2011; Pyne et al., 2002; Sambisa, Curtis, & Mishra, 2010).

Social support and adherence in the Caribbean. There are limited studies focusing specifically on Caribbean women and social support. Numerous studies conducted in LAC nations have presented similar findings regarding the importance of perceived social support and adherence to regimen and access to care (Bing et al., 2001; Bingham et al., 2003). Similar findings were also made in studies conducted in the Dominican Republic, which aimed at determining risk factors to medication non-adherence in HIV infected individuals; researchers concluded that perceptions of less social support were related to low adherence to ART (Bing et al., 2001).

Belief about medicine and adherence. Similar to perceived social support and self-efficacy, a high level of belief about the effectiveness of medicine also has a

significant correlation with adherence to treatment (Dilorio et al., 2009; Tyler-Viola et al., 2014; Sowell & Phillips, 2010). Studies aimed at identifying the determinants to adherence to ART among HIV patients found that predictors of high adherence were: high perception of self-efficacy (Dilorio et al., 2009; Tyler-Viola et al., 2014; Sowell & Phillips, 2010), positive attitude towards taking medication (Dilorio et al., 2009; Horne & Weinman, 1999; Horne, Weinman, & Hankins, 1999), not living alone (Ross et al., 1992; McKenzie, 1993) and being a male (Ncama et al., 2008). Further analysis demonstrated that high physician satisfaction, high-perceived social support, and experiencing no side effects were some of the factors related to positive attitude about taking medication. Also, a high level of self-efficacy was associated with positive perception of social support, a high level of physician satisfaction, and not living alone (Horne & Weinman, 1999; Horne et al., 1999; McInerney et al., 2008).

Belief about medicine in Haiti. A study that examined the association of depression, substance abuse, and other contextual predictors among HIV-positive Haitians, found that along with depression, negative attitudes about ART directly predicted poor adherence (Malow et al., 2013). Similar to other research, this study also found that belief about medication predicted participants' adherence better than depression (Malow et al., 2013; Nachega et al., 2005). Additionally, greater partner conflict, maladaptive coping, such as avoidance and denial, and alcohol problems predicted more depression; furthermore, maladaptive coping predicted a negative attitude about ART (Malow et al., 2013; DiMatteo et al., 2000; Starace et al., 2002; Weaver et al., 2005). Other studies also presented similar findings, suggesting that incorporating communication about the significance of ART adherence (Cook et al., 2005; Meena et

al., 2014) and enhancing relations between patients and care providers (Root & Whiteside, 2013) are essential for positive health outcomes.

Gender differences and belief about medicine. There are few studies that focus on HIV-positive females and adherence to ART as it relates to beliefs about medicine. Studies that focused on adherence to medication in female populations concluded that side effects of the medication were the main reason for non-adherence (Cocohoba et al., 2013; Kibicho & Owczarzak, 2011; Bask, van Mill & Sathyanarayana, 2009). The importance of the role of health professionals in educating on the purpose of the treatment, which may lead to increased confidence in medication (Silveira et al., 2014; Nachege et al., 2012; Garvie et al., 2011), and developing symptom-management interventions for individuals were also significant factors related to adherence (Garvie et al., 2011; Campos et al., 2008; Sumari-deBoer et al., 2012).

Depression and anxiety and ART adherence. In numerous studies, depression was a major predictor of lower adherence (Dévieux et al., 2009; DiMatteo et al., 2000; Weaver et al., 2005; Krain & Fitzgerald, 2005; Ghose et al., 2013). These conclusions provide evidence that suggests that including treatment for depression and anxiety may have a positive outcome on adherence (Kong et al., 2012; Monroe et al., 2013; Maharaj et al., 2013; Garcia Bayer & Carcamo, 2014). Findings suggest that using a brief screening procedure to assess anxiety and depression symptoms before initiating ART helps to identify individuals for interventions, and therefore, improve adherence and quality of life (Monroe et al., 2013; Maharaj et al., 2013; Garcia Bayer & Carcamo, 2014).

Depression and anxiety in Haiti. Caribbean women have the highest HIV-infection rates among women in the Americas (UNAIDS Global report, 2013; Castro &

Farmer, 2005; Deacon, 2006). In a study conducted in Haiti, it was found that depression and negative attitudes about ART directly predicted poorer adherence (Malow et al., 2010). Findings demonstrate that depression and anxiety are common among the target population and rank among the strongest predictors of non-adherence to ART. Other studies have presented similar findings in Haiti and other Caribbean countries (Malow et al., 2013; Monroe et al., 2013; Maharaj et al., 2013; Garcia, Bayer, & Carcamo, 2014; Baird et al., 2012)

Social Factors

In addition to psychological factors, this proposed dissertation also examined the role of some social factors, such as availability of perceived stigma, marital status, and education, on adherence to medication.

Perceived Stigma. The first seminal work on the role of stigma on health was published in the 1880s by Erving Goffman. Goffman, a sociologist, developed the benchmark social theory of the association between stigma and disease (Sumari-deBoer et al., 2012). Stigma is defined as an attitude and behavior toward a social group of a set of people based on some physical, behavioral, or social trait perceived as being different from the group norms (Sumari-deBoer et al., 2012). There are multiple studies focused on AIDS-related stigma as a barrier to counseling and testing, as well as its role in negatively affecting HIV care (Gordillo et al, 1999; Neame & Hammond, 2005; Riekert & Drotar, 2002; Reynolds et al., 2004; Sumari-deBoer et al., 2012; Herek, 1999; Deacon, 2006; Brown, Trujillo, & Macintyre, 2001). Stigma has several challenges, but the mechanisms by which it relates to AIDS still needs to be studied further. Due to this

complexity, most researchers advocate for a blend of anti-stigma interventions for HIV/AIDS (Brown et al., 2001), such as community educational communication campaigns, and suggest that education about stigma is also included in counseling, coping skills, and contact with PLWH (Sankar et al., 2002; Lopez et al., 2007).

Perceived stigma and adherence. Fear, discrimination, and shame are all associated with stigma. This can cause an individual with HIV/AIDS to have negative psychological outcomes (Gordillo et al., 1999), avoid care and services (Cats et al., 2000; Sumari-deBoer et al., 2012; Herek, 1999; Deacon, 2006; Brown et al., 2001), impede adherence to ART (Sowell & Phillips, 2010; Katz et al., 2013; Ansari & Gaestel, 2010; Li et al., 2011) and subsequently continue the spread of the disease (Gordillo et al., 1999; Sumari-deBoer et al., 2012).

Perceived stigma and adherence in females. Studies have found that stigma may be problematic especially among females (Fawzi et al., 2010; DeSantis, Thomas, & Sinnett, 1999; Arrivillaga et al., 2011; Do et al., 2010; Mills et al., 2006; Lillard & Panis, 1996; Smith & Waitzman, 1994; Bourne, 2009; Waldron, Hughes, & Brooks, 1996). Researchers found that women reported selective adherence to ART in order to protect themselves and their children (Smith & Waitzman, 1994; Bourne, 2009; Waldron et al., 1996; Mitiku, Abdosh, & Tekelmariam, 2014) and noted that taking medication reminded them of their diseases (Mitiku et al., 2014; Peltzer et al., 2010). Researchers have found that social forces, such as racism, sexism and poverty, not only aggravate perceived stigma when all are present, but especially more where political violence and social inequalities also exist (Sumari-deBoer et al., 2012). Additionally, gender inequality also plays a significant role in AIDS-related stigma; the disclosure of HIV infection can lead

to higher risk of domestic violence than in environments where women enjoy gender equality (Lucas, 2005; Kobin & Sheth, 2011; Bangsberg et al., 2001; Sumari et al., 2012), and lead to declines in HIV testing (Paasche-Orlow et al., 2006).

Relationship status and educational attainment. There are multiple studies that indicate that literacy, especially low health literacy (Franke, Murray, & Shin, 2011; Weiss et al., 1994), and marital status (Parsons, Rosof, & Mustanski, 2008) has been associated with low adherence to ART. A study in Ethiopia, examining ART adherence among 238 HIV-positive individuals, found that higher adherence rate was observed among participants with high school and above education and single study participants, compared to married study participants. However, these factors did not significantly affect the adherence rate of the participants (DiMatteo, 2004; Paasche-Orlow et al., 2006). Similar findings and results were also reported by other studies (DiMatteo, 2004; Paasche-Orlow et al., 2006; Mitiku, Abdosh, & Teklemariam, 2013; Peltzer et al., 2010). Since the formal education rates in Haiti are reported to be among the lowest in the Western Hemisphere (UNICEF, 2009; WHO, 2013), this study evaluated whether similar results were obtained.

Summary of the literature

This study examined the relationship between adherence to ART and a number of variables, including depression and anxiety, beliefs about medicine, social support, perceived stigma, relationship status and educational attainment among HIV-positive female Haitian alcohol users. The Theory of Planned Behavior/Reasoned Action and the

Information Motivation Behavioral (IMB) Skills model were utilized to help contextualize the research findings.

