

1-1-2013

The Relationship Between Generalized Anxiety Disorder In Women And Hormonal Imbalances, Self-Efficacy And Lifestyle: Implications For Licensed Professional Counselors And Counselor Educators

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**THE RELATIONSHIP BETWEEN GENERALIZED ANXIETY DISORDER IN
WOMEN AND HORMONAL IMBALANCES, SELF-EFFICACY AND
LIFESTYLE: IMPLICATIONS FOR LICENSED PROFESSIONAL
COUNSELORS AND COUNSELOR EDUCATORS**

by

GILLIAN ROBBINS

DISSERTATION

Submitted to the Graduate School

of Wayne State University,

Detroit, Michigan

in partial fulfillment of the requirements

for the degree of

DOCTOR OF PHILOSOPHY

2013

MAJOR: COUNSELING

Approved by:

Advisor

Date

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DEDICATION

To My Father and Mother

Clinton and Bianca Ramberansingh

and

Brothers - Nigel and Craig

*Thank you for supporting my freedom to make choices in pursuit of personal evolution,
life satisfaction and fulfillment*

To Dad and Mom

*Thank you for the sacrifices you both made for me to have the privilege of higher education and
personal independence*

My Path

There is a path, my path that I have walked my whole life
And all along the way, I have felt the presence of those who have walked before me
And like them, I went to many doors along the way that were closed
But each time I walked past another larger door would open up before me
Leading me to a brighter portion of my journey
As I look back I now understand how many doors must have been closed to them
And how costly their journey must have been
And now that I approach this landmark on my way
I understand how the burdens they bore helped to lead me here
For their effort, their courage, and their love – I am eternally grateful

By Darthu & Thea

In Loving Memory of My Grandparents

Paulina Bryce, Elmie Ramberansingh, Solomon Ramberansingh, and George Bryce

ACKNOWLEDGMENTS

Dr. William B. Talley –Thank you for being my mentor, friend, kindred spirit, and one of the greatest gifts bestowed to me in this life. For being the first to plant the seed that grew into this doctoral degree. You saw in me what I would become before I could conceive of it and you never lost sight of that vision. It has been an honor, privilege, and joy to have the benefit of your guidance, wisdom, and experience.

President and Primary Care Physician (Medical Health Spa – Ontario, Canada) – Thank you for the many ways in which you, your nurse practitioner, and other staff supported the study; including the recruitment of your patients for participation.

To the women who participated in the study – Without your participation this study would not have come to fruition. Thank you for being primary contributors to the further understanding of women’s mental, emotional, and physical health.

Dr. Joanne Holbert – Your contribution to making my endeavor a reality has fueled my journey; particularly towards my journey’s end. Your willingness to do so will always be remembered. I am truly grateful for your efforts.

Dr. Antonio Gonzalez-Prendes and Dr. Stuart Itzkowitz – You will both always be appreciated, valued, and remembered for your unconditional positive regard, guidance, training, and support of me as a graduate student, supervisor, and professional counselor.

Dr. Arnold Coven – You believed in my ability to be “plenty academic” as you have said. Thank you for challenging me to be a confident critical thinker and trust in my own judgment by primarily responding to most of my questions with a question.

Dr. Paige Dunlap – Thank you for assuming the role of one of my committee members without seeming hesitation. I am truly grateful for your generosity.

Dr. Bede Ryan – I will be eternally grateful for our connection as peers and your generosity in sharing your knowledge and process in regard to successful completion of your doctorate.

Dr. Rachael Evans – Thank you for modeling by relentless pursuit of your doctorate, despite challenges. Your example made it impossible for me to have any excuses and indirectly reinforced my courage and determination.

Dr. Jennifer Crystal – Thank you for giving valuable perspective and feedback throughout the process of dissertation completion. Your presence in my life is a true blessing.

Paul W. Johnson – I appreciated the directions you provided as I navigated through the graduate school. You have modeled professionalism, a strong work ethic, patience, and compassion. Thank you for these gifts.

TABLE OF CONTENTS

Dedication	ii
Acknowledgements	iii
List of Tables	ix
List of Figures	x
CHAPTER 1 INTRODUCTION	1
Anxiety Disorders	2
Women and Anxiety Disorders	4
Generalized Anxiety Disorder (GAD)	7
Women and Generalized Anxiety Disorders (GAD)	9
Statement of the Problem	11
Research Questions	13
Definition of Terms	13
Assumptions of the Study	17
Limitations of the Study	17
CHAPTER 2 LITERATURE REVIEW	18
Women and Anxiety Disorders	18
Psychosocial Factors	18
Female Hormonal Factors	19
Estrogen and Progesterone	19
Cortisol	20
Testosterone	22
Dehydroepiandrosterone (DHEA)	23