The literature shows that inadequate ART adherence is associated with increased progression to AIDS, mortality, emergence of viral resistance, and higher risk of HIV/AIDS transmission. There is limited research on adherence among women in the Caribbean, however studies suggest that increased access to ART has had a significant impact on life expectancy. Improvements in ART adherence in the Caribbean may be achieved by improving counseling, reducing side effects of medications, and most importantly, focusing attention on alcohol users.

The research has shown that social support is a critical factor in improving adherence. This support may include emotional and instrumental support as well as having supportive family members. An individual's beliefs about medicine are also an important contributor to whether they will adhere to their medication regimen or not. Some research has even shown that beliefs may predict adherence better than their levels of depression.

In numerous studies, depression was a major predictor of lower adherence and several found that including treatment for depression and anxiety may have a positive outcome on adherence. Studies conducted in Caribbean countries demonstrate that depression and anxiety are common and rank among the strongest predictors of non-adherence to ART.

The impact of social factors on adherence was also investigated. For many individuals living with HIV, the fear associated with being stigmatized may cause them to avoid care and services. Racism, sexism and poverty have also been found to aggravate

perceived stigma. Research has shown that a blend of anti-stigma community interventions, counseling, and coping skills may be effective in reducing stigma. In terms of other social factors, higher adherence rates have been observed among participants with high school and higher education and among single study participants, compared to married study participants, however these factors were not significant.

These studies provide context for this current study and indicate the factors that may be related to adherence in the literature. The next chapter demonstrates how the measures, scales, and instruments used in this study fit into the model chosen for analysis.

CHAPTER III

METHODS

This dissertation research analyzed pre- and post-intervention measures from the parent study which utilized a randomized clinical trial and is described in the following paragraphs.

Parent Study. In 2008, Florida International University's (FIU) AIDS Prevention Program (APP), located in Miami, Florida, was awarded a grant by the National Institute of Alcohol Abuse and Alcoholism (NIAAA), entitled "Intervening with Haitian HIV+ Alcohol Users: An Environmental Psychosocial Framework." This five-year study was an adaptation and randomized trial of a Cognitive-Behavioral Stress Management (CBSM) intervention for enhancing safer sex practices, adherence to ART, and reducing alcohol or other drug (AOD) use in a predominantly poor urban population in Haiti. The study was conducted at the site of clinical research partner, the Groupe Haitien d' Etude du Sarcome de Kaposi et des Infections Opportunistes (GHESKIO) in Port-au-Prince, Haiti. A key focus of the study was to observe how HIV intervention outcomes could be influenced by environmental and psychological factors.

Parent Study: Design. Data were analyzed from this NIH-funded study, which was conducted by Dr. Jessy G. Dévieux and the late Dr. Robert Malow. Participants who met the study criteria and agreed to participate in the study completed the intake assessment; participants were recruited in cohorts of sixteen. At the end of the interventions, participants in both groups completed the post assessment, and then 3-, 6- and 12-month face-to-face follow up visits. Once a single-sex cohort of 16 males or 16 females had consented, participants completed baseline assessments and were

randomized in equal numbers to either the experimental group (CBSM-A) or the wait-list control group.

Participants in a given cohort followed the same assessment schedule in both conditions; they were interviewed at baseline, then within a week post-intervention, and at 3-, 6-, and 12 month post intervention. While the group assigned to the experimental condition participated in the small group CBSM intervention within a week of completing their baseline assessment, those randomized to the wait-list control group received the intervention after the 6-month assessment point. The primary proposed outcome for the parent study was a reduction in sexual risk behaviors, and the secondary proposed outcomes were reductions in AOD use, improved adherence to ART, utilization of HIV primary care services, and enhanced psychosocial health.

Parent Study: Recruitment. The recruitment sites were the clinics at the GHESKIO centers in Port-au-Prince, Haiti. GHESKIO was the first institution in the world dedicated exclusively to respond to HIV/AIDS. Established in 1982, GHESKIO has and continues to provide free medical care to all their HIV-positive patients. GHESKIO has the most experienced medical team in Haiti for the treatment and diagnosis of diarrheal diseases, tuberculosis, and STIs, including HIV infections (GHESKIO, 2013). GHESKIO and its network of clinics provide ART to approximately half of the Haitians who receive ART. Currently, the center receives about 200,000 patient visits annually; the population served by the clinic is comprised of Haiti's extreme poor and includes those at highest risk for communicable diseases (GHESKIO, 2013).

Parent Study: Inclusion/Exclusion Criteria. Participants were HIV-positive alcohol users (both men and women) living in Port-au-Prince, Haiti. Inclusion and exclusion criteria included:

- > 18, but < 60 years of age,
- Fluency in spoken Haitian Creole which is required to complete assessments and to participate in the intervention groups,
- Documentation of HIV seropositivity,
- At least one episode of unprotected anal or vaginal sex in the past 90 days,
- Recent alcohol consumption indicated by a score >7 on the AUDIT, which is a 10-item survey measuring alcohol consumption, dependence symptoms, and personal and social harm reflective of drinking over the past 30 days,
- Currently not cognitively impaired, since cognitive impairment may compromise the ability to comprehend and participate in the assessment and intervention,
- Currently not showing symptoms of a major psychiatric disorder, including psychosis or a high risk for suicide, since these conditions might compromise the ability to comprehend and participate in the assessment and intervention.

Parent Study: Method and procedures. All potential eligible participants at the GHESKIO Centers were informed of the study by the research staff. Those potential participants who were interested were offered a pre-screening interview. At meeting appointments, recruiters explained all aspects of the consent forms and the study

procedures, including assessment and group sessions, confidentiality, and the incentive structure. Special attention was given to ensure that participants understood that their involvement was strictly voluntary. After entering the GHESKIO center and meeting inclusion criteria, the contents of the 8 (eight) group sessions, the assessment instruments, and the sequence of events, which typical study participants experienced, are listed below:

1. First intake assessment
2. Second intake assessment
3. Randomization to one of the two conditions, CBSM-A or wait-list control
4. CBSM-A and wait-list control Post assessment
5. 3 month face-to-face follow-up
6. 6 month face-to-face follow up
7. Intervention: Wait list control group
8. 12 month face-to-face follow up

Parent Study: Participant Incentives. At each assessment visit, participants received reimbursement for transportation in Haitian currency (100 Gourdes = U.S. \$2.50), and were offered a phone card, and light refreshments equivalent to a total of U.S. \$5 per visit for the pre-and post-assessment visits. At the 3-month, 6-month and 12-month post-intervention follow up visits, participants received phone cards valued at 200, 250, and 300 Gourdes (U.S. \$5, U.S. \$6.25 and U.S. \$7.5) respectively, in addition to receiving reimbursement for transportation and light refreshments. Incentives for subject participation were provided immediately upon completion of each follow-up assessment. At each intervention group session, participants were also reimbursed for transportation

and received light refreshments. They also received one gift certificate to purchase food at a local store only after attending all the 8 intervention sessions.

Parent Study: Intervention. Cognitive Behavioral Stress Management – Adapted (CBSM-A) occurred in a structured weekly group format, and the sessions took place twice a week in 2-hour sessions for a total contact time of four hours per week for 4 consecutive weeks. In tailoring the intervention for this particular population, researchers were acutely aware of the importance of maximizing the cultural appropriateness of treatment strategies to all participants. Some considerations included participants’ familial orientation and the importance of trust and respect in interpersonal relationships, as well as specific Haitian attitudes toward sexuality and drug use. The format of this intervention was structured to: a) use group members and group leaders as coping role models (positive social comparisons and use of social support for informational purposes), b) encourage emotional expression and provide the opportunity to seek emotional and instrumental social support, c) replace feelings of powerlessness with a sense of mastery and altruism (self-efficacy changes), and d) discourage avoidance and encourage acceptance, reframing, planning, and active coping as strategies for dealing with HIV symptoms and their management.

Wait-list control group condition. In the parent study, the randomized design compared participants assigned immediately to the CBSM-A to those assigned to the wait-list control group who received the 8-session group intervention after their 6-month follow up assessment visit. Participants in the wait-list control were only contacted at their monthly medical clinic visit to ensure their well-being and continued interest in the study.

Secondary Analysis of Data Collected in Parent Study

Current Study

The parent study was used as a model in the design of this dissertation's study with the exception of a few changes, noted below in the design and participants sections.

Current Study: Design. The current study utilized the randomized controlled design, examining pre and post assessments for intervention effectiveness on ART adherence, as well as impacts of moderating variables upon the proposed outcome, but focusing on the female participants only.

Current Study: Participants. In addition to the parent study's inclusion/exclusion criteria, this dissertation research required the exclusion of male participants, as well as those who have not been prescribed antiretroviral medication since ART adherence is a primary outcome measure. Information regarding ART adherence was collected at the baseline and post-intervention. All potential eligible participants at the GHESKIO Centers were informed of the study by the research staff, and those interested were offered a pre-screening interview. During the pre-screening interview, the staff provided an overview of what the study involved, assured that the confidentiality of all data and test results and emphasized that the study was voluntary. Once it was clear that the participant understood and agreed to participate in the study, the informed consent form was signed, and the participant was provided a copy.

Variables and Measures

From the battery of measurement instruments utilized throughout the course of the parent study, the following instruments were selected to measure variables in this research.

Outcome Measure

- ART Adherence – adherence was determined by using the **Adherence to Combination Therapy in AIDS Clinical Trials Group (ACTG)** instrument. The ACTG was developed by the Adherence and Retention Sub-Committee of the ACTG Outcomes Committee (Reynolds et al., 2007). This ACTG instrument, which comprised of two self-reported questionnaires (baseline and follow-up), includes a measure of medication used in the week prior to assessment. The questionnaires and a 5-item options self-report responses have been used extensively to measure adherence to ART, both in the US and globally (Reynolds et al., 2007). The questionnaires not only measure medication adherence, but also assisted in assessing the understanding of adherence, as well as the participants' self-assessment of their adherence to the schedule and their reasons for non-adherence (Reynolds et al., 2007). For the purpose of the current study, participants' responses ranged from 1= all my pills every day (100%), 2= most of my pills (80%), 3 = about one half of my pills (50%), 4= very few of my pills (20%) and 5 = none of my pills (0%). In order to conduct more extensive analyses with the adherence variable, the parent study team converted the ordinal scale into a quasi-continuous scale using the percentages noted above (for example, all my pills = 1.0, very few of my pills = 0.2).

The Alcohol Use Disorders Identification Test (AUDIT)

- Severity of Alcohol Use: The AUDIT is a 10-item survey, which measures alcohol consumption, dependence symptoms, and personal and social harm, reflective of drinking over the past 30 days (Sanders et al., 1993). Each of the questions has a set of responses and each has a score ranging from 0 to 4; all the response scores are

added to determine the final score (Maisto et al., 2000). A score of eight or more on the AUDIT suggests hazardous or problem-level drinking (Maisto et al., 2000; Bohn, Babaor, & Kranzler, 1995; Babor et al., 2001). In previous external research, the AUDIT demonstrated good content, criterion, and construct validity and reliability (α from .77 to .83) (Bohn et al., 1995). According to Barbor et al, 2001, scoring and interpretation of the AUDIT are illustrated in Figure 6.

Figure 6. AUDIT Scores meaning and interpretations.

| Risk Level | AUDIT Scores | Description |
|-------------------|---------------------|--|
| Zone 1 | 0 – 7 | Low drinking risk or abstinence |
| Zone 2 | 8 – 15 | Consist of alcohol use in excess |
| Zone 3 | 16 – 19 | Harmful and hazardous drinking managed by counseling and continued monitoring |
| Zone 4 | 20 – 40 | Harmful and hazardous drinking managed by specialist for diagnostic evaluation and treatment |

Psychological Factors – the following instruments were used and collected data at baseline and post-assessment period:

- Social Support: using the **Perceived Availability of Support Scale (PAS)**, social support was determined using an 8-item scale to indicate the likelihood that an individual could count on others for emotional, financial, and instrumental support (Ethier et al., 2002). This scale was originally developed for a study of persons with HIV, and responses for each item range from 1 (definitely not) to 5 (definitely yes). Responses ranged from 0 = never to 4 = always. For the purpose of this current study,

only 7 items from the scale focusing on partner support were utilized to measure partner support. A high score in this survey instrument indicated more perceived support, the minimum possible score was 0 and maximum score of 28. For the purpose of this current study, perceived availability of support range meaning and interpretations were as follow 0 – 16 = low perceived support and 17 – 28 = high perceived support. In previous external research, Cronbach's alpha for this measure was found to be excellent, which was .85 for the HIV-positive cohort (Ethier et al., 2002; Ickovics et al., 2000).

- Beliefs about Medicines: **The Belief about Medicines Questionnaire (BMQ)** measures participants' personal beliefs about the necessity of their prescribed medication and their concerns about taking it. It also assists in assessing relations between beliefs and reported adherence (Castro, 2005). The BMQ includes two sections: (1) the BMQ-Specific (two 5-item factors) which assesses representations of medication prescribed for personal use and (2) the BMQ-General (two 4-item factors) which assesses beliefs about medicines in general. In the parent study, a revised version of the BMQ (14-items) was utilized. The questionnaire was broken down into four subscales on a 5-point scale (1 = strongly agree; 2 = agree; 3 = uncertain; 4 = disagree and 5 = strongly disagree). The 4 subscales in total, 2 about medications in general – Distrust (8-items) and Benefit (5 items) which assessed perceptions about medicine in general; and 2 about highly active antiretroviral therapy (ART) – Necessity (8 items) and Concerns (11 items) assessed perceptions about ART (Gonzalez et al., 2007). The revised version has the same subscales but fewer items were utilized in the current study. The subscales were scored by multiplying number

of items in each subscale by number of scale responses and composite scores of each subscale were interpreted as follows and illustrates on Figure 7.

- Distrust Subscale - scores near 20 (the maximum score) indicated that the person trusts medications a lot; the higher the score, higher the trust.
- Benefits Subscale - scores near 10 (the maximum score) meant that the person *does not* see any benefits to taking medications; the Lower the score, greater the benefit
- Necessity of ART subscale -: scores near 20 (the maximum score) meant that the person *does not* see the necessity of taking medications; lower the score, greater the necessity.
- Concerns about ART subscale - scores near 20 (the maximum score) indicated that the person *has no* concerns about taking medications; higher the score, lower the concern.

Figure 7. Beliefs about medicines scores and interpretations

| <i>Beliefs about Medicines Subscales</i> | | | | |
|--|---|--|--|--|
| | Distrust | Benefit | ART – Necessity | ART – Concerns |
| Minimum score | 4 | 2 | 4 | 4 |
| maximum score | 20 | 10 | 20 | 20 |
| Low score range | 4 – 12 does not trust medicine in general | 2 – 6 greater benefit about medicine in general | 4 – 12 greater the necessity of medications | 4 – 12 high concern about medications |
| High score range | 13 – 20 does trust the medicine in general | 7 – 10 does not see benefit about medicine in general | 13 – 20 does not see the necessity of medications | 13 – 20 low concern about medications |

Studies found that adherence was associated with general attitudes to medicines; people who believed that medicines were harmful were less likely to take medicines as prescribed (Ickovics et al., 2000). In a previous research, the Cronbach's alpha for this instrument was found to be satisfactory and ranged from 0.69 - 0.76 (Berger, Ferrans, & Lashley, 2001).

- The **Center for Epidemiological Studies-Depression (CES-D)**, published in 1977, is a 15-item measure that asks how often an individual has experienced symptoms associated with depression, such as restless sleep, poor appetite, and feeling lonely, over the past week. Response options range from 0 to 3 for each item (0 = rarely or none of the time, 1 = some or little of the time, 2 = moderately or much of the time, 3 = most or almost all the time). Scores range from 0 to 60, with high scores indicating greater depressive symptoms (Mardby, Akerlind, & Jorgensen, 2007; Lewinsohn et al., 2007). The CES-D also provides cutoff scores (e.g., 16 or greater) that aid in identifying individuals at risk for clinical depression, with good sensitivity and specificity and high internal consistency (Radloff, 1977). CES-D, scores of 16 – 26 are considered indicative of mild depression and scores of 27 or more indicative of major depression (Zich, Attkison, & Greenfield, 1990; Ensel, 1986). Previous studies found the cut-off scores of 27 more useful for screening medical patients for depression than the standard cut-off of 16 (Ensel, 1986; Zich et al., 1990; Roth et al., 2008). In a previous study, the internal consistency reliability was good for the overall CES-D scale ($\alpha = 0.88$) and for its four factors ($\alpha = 0.67 - 0.88$) (Roth, Ackerman, Okonkwo, & Burgio, 2008).

- **The State Trait Anxiety Inventory (STAI)** a 20-item questionnaire measures anxiety in adults (Thombs et al., 2008). The STAI measures two types of anxiety – temporary condition of “state of anxiety” (STAI-S-Anxiety) and general and long-standing “trait anxiety” (STAI-T-Anxiety). Each item is rated on a four-point scale with higher scores positively correlated with higher levels of anxiety (Spielberger et al., 1983). Responses range from 1 = not at all, 2 = somewhat, 3 = moderately and 4 = very much. Range of scores is from 20 – 80; with higher scores indicating higher anxiety in the present state. For purpose of the current study, STAI scores were analyzed as 20 – 40 = low level of anxiety and 41 – 80 = higher level of anxiety. The essential qualities evaluated by the STAI-S-Anxiety scale are feelings of apprehension, tension, nervousness, and worry. Scores on the STAI-S-Anxiety scale increase in response to physical danger and psychological stress. Additionally, the STAI-S-Anxiety score decreases as a result of relaxation training. On the STAI-T-Anxiety scale, consistent with the trait anxiety construct, psychoneurotic and depressed patients generally have high scores. A previous study found that the internal consistency coefficients for the scale range from .86 to .95 (Spielberger, 1989).

Social Factors – these instruments were used and collected data at baseline only:

- Demographic/Background Characteristics (baseline) – adapted from the Centers for Disease Control and Prevention’s Intervention for HIV-Seropositive IDUs—Research and Evaluation (Barnes, Harp, & Jung, 2002), assesses general questions about the participants’ life. This instrument was used to collect variables such as **relationship status** and **educational attainment**. **Relationship status** was obtained by asking

about marital status; responses range from 1 = single, 2 = married, 3 = separated, 4 = divorced, 5 = widowed and 6 = common law. **Educational attainment** responses range from 1 = 6th grade or less to 5 = any graduate training.

- **Stigma: The Perceived Stigma of HIV/AIDS** scale (Krain & Fitzgerald, 2005; Ghose et al., 2013; Castro & Farmer, 2005) was used to assess the participants' perceptions of HIV/AIDS related stigma. The scale is based on the conceptualization of stigma as having internalized as well as externalized components. The authors, Westbrook and Bauman (1996), hypothesize that stigma will cause greater distress and lower self-esteem when the stigmatizing beliefs of others and the externalized dimensions are internalized. The instrument has two scales. **The Perceived Stigma of HIV/AIDS: Personal View** subscale is a 24-item instrument including stigma items that reflect shame, guilt, blame, embarrassment, and poor self-worth because of HIV. Scores ranged from 24 to 96, with lower scores indicating more internalized stigma. **The Perceived Stigma of HIV/AIDS: Public View** subscale contains 24 items designed to obtain the participant's perception of social stigma. Scores ranged from 24 to 96, with lower scores indicating more perception of public stigma. For the purpose of this study, participants are asked to respond to each item using the Likert scale (strongly agree, agree, disagree and strongly disagree) and possible total combined scores ranging from 48 to 192, with a higher scale score indicating a lower degree of perceived HIV-related stigma. In a previous study, the HIV Stigma Scale was reliable and valid with a large, diverse sample of people with HIV; coefficient alphas between .90 and .93 for the instrument provided evidence of internal

consistency reliability (Berger, Ferrans, & Lashley, 2001). In the parent study, this questionnaire was only administered at baseline.

Statistical analysis

Sample Size and Data Analysis

From the parent study, a total of 272 participants completed the intervention sessions, and pre- and post-test data have been collected on the variables of interest for this proposed dissertation; 173 (63.6%) were female of whom 94 (54.3%) were randomly assigned to the intervention and 79 (45.7%) to the wait-list comparison group. The addition of new exclusions (i.e. male participants, as well as those who have not been prescribed nor taking ART) in this study reduced the available sample to 116 participants. In order to determine power for independent samples, the latest version of G*Power, a tool to compute statistical power analyses, was used (Faul, Erdfelder, Lange, & Buchner, 2007; Faul, Erdfelder, Bucher, & Lang, 2009).

ANOVAs, point biserial correlations and t-tests were used to test hypotheses for determination of a significant difference between experimental and control groups (hypothesis #1) and to also analyze strengths of associations between ART Adherence and other covariates (hypothesis #2 - #5 and #8). Analysis of Variance (ANOVA) is a collection of statistical models used to analyze the differences between group means and their associated procedures, such as variation among and between groups. Developed by R.A. Fisher, in the ANOVA setting, the observed variance in a particular continuous variable is portioned to components attributable to different sources of variation.

ANOVA will be used to test hypotheses to analyze the significant difference between social factors, such as perceived stigma, relationship status, and educational attainment as well as the effect of alcohol abuse (hypothesis #6 - #8), on the dependent variable (adherence to ART) (Montgomery, 2001; Gelman, 2005).

In the next chapter, the reported results will be summarized.

CHAPTER IV

RESULTS

Study Participants

Of, 173 (63.6%) female patients, 94 (54.3%) were randomly assigned to the intervention and 79 (45.7%) to the wait-list comparison group. Of the 173 females in the total sample, the study sample was reduced to 116 (65 in the intervention and 51 in the wait-list control group) participants after exclusion of those who had not been prescribed ART or who reported not taking ART at the initial assessment.

Characteristics of sample at Baseline

Participants' ages ranged from 19 to 55 years old. The average age was 36 years with a standard deviation of 7.96. There was no significant difference between the intervention group and the wait list control group on age ($t(114) = -.05, p = .963$). Participants answered questions on both the name of the antiretroviral medications they took, and the doses and number of pills consumed each day. Among the participants in the current study, approximately 25.9% ($n = 30$) reported taking only one pill per day, while the majority ($n = 82, 70.7%$) reported taking two pills per day. Only four individuals (3.4%) reported taking their ART as three pills a day.

Participants in the study reported on their marital status. The sample was primarily composed of women who were involved in a relationship ($n = 67; 57.76%$). Among those in a relationship, 6.9% ($n = 8$) were married and 50.8% ($n = 59$) were in a common law relationship ($n = 59$). There was no significant difference between the intervention group and the wait list control group with regard to marital status (chi square

= .34, $p = .576$). Participants also reported on the highest level of education or schooling that they completed. The sample population was homogenous with little variability in educational attainment among this group of Haitian females. The vast majority (93.3%) had less than a high school diploma. Women in the intervention group were over 1.6 times as likely to have had more than six years of education than control group members ($p = .048$).

Table 1

Comparison of characteristics at baseline, by assignment, in women participating in the randomized clinical trial of the adapted Cognitive-Behavioral Stress Management (CBSM-A), confined to (a) categorical variables and (b) continuous variables.

1a. Categorical variables at baseline, by study assignment

| Characteristic | CBSM-A N=65 (%) | Comparison N=51 (%) | Total | P |
|---|-----------------------|---------------------------|-----------|-------|
| Marital status: in a relationship n (%) | 36 (55.4) | 31 (60.8) | 67 (57.8) | .576 |
| Education: more than six years n (%) | 30 (46.2) | 15 (30.0) | 45 (38.8) | .048* |
| Baseline AUDIT* score=8 or more | 54 (87.1) | 36 (76.6) | 90 (82.6) | .152 |
| Baseline ART Adherence | | | | |
| Perfect (all doses) | 25 (38.5) | 21(41.2) | 46 (39.7) | .624 |
| Most | 11 (16.9) | 7 (13.7) | 18 (15.5) | |

*Significant at $\alpha < .050$

1b. Continuous variables at baseline, by study assignment

| Characteristic | CBSM-A Mean (SD) | Comparison Mean (SD) | Total | P |
|------------------------|---------------------|-------------------------|------------|------|
| Mean age (years) (SD) | 35.97 (8.16) | 36.04 (7.8) | 36.0 (7.9) | .963 |
| Mean AUDIT Score | 17.4 (8.7) | 14.8 (8.2) | 16.3 (8.6) | .110 |
| Baseline ART Adherence | | | | |
| Perfect (all doses) | 25 (38.5) | 21(41.2) | 46 (39.7) | .624 |
| Most | 11 (16.9) | 7 (13.7) | 18 (15.5) | |
| Mean ART Adherence | .66 (.35) | .64 (.39) | .66 (.37) | .740 |

| Score | | | | |
|--|--------------|--------------|--------------|-------|
| Mean Stigma Score | 126.9 (16.5) | 129.1 (16.3) | 127.9 (16.4) | .510 |
| Mean Social Support Score | 15.4 (4.9) | 16.5 (5.4) | 15.9 (5.1) | .271 |
| Mean Score, Depression | 33.9 (9.8) | 34.4 (9.5) | 34.1 (9.7) | .833 |
| Mean Score, General Distrust of Medication | 10.4 (2.4) | 10.1 (1.9) | 10.3 (2.2) | .590 |
| Mean Score, General Benefit of Medication | 3.9 (.65) | 3.8 (.54) | 3.9 (.60) | .766 |
| Mean Score, ART Concerns of Medication | 12.0 (2.8) | 11.6 (2.5) | 11.8 (2.7) | .387 |
| Mean Score, ART Necessity of Medication | 7.6 (1.8) | 7.6 (1.0) | 7.6 (1.5) | .8925 |
| Mean score of Anxiety | 52.8 (8.2) | 54.7 (8.4) | 53.6 (8.3) | .225 |

Study Outcomes

There was no significant difference on alcohol use, perceived stigma and partner support, and beliefs about medicine between the intervention and wait-list control groups at post-assessment (Table 2). Adherence to ART was determined by the average percent of time participants self-reported taking pills as prescribed during the last seven (7) days. In the sample at baseline, a higher percentage of optimal adherence, meaning taking medication 100% of the time as prescribed was seen in 39.7% of subjects (n = 46) compared to only 29.3% (n = 32) at post-assessment. The mean adherence score at post-assessment was .52 (SD = .38). This analysis suggests an overall decline in adherence from baseline to post-assessment in the total sample (which includes intervention and wait-list control groups). At post-assessment, only 24 (36.9%) of intervention and 14 (27.4%) of wait-list control group members reported perfect adherence or having taken “most” doses in the past seven days (p=.846); which was not significant.

At baseline depression scores ranged from 1 - 56 (n = 116; M = 34.14; SD = 9.66) and did not differ significantly between the intervention and control groups (Table 1). At

post-assessment, depression symptomatology was significantly lower in in the intervention than in the wait-list control group (Table 2). Further analyses are discussed in the hypotheses section. Similarly, anxiety scores, which did not differ significantly at enrollment, were significantly lower in the intervention group members than wait-list control group members post-assessment.

Table 2

Comparison of social and psychological factors at post-assessment, by assignment to the adapted Cognitive Behavioral Stress Management (CBSM-A) intervention or wait-list control condition.

| Factor | CBSM-A N (%) | Wait-List Control N (%) | t/chi square | P |
|--|-------------------------|--|---------------------|----------|
| Proportion AUDIT* score=8 or more | 38 (58.5) | 24 (47.1) | .11 | .737 |
| Mean Score, Depression Screen | 26.4 (11.3) | 33.3 (9.4) | -3.42 | .001** |
| Mean Score, Anxiety | 51.9 (8.4) | 55.9 (8.3) | -2.51 | .014* |
| Mean Score, General Distrust of Medication | 10.3 (2.7) | 10.2 (2.6) | .26 | .798 |
| Mean Score, General Benefit of Medication | 3.8 (.91) | 3.87 (1.1) | -.08 | .933 |
| Mean Score, ART Concerns of Medication | 12.7 (3.5) | 11.6 (3.4) | 1.61 | .111 |
| Mean Score, ART Necessity of Medication | 7.3 (1.8) | 7.2 (1.4) | .25 | .801 |
| Mean score, Social Support | 15.9 (5.2) | 15.6 (5.2) | .29 | .776 |

*Significant at $\alpha < .050$; ** Significant at $\alpha < .010$

Statistical Analyses

Research Question 1: Is the Cognitive Behavioral Stress Management – Adapted (CBSM-A) intervention effective in improving ART adherence among HIV-positive Haitian female alcohol users?

Hypothesis 1: Female participants in the CBSM-A group will show better ART adherence than those in the wait-list control group.

Adherence rates significantly decreased for both groups combined ($F(1, 108) = 8.79, p = .004$). On average, for both groups combined, adherence decreased from .65 (SD = .37) at baseline to .52 (SD = .38) at post assessment. There was no significant difference between the intervention and control groups with regard to the magnitude of change between baseline and post assessment [$F(1, 108) = 1.21, p = .274$]. In addition, there was no significant difference between the intervention and control groups irrespective of time [$F(1, 108) = 1.49, p = .226$]. Hypothesis 1 was not supported.

Table 3

Descriptive statistics for ART adherence scores for CBSM-A and wait-list control group at baseline and post-assessment (n=110)

| <u>Intervention Status</u> | <u>N</u> | <u>Mean</u> | <u>Standard Deviation</u> |
|----------------------------|----------|-------------|---------------------------|
| <i>Baseline</i> | | | |
| CBSM-A | 63 | .66 | .35 |
| Wait-list control | 47 | .64 | .39 |
| <i>Post-Assessment</i> | | | |
| CBSM-A | 63 | .57 | .36 |
| Wait-list control | 47 | .46 | .40 |

The overall adherence survey also examined some of the common reasons why participants failed to take their ART medications. A total of 10 questions, completed both at baseline and post-assessment, focused on possible reasons for which participants missed their pills during the past seven days. Table 4 demonstrates the descriptive statistics at baseline (n = 116). The following were the three most common reasons participants failed to take ART as prescribed at baseline: 18% reported ‘I had problems taking pills at specified times (with meals, on empty stomach, etc.); 14.6% each reported ‘I forgot to take the pills’ and ‘I did not want others to notice.’ At post-assessment, of the 110 participants who responded to the ART questionnaire, only 23 participants (21%) responded to these questions; the remaining 79% (n = 87) responded that these statements were not applicable. Analysis was not conducted for these questions for post-assessment due to the very low percentage of responses. Adherence did not vary significantly at baseline by whether patients reported that they felt worse when they took the pills, had too many pills, ran out, did not think they needed the pills, were away from home or were confused or uncertain on how to take the pills. However, reporting forgetting to take the pills, not wanting other to notice, being too busy or having problems taking pills at certain times, were correlated with significantly lower adherence (Table 4).

Table 4

Statistics for common reasons participants failed to take ART among CBSM-A and wait-list group members at baseline (n = 116)

| | I forget to take the pills | I did not want others to notice | I am too busy | I had problems taking pills at specified times (with meals, on empty stomach, etc.) |
|-----|----------------------------|---------------------------------|---------------|---|
| No | 99 | 99 | 111 | 95 |
| Yes | 17 | 17 | 5 | 21 |

| | | | | |
|----------------|-------|-------|--------|-------|
| Correlation | -.230 | -.197 | -.247 | -.207 |
| Sig (2-tailed) | .013* | .034* | .008** | .026* |

*Correlation is significant at the 0.050 level (2-tailed)

** Correlation is significant at the 0.010 level (2-tailed)

Research Question 2: Are the psychological factors—social support, depression, anxiety, and beliefs about medicine—associated with ART adherence at baseline and post-assessment among HIV-positive Haitian female alcohol users in the intervention group?

Research Question 3: Do psychological factors—social support, depression, anxiety, and beliefs about medicine— improve from baseline to post-assessment among HIV-positive Haitian female alcohol users at the end of the intervention?

Point biserial correlations were calculated to determine the relationships between psychological factors – social support, depression, anxiety, and beliefs about medicine – and ART adherence. Table 3 demonstrates findings.

Hypothesis 2a: Lack of social support will be inversely related to ART adherence among HIV-positive Haitian adult females.

There was no significant relationship between social support and ART adherence at baseline ($r = -.097$, $p = .440$). However, at post-assessment adherence was significantly correlated with social support ($r = -.249$, $p = .049$). This hypothesis was partially supported.

Hypothesis 2b: Social support will improve among HIV-positive Haitian adult females at the end of the intervention.

Among those in the intervention group, social support did not change from baseline ($M = 15.36$, $SD = 4.94$) to post-assessment ($M = 15.86$, $SD = 5.18$); $t(64) = -.93$, $p = .356$). This hypothesis was not supported.

Hypothesis 3a: Depression and anxiety will be inversely correlated with ART adherence among HIV-positive Haitian adult females.

Depression. There were no significant relationships between depression and ART adherence at baseline ($r = -.023$, $p = .856$) or at post-assessment ($r = .058$, $p = .655$). This hypothesis was not supported.

Anxiety. There were no significant relationships between anxiety and ART adherence at baseline ($r = .195$, $p = .120$) or post-assessment ($r = -.175$, $p = .174$). This hypothesis was not supported.

Hypothesis 3b: Depression and anxiety will improve among HIV-positive Haitian adult females at the end of the intervention.

Depression. A paired samples t-test was utilized to assess changes in depression between baseline and post assessment for those in the intervention group. On average depression decreased from 34.06 ($SD = 9.85$) to 26.37 ($SD = 11.27$) ($t(62) = 5.54$, $p < .001$). At post-assessment, patients assigned to the CBSM-A had significantly lower depression scores than patients assigned to the wait-list controls

Anxiety. A paired samples t-test was utilized to assess changes in anxiety between baseline and post assessment for those in the intervention group. On average anxiety scores did not improve from baseline 52.65 (SD = 8.25) to post-assessment 51.89 (SD = 8.35) ($t(63) = .74, p = .462$). Hypothesis 3b was partially supported.

Hypothesis 3c. Patients randomized to CBSM-A will have lower depression and anxiety scores at post-assessment than those assigned to wait-list control group.

Depression. At post-assessment, patients assigned to the CBSM-A had significantly lower depression scores than patients assigned to the wait-list controls (26.4 [SD=11.3] versus 33.3 [SE=9.4]; $p=.001$).

Anxiety. Similarly, at post-assessment, patients assigned to the CBSM-A had lower anxiety scores than control-group members (51.9 [SD=8.4] versus 55.9 [8.3]; $p=.014$). Hypothesis 3c was supported.

Hypothesis 4a: High beliefs in the value of medicines will be positively associated with ART adherence among HIV-positive Haitian adult females.

Scores in distrust ($r = .111, p = .382$); benefits ($r = -.141, p = .263$); ART concerns ($r = -.025, p = .842$) and ART necessity subscales ($r = -.067, p = .597$) at baseline were not associated with significant differences in adherence. Similarly scores at post-assessment, (distrust ($r = .136, p = .289$); benefits ($r = -.054, p = .673$); ART concerns ($r = .076, p = .569$) and ART necessity subscales ($r = .031, p = .816$) were not associated with significant differences in adherence. This hypothesis was not supported.

Hypothesis 4b: Beliefs in the value of medicines will improve among HIV-positive Haitian adult females at the end of the intervention. Hypothesis 4b was not supported.

Paired-sample t-tests were conducted to compare baseline and post-assessment scores:

- BMQ scales: general distrust did not significantly change between baseline 10.35 (SD = 2.38) and post-assessment 10.30 (SD = 2.72) for the intervention group $t(62) = .126, p = .900$.
- BMQ scales: general benefits did not significantly change between baseline 3.88 (SD = .65) and post-assessment 3.75 (SD = .91) for the intervention group $t(63) = 1.07, p = .289$.
- BMQ scales: ART concerns did not significantly change between baseline 12.07 (SD = 2.74) and post-assessment 12.68 (SD = 3.52) for those in the intervention group $t(59) = -1.38, p = .173$.
- BMQ scales: ART necessity benefits did not significantly change between baseline 7.57 (SD = 1.72) and post-assessment 7.28 (SD = 1.82) for those in the intervention group $t(59) = 1.25, p = .217$.

Table 5

Comparison of behavioral and psychological factors at post-assessment, for the adapted Cognitive Behavioral Stress Management (CBSM-A) intervention.

| Factors | Adherence Mean (SD) | Prevalence 95% CI | t | P |
|---------------|---------------------|-------------------|------|------|
| Depression | .64 (.46) | -.27 to .20 | -.31 | .761 |
| Not depressed | .68 (.30) | | | |
| High Anxiety | .67 (.34) | | | |

In summary, regarding psychological factors – social support, beliefs about medicines, depression and anxiety were not correlated with adherence. However, citing various reasons why they would not take their medication (forgetting, not wanting others to notice, being too busy, and having problems taking pills at specific times relative to meals) was significantly associated with lower adherence.

Social support and all scores in the BMQ subscales did not significantly change between baseline and post-assessment. However, depression significantly decreased from baseline to post-assessment in the intervention group. Anxiety did not decrease from baseline to post-assessment. At post-assessment, both depression and anxiety scores were significantly lower in patients in the CBSM-A group than in controls.

Research Question 4: Do the social factors — perceived stigma, relationship status and educational attainment — affect ART adherence among HIV-positive Haitian female alcohol users?

Hypothesis 5: Lack of perceived stigma will be inversely related to ART adherence among HIV-positive Haitian adult females.

There was no significant relationship between stigma and ART adherence at baseline ($r = -.021$, $p = .880$) or stigma at baseline with ART adherence at post-assessment ($r = -.087$, $p = .521$). This hypothesis was not supported.

Hypothesis 6: Participants in a relationship will have higher adherence than those not in a relationship.

No significant difference was seen in mean adherence scores at baseline or post-assessment by relationship status; (baseline: ‘in a relationship’ $M = .64$; $SD = .38$, ‘not in a relationship’ $M = .70$; $SD = .32$; $t [63] = .58$, $p = .566$; post-assessment: ‘in a relationship’ $M = .58$; $SD = .37$, ‘not in a relationship’ ($M = .56$; $SD = .36$; $t [61] = -.24$, $p\text{-value} = .812$). This hypothesis was not supported.

Hypothesis 7: Participants with lower educational attainment will have lower ART adherence values.

There was no significant difference in ART adherence for participants who reported having ‘less than a 6th grade education’ in this sample at baseline ($M = .62$; $SD = .36$) and those who reported ‘more than a 6th grade education’ ($M = .71$; $SD = .36$); $t (60) = -1.05$, $p = .296$ at baseline or at post-assessment (‘less than a 6th grade education’ ($M = .60$; $SD = .36$ ‘more than a 6th grade education’ $M = .51$; $SD = .37$; $t [58] = .968$, $p = .337$). This hypothesis was not supported.

Research Question 5: Does the degree of alcohol abuse affect ART adherence among HIV-positive Haitian female alcohol users?

Research Question 6: Does the degree of alcohol abuse change between baseline and post-assessment in response to the intervention among of HIV-positive Haitian female alcohol users?

Hypothesis 8a: Alcohol use will decrease among HIV-positive Haitian adult females at the end of the intervention.

For both groups combined, alcohol use significantly decreased between baseline and post-assessment from 18.58 (SD = 7.91) at baseline to 13.78 (SD = 6.93) at post-assessment ($F(1, 78) = 34.70, p < .001$). There was no significant difference between the intervention and control groups with regard to the magnitude of change between baseline and post-assessment ($F(1, 78) = 3.20, p = .078$). In addition, there was no significant difference between the intervention and control groups irrespective of time $F(1, 78) = .005, p = .943$. This hypothesis was partially supported.

Hypothesis 8b: Greater alcohol use severity will be associated with lower ART adherence among HIV-positive Haitian adult females.

There were no significant relationships between alcohol use and ART adherence at baseline ($r = .03, p = .804$) or at post-assessment ($r = .007, p = .961$) (Table 7). This hypothesis was not supported.

Table 7

Alcohol and ART adherence between baseline and post-assessment for both groups

| <u>Intervention Status</u> | <u>N</u> | <u>Mean</u> | <u>Standard Deviation</u> |
|----------------------------|----------|-------------|---------------------------|
| <i>Baseline</i> | | | |
| CBSM-A | 62 | 17.43 | 8.69 |
| Wait-list control | 47 | 14.79 | 8.24 |
| <i>Post-Assessment</i> | | | |
| CBSM-A | 50 | 13.34 | 6.40 |
| Wait-list control | 33 | 14.24 | 7.72 |

In summary, results from this current study show that none of the psychological factors - perceived social support, beliefs about medicines, depression and anxiety were

correlated with adherence neither at baseline nor at the end of the intervention. Additionally, social support, anxiety and the BMQ subscales did not significantly change between baseline and post-assessment. Depression significantly decreased from baseline to post-assessment, only in the CBSM-A group. However, at post-assessment, women in the CBSM-A group had significantly lower depression and anxiety scores than controls. Overall, there was a decrease in ART adherence from baseline to post-assessment among both the CBSM-A and wait-list control group. At the end of the intervention, there was a 23% decrease in the number of HIV-positive, female Haitian alcohol users who reported consuming alcohol. Furthermore social factors analyzed in this study, marital status, perceived stigma and education attainment, were also not correlated with adherence among the sample population. Several reasons for not taking medications were associated with reporting lower ART adherence, specifically, forgetting, not wanting others to notice, being too busy, and having problems taking pills at specific times relative to meals.

The next chapter will discuss the results illustrated in Chapter IV. The following chapter will also address limitations of the study, practical implications and recommendations for future research.

CHAPTER V

DISCUSSION

The purpose of this study was to determine whether an intervention that has been used successfully for treatment of depression had an impact on ART adherence, as well as on depression and anxiety, in female Haitian alcohol-abusing ART patients. It also sought to examine psychological predictors, such as, depression, anxiety, beliefs about medicine, and social support, as they relate to adherence to ART among HIV-positive female Haitian alcohol users. In addition, this study examined the role of stigma on adherence to ART. Participants' relationship status and education were also investigated in order to establish whether there was a link to ART adherence. Next, the study explored how the level of alcohol consumption among the participants affected their adherence to prescribed ART.

Several interesting findings emerged from this study. First, none of the psychological or social factors was statistically associated with ART adherence in this sample. Secondly, depression scores declined among the participants in the CBSM-A group and at post-assessment were significantly lower than in the controls, suggesting that the intervention was at least as effective in this group as in other populations. Similarly, the intervention group had significantly lower anxiety scores at post-assessment than controls. Lastly, alcohol use decreased significantly among the participants in both groups at the end of the intervention. The sample reported relatively high scores of perceived stigma and depression, as well as low scores of perceived social

support during the study, but these factors were not found to have a relationship with ART adherence. Statistically significant findings are summarized in this chapter.

Research Questions

Hypothesis 1: Female participants in the CBSM-A group will show better ART adherence than those in the wait-list control group.

In studies based in low-resource settings, ART adherence has ranged widely from as low as 54% (Weiser et al., 2003) to as high as 94% (Oyugi et al., 2004) in the sample under study. In the current study, there was an overall decrease in adherence. At post-assessment, there was an overall 16.4% decrease among the participants (CBSM-A and wait-list control) who reported taking all and most of the pills when compared to the baseline. There was also an increase in the percentage of participants who reported not taking any of the pills during the past seven days by 9.5%, at the end of the intervention. The reported decrease in adherence rates at post-assessment may be related to the desire of the sample population to please the interviewer and report higher compliance to medications at baseline; it is possible that participants felt more comfortable at the end of the intervention and were more honest about their levels of adherence (Simoni et al, 2007; Safren et al, 2006). The overall decrease in ART adherence was observed among both the CBSM-A and wait-list control group. Some of the most common reasons for missing the pills at baseline were aligned with perceived stigma. These findings are similar to other research that indicated addressing stigma (Colombini et al., 2014) improve adherence outcomes. Moreover, the association between lower adherence and

more banal issues (forgetting, busy, difficulty taking pills on an empty stomach or with meals) point to the possibility that the issues that drive non-adherence in this population have less to do with belief in the medication and more to do with the complicated lives that they lead, and the stigmatization of HIV.

Similar to the current study, others research has shown no significant improvement in adherence among participants who participated in group education and counseling in poor-resource settings (Safren et al., 2013; Berger et al., 2008; Sampaio-sa et al., 2008), suggesting that the study populations may have benefited from diverse types of intervention approaches, for example, an individual component, support for group members or environmental support (Thompson et al., 2012; Kagee et al., 2011; Chung et al., 2010; Kalichman et al., 2011; Haberer et al., 2013). However, several previous studies conducted in Haiti showed an improvement in HIV care and ART adherence associated with group members support (Naslund et al., 2014; Kimmel et al., 2013; Severe et al., 2010). These outcomes suggest further investigations are needed to determine the components which may contribute the most to improved adherence.

Hypothesis 2a: Lack of social support will be inversely related to ART adherence among HIV-positive Haitian adult females.

Hypothesis 2b: Social support will improve among HIV-positive Haitian adult females at the end of the intervention.

Hypothesis 2a was partially supported while 2b was not supported. The current study found that social support was related to adherence in this sample. Previous studies reported mixed outcomes with social support and ART adherence (Kovarth et al., 2015;

Langebeek et al., 2014; Kagee et al., 2010; Beng et al., 2011; Rivero-Mendez et al., 2010; Harris et al., 2011; Tabatabai et al., 2014; Kalichman et al., 2011; Haberer et al., 2013; Kagee et al., 2011). Previous studies among Caribbean women that examined social support generally found a relationship between social support and adherence to regimen (Beng et al., 2011; Rivero-Mendez et al., 2010; Harris et al., 2011). However some studies concluded that the presence of social support and knowledge about consequences of treatment interruptions were not sufficient to improve ART adherence; they suggested that adherence counseling sessions that provide problem-solving strategies for common barriers to HIV care may be required in order for adherence to improve (Tabatabai et al., 2014; Kalichman et al., 2011; Haberer et al., 2013; Kagee et al., 2011).

The current study analysis showed that for those in the intervention group, social support did not significantly change from baseline to post-assessment. Overall perceived social support was very low in both CBSM-A and wait-list control groups, with an overall average of 15.73 at both baseline and post-assessment. This finding suggests that HIV-positive female Haitian alcohol users in this sample were perhaps not receiving the level of social support that they felt that they needed and may have benefited from support from spouses and from others on ART (Sambas et al., 2010; Hovarth et al., 2013; Sasaki et al., 2012). These findings also suggest that there might be other confounding variables within this sample population, such as support or lack of support from health care staff and peer support, which were not examined in this study (Hovarth et al., 2013; Sasaki et al., 2012; Mugavero, Norton, & Saag, 2011). These other psychological factors may be associated with life circumstances that might play a role in reducing adherence.

Hypothesis 3a: Depression and anxiety will be inversely correlated with ART adherence among HIV-positive Haitian adult females.

Hypothesis 3b: Depression and anxiety will improve among HIV-positive Haitian adult females at the end of the intervention.

Hypothesis 3c: Patients randomized to CBSM-A will have lower depression and anxiety scores at post-assessment than those assigned to wait-list control group.

Hypothesis 3a was not supported by the analysis while Hypothesis 3b was only partially supported and Hypothesis 3c was supported. The current study found that neither depression nor anxiety were related to adherence in this sample. In this sample, no relationship was found between depression and ART adherence, it is possible that the participants overestimated their self-reported psychopathology and data regarding level of depression would have been strengthened if the depression diagnosis had been derived from diagnostic interviews instead of self-report (Simoni et al., 2011). Furthermore, changes in depression over time are often associated with changes in adherence; in this study, the relationship between depression and ART adherence was only examined at the beginning and end of the intervention, therefore it is possible that a longer follow-up might have yielded a significant relationship (Wagner et al., 2011).

With regard to depression, a majority of previous studies found a relationship between depression and ART adherence, with higher depression being associated with less adherence (Blashill, Gordon, & Safren, 2014; Langebeek et al., 2014; Sheth et al., 2015; Beer & Skarbinski, 2014; Ghose et al., 2013; King et al., 2012). However, some have shown an association with viral suppression, but not with adherence (Beck-Sague et al., 2014). Moreover, depression intervention studies have yielded inconclusive findings

to date with regards to ART adherence outcomes (Bottonari et al., 2013; Johnson et al., 2012; Springer, Dushai, & Azar, 2012) with some studies finding that antidepressant medication treatment use increased the probability of antiretroviral intake, rather than the intervention (Tsai et al., 2010; Tsai et al., 2013).

The current study's results showed no relationship between anxiety and ART adherence. In similar resource-poor settings other studies have reported higher anxiety levels being associated with lower ART adherence (Langebeek et al., 2014; Prappin, Wouters, & Booyesen, 2012; Tesfave & Bune, 2014). In this sample, it is possible that a relationship was not found between anxiety and adherence because of the current high levels of post-traumatic stress disorder associated with the aftermath of the 2010 earthquake; these levels, and the consequent resistance to change may explain the lack of significant findings (Cerdá et al., 2013; Koenig et al., 2014). The high level of anxiety among this population may also be related to partner conflict and other psychological factors related with life circumstance which may need to be addressed in order to improve adherence (Li et al., 2014; Siemieniuk, Krentz, & Gill, 2013; Trimble, Nava, & McFarlane, 2013).

For those in the intervention group, depression decreased significantly. Patients assigned to CBSM-A had significantly lower depression scores at post-assessment than controls, suggesting that the intervention, which is intended to treat depression, was effective in reducing depression. This improvement in mental health status is similar to other studies with racial/ethnic minority women infected with HIV and HPV which also implemented multi-component interventions focusing on coping skills and stress management techniques (Lopez et al., 2013; Logie James, Tharao, & Loutfy, 2014; King

et al., 2012; Duncan et al., 2012). Intervention group members also had significantly lower anxiety scores in post-assessment than controls, suggesting that the intervention was also effective in anxiety reduction.

Hypothesis 4a: High beliefs in the value of medicines will be positively associated with ART adherence among HIV-positive Haitian adult females.

Hypothesis 4b: Beliefs in the value of medicines will improve among HIV-positive Haitian adult females at the end of the intervention.

Neither hypothesis 4a nor 4b were supported. The current study also found that beliefs in the value of medicines were not related to ART adherence in this sample. The majority of previous studies have found a relationship between beliefs about medicine and adherence, with higher levels of beliefs of medicines associated with higher adherence and also the opposite (Cooper et al., 2011; Malow et al., 2013; Horne et al., 2013; Batchelder, Gonzalez, & Berg, 2014; Cooper et al., 2010; Groh et al., 2011). However, similar to this current study, another study also found that beliefs about medicines was not related to adherence (Adefolalu et al., 2015) concluding that ART adherence was more closely related to self-efficacy (Tyler-Viola et al., 2014; Adefolalu et al., 2015). When addressing psychological factors, TRA/TPB theory has tended to focus on attitudinal beliefs, self-efficacy, and normative and norm-related beliefs and activities. The current study suggest that the issues related to non-adherence in this sample are not so much related to intention or beliefs in the medication, but rather, practical issues related to the complex lives that alcohol-abusing female ART patients may lead. This is further complicated by the fact that they must juggle medication use while hiding it from

others, missing out on the adherence enhancement related to sympathetic “accompaniment” and support from others, suggesting that providing such support in the context of care may promote adherence (Behforouz, Farmer, & Mkherjee, 2004). In this sample, an integrative model of behavior change, whereby behavioral intentions combined with skills and environmental limitations affecting individual behavior, may be more suitable.

After assessing each of the four subscales of the BMQ questionnaire for both the CBSM-A and wait-list control groups, from baseline to post-assessment, none of the BMQ subscales improved significantly from baseline to post-assessment, in either group. Similarly, for those in the intervention group, none of the BMQ subscales improved significantly from baseline to post-assessment.

Hypothesis 5: Lack of perceived stigma will be inversely related to ART adherence among HIV-positive Haitian adult females.

Statistical findings offer no significant findings for Hypothesis 5. As mentioned in the previous chapter, perceived stigma was only assessed at baseline. This was due to the fact that the main goals of the intervention were to improve participants’ social network and decrease conflict by enhancing communication skills through assertion techniques. No relationship was found between stigma and ART adherence among the combined CBSM-A and wait-list control groups. Previous studies have found mixed outcomes in the relationship between stigma and adherence to medications, however most reported a higher level of perceived stigma being associated with lower ART adherence (Onyebuchi-Iwudibia & Brown, 2014; Sumari-de Boer et al., 2012; Masquillier et al.,

2015; Musheke et al., 2012; Bogart et al., 2013; Musheke et al., 2013; Cardarelli et al., 2008; Franke et al., 2011; Martinez et al., 2012; Katz et al., 2013). It is possible that a relationship was not found between stigma and adherence in this sample of HIV-positive Haitian female alcohol users because stigma was not measured at post-assessment. It is possible that an improved sense of peer-support and having an environment to confidentially discuss their experience with HIV may have increased adherence in this sample (Rasschaert et al., 2014; Naslund et al., 2014; Allen et al., 2011).

Although stigma was not significantly related to adherence, one of the more common (and significant) reasons reported for missing pills in the past seven days was that the participants were afraid that someone would notice them taking their medications. This reason appears to be indirectly associated with stigma.

Hypothesis 6: Participants in a relationship will have higher adherence than those not in a relationship.

Hypothesis 6 was not supported. Over half of the population reported being in a relationship, however no correlation was found between adherence and being in a relationship vs. not being in a relationship. Findings in this sample are similar to other studies in which marital status was not related to adherence; the researchers concluded that the role of gender and household dynamics may prevent females from successfully adhering to ART and the fact that partners may not be aware of their HIV-positive status (Mitiku, Abdosh, & Teklemariam, 2013; Peltzer et al., 2010; Skovdal et al., 2011).

Hypothesis 7: Participants with lower educational attainment will have lower ART adherence values.

Statistical findings offer no support for Hypothesis 7. Education may not have been a factor in this sample due the lack of variance. Over 90% of the participants had not obtained a high school diploma, with the majority reporting only a 6th grade level education and below. Similar findings were made in poor-resource settings which concluded that closer doctor-patient relationships and promoting self-efficacy among patients were predictors of successful of ART adherence, more so than education level (Campos et al., 2011; Arrivillaga et al., 2011). This finding does not imply that education is not an important predictor of adherence; further research with a sample with more diverse educational attainment may be necessary. No significant differences were found among the groups at either baseline or post-assessment.

Hypothesis 8a: Alcohol use will decrease among HIV-positive Haitian adult females at the end of the intervention.

Hypothesis 8b: Greater alcohol use severity will be associated with lower ART adherence among HIV-positive Haitian adult females.

Hypothesis 8a was only partially supported by the analysis while Hypothesis 8b was not supported. The current study found that for both CBSM-A and wait-list control groups, alcohol use significantly decreased from baseline to post-assessment. Although there was a 23% decrease in the number of participants who reported consuming alcohol at the end of the intervention, at post-assessment, the majority (74.7%) still reported an

AUDIT score of 8 and above (Zone 2), which indicates hazardous or problem-level drinking. This represents a decrease from Zone 3 (score ranging from 16 -19) at baseline.

The current study found that alcohol use was not related to adherence. Finding from previous studies report contradictory outcomes, with the majority reporting a relationship between alcohol and adherence, with higher alcohol use being associated with lower adherence (Harris et al., 2011; Teixeira et al., 2013; Raboud et al., 2011; Broyles et al., 2011). In this study, it is possible that a relationship was not found between alcohol use and adherence because data were assessed at baseline and end of the intervention, it is possible that more changes could have been observed at 3, 6 months and 12 months post-intervention. For future studies, alcohol users may require more focused attention and customized care in promoting adherence (Allen et al., 2011; Kekwaletswe & Morojete, 2014).

Limitations

One of the major limitations of this study was that the instrument used to measure adherence to ART was based on self-reported information and collected by interviewers at the GHESKIO Center. It is possible that participants provided responses that they thought were appropriate and/or wanted to please the interviewers. Other methods could have been used to indirectly measure adherence to medication within the sample population by viral load testing, which is very sensitive, particularly in the short term, to adherence recommended by the WHO (WHO, 2003). Other more direct method could be a time-sensitive pill count as well as electronic bottle-caps that record use, Medication Event Monitoring Systems (MEMS) (Parianti et al., 2001). These methods may have

yielded more accurate results among the population (Malow et al., 2013). Another general limitation is that all other measures used in this study were self-reported, though in general, such instruments have been reliable, especially among individuals in poor-resource settings.

Gathering a representative sample is vital to sound research. Analyses were also limited by sample size and sampling method. Convenience sampling does not ensure that the sample is representative of the population (Trochim, 2005). The sample of HIV-positive female Haitian alcohol users for this study was composed of women who were attending the GHESKIO center and seeking HIV care and management. Results from this study may not be generalized to the total female Haitian population as the sample may not have been representative. The sample was further limited by incomplete data on individual instruments.

Another limitation of the current study that merits more research is the issue of examining participants' responses for some of the variables at one point in time. In addition, due to the relatively short length of the intervention, it is possible that more changes could have been observed at 3, 6 months and 12 months post-intervention. Additionally, this study was limited to females' current psychological and social factors, which excluded their family and sexual history; these factors may have added more to the findings. Furthermore, discussion with participants, as they navigate and deal with treatment and management, how they acquired the disease and the amount of time since diagnosis would be valuable; these variables would have provided information regarding attitude and beliefs about their HIV status and willingness to enhance their health.

Finally, the fact that the results did not link psychological factors and adherence to ART could indicate that TPA/TPB was not the best theoretical model to predict adherence in the sample population. It is also possible that findings were not predictive of the variance in adherence because there were confounding variables that were not studied. For example, partner conflict and sexual violence were not examined in this study and could have provided additional information regarding barriers to adherence within the sample population. Although perceived social support was examined in this study, it mainly focused on financial and emotional support obtained from close family members and friends. Other factors, such as familial responsibilities, participants who are mothers and have children to take care of, and other responsibilities were not examined, and could have added to the reasons for non-adherence among the population.

Recommendations

The findings provided in the current study may provide a valuable contribution to the development of intervention programs among persons living with HIV/AIDS, especially among females in poor-resource settings. Haiti, which now has the second highest rate of HIV/AIDS in the Western Hemisphere, is still coping with the repercussions of the 2010 earthquake. Many individuals living in Haiti are now living with post-traumatic stress disorder, in addition to other mental health disorders which often go untreated and undiagnosed (Raviola et al., 2012). Assessing participants' mental status using an effective diagnostic method before introducing an intervention program is a valuable research opportunity. The WHO issued a call to action and proposed integrated mental health issues in intervention programs, especially in poor-resource settings

significantly impacted by the HIV/AIDS epidemic. This recommendation has particular relevance for Haiti (Bass et al., 2012) and more specifically among female alcohol users. Additionally, recommendations that interventions be focused on nutrition support and education should be prioritized for PLWH in Haiti and similar resource-poor settings (Palar et al., 2014).

Since adherence did not increase in this sample, the findings suggest that additional supportive and psychological services may be needed in order to promote higher adherence to ART among HIV-positive female women in third world countries devastated by the impact of HIV/AIDS. In addition, although neither depression nor anxiety were related to adherence, depression decreased in the intervention group, which is a positive finding in and of itself. Conversely, because of the limitations of self-reporting, especially in the clinic and/or to clinic staff, it is helpful to indirectly measure adherence by measuring viral load; in the end, the important outcome is viral load not adherence.

Beyond improving stress management skills to enhance adherence, there is an opportunity for improving interventions aimed at increasing support. An intervention that addresses support needs such as peer support and support from health care professionals could improve adherence to ART (Martinez et al., 2014; Palar et al., 2014). Allocating research funds to discovering significant factors affecting barriers to adherence among women, especially in the Caribbean and poor-resource settings, will lead to more effective interventions among this understudied population. Among the most promising such interventions are approaches that address the isolation, need for secrecy and chaotic lives that many underserved women endure including accompaniment (Behforouz et al.,

2004) and mobile text messages to remind patients to take their medication (Horvath et al., 2012). Both simplification of regimens so that there are no requirements for taking medications with food (Kalichman et al., 2015) and addressing food insecurity (Martinez et al., 2014) may be effective in addressing common problems with adherence in Haitian women. Eventually, effective interventions addressing mental health issues, particularly depression, anxiety and belief about medicine, in addition to providing peer and structural support could guide the development of programs that would enhance adherence.

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APPENDIX

ACRONYMS AND ABBREVIATIONS

| | |
|---------|---|
| AOD | Alcohol or Other Drug |
| ART | Antiretroviral Therapy |
| CBSM | Cognitive Behavioral Stress Management |
| CBSM-A | Cognitive Behavioral Stress Management-Adapted |
| GHESKIO | Groupe Haitien d'Etude du Sarcome de Kaposi et des Infections Opportunistes |
| HDI | Human Development Index |
| IMB | Information, Motivation, Behavior |
| NIAAA | National Institute of Alcohol Abuse and Alcoholism |
| NIH | National Institutes of Health |
| PLWH | People Living with HIV |
| TPB/TRA | Theory of Planned Behavior/Reasoned action |

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