Women and Generalized Anxiety Disorder (GAD).....	24
Psychosocial Factors.....	24
Female Hormonal Levels and GAD	25
Self-Efficacy and Anxiety in Women.....	28
Healthy/Unhealthy lifestyle and Anxiety in Women.....	29
Exercise/Physical Activity	30
Diet/Nutrition.....	32
Smoking (Tobacco).....	34
Sleep.....	35
CHAPTER 3 METHODOLOGY	39
Introduction	39
Restatement of the Problem.....	39
Research Design.....	39
Setting of the Study.....	40
Participants.....	41
Sample Size.....	41
Instrumentation	42
Generalized Anxiety Disorder	42
The General Self-Efficacy Scale.....	44
FANTASTIC Lifestyle Checklist	45
Demographic Survey	46
Data Collection Methods	46
Data Analysis	48

CHAPTER 4 RESULTS OF DATA ANALYSIS	51
Description of the Sample.....	51
Description of the Variables	56
Research Questions.....	58
Summary.....	62
CHAPTER 5 SUMMARY AND DISCUSSION	63
Summary.....	63
Restatement of the Problem.....	63
Literature Summary	64
Review of Methods and Procedures	73
Summary of Findings.....	75
Research Questions.....	76
Discussion of Findings.....	78
Implications of the Study	79
Limitations of the Study.....	82
Recommendations for Future Research	82
Appendix A Survey.....	84
Appendix B Invitation Letter	88
Appendix C Informed Consent Form	89
Appendix D Wayne State University Institutional Review Board Approval	94
References.....	95
Abstract.....	108
Autobiographical Statement.....	110

LIST OF TABLES

Table 1	Statistical Analysis.....	49
Table 2	Descriptive Statistics - Ages of the Participants.....	52
Table 3	Descriptive Statistics - Ethnic Groups.....	52
Table 4	Descriptive Statistics - Marital Status.....	53
Table 5	Descriptive Statistics - Employment Status.....	54
Table 6	Descriptive Statistics – Number of Children.....	54
Table 7	Descriptive Statistics – Length of Time Since First Treatment.....	55
Table 8	Descriptive Statistics – Hormonal Levels and Scaled Variables.....	56
Table 9	Pearson Product Moment Correlations: Hormonal Levels and Generalized Anxiety Disorders.....	59
Table 10	Stepwise Multiple Linear Regression Analysis: Generalized Anxiety Disorder, Hormone Levels, Self-Efficacy, and Healthy and Unhealthy Lifestyles.....	60
Table 11	Mediation Analysis: Insight as a Mediator in the Relationship between GAD and Estriol.....	61

LIST OF FIGURES

Figure 1	Sample Size Calculation	42
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CHAPTER 1

Introduction

Historically, most counselor education programs in the United States have not included a psychosocial/medical aspects course(s) as a standard requirement for all graduate students, regardless of their chosen counseling specialization. However, it may be argued that it is addressed within the domain of rehabilitation counselor training as it relates to the psychosocial/medical aspects of disability. As a result, the potential importance of an individual's physiological functioning to emotional/mental/behavioral well-being may be neglected in the counseling process. Counselors may make appropriate referrals to medical professionals when there is a need for a psychiatric diagnosis. However, it is questionable that counselors are systematic and effective in referring clients for medical evaluations to rule out more subtle physiological issues that may be a primary driver of some clients' thoughts, feelings, and/or behaviors.

As a result, treatment outcomes may be compromised in certain cases because talk therapy and other forms of counseling interventions are not enough to bring resolution to the issue. Some clients could experience frustration with themselves, the counseling process, and/or their counselor because they are merely learning how to temporarily manage or cope with symptoms rather than resolve them. Clients who fall into this category may need a combination of psychotherapy and traditional or non-traditional medical treatment. The benefits of a combination of psychotherapy and medical intervention have been debated; yet supported by at least a few researchers. Medical intervention has been more specifically in the form of medication. For example, this was demonstrated in a study conducted by Blom et al. (2007) which provided some supportive evidence for the use of combining medication with

psychotherapy, instead of using medication only in the treatment of depressed outpatients. There are other recent studies that have also provided similar findings with samples of participants who have depressive symptoms (Frank et al., 2000; Hollon et al., 2005; Keller et al., 2000). However, there are fewer notable studies that have focused on anxiety disorders as it relates to the combination of psychotherapy and medication.

The above concerns may be highly relevant when counseling women who may have symptoms that meet the criteria for anxiety disorders for example. In turn, a question that requires attention is whether counselors are mindful enough of less overt physiological factors that may give notable definition to the initial assessment, medical referral, and treatment process when addressing the challenges of managing anxiety in women. In order to come closer to answering such a question, it is important to first explore the relationship between more subtle physiological factors and anxiety disorders. Therefore, a first step will be taken here to understand how generalized anxiety disorder (GAD) in women is related to factors such as hormonal imbalances, a healthy vs. unhealthy lifestyle, and level of self-efficacy. It is anticipated that this may provide a preliminary perspective on how a more subtle medical or physiological factor, such as hormonal imbalances in women, relate to symptoms of GAD. Other factors such as healthy vs. unhealthy lifestyle and level of self-efficacy will be considered other than physiological factors which may also correlate with GAD.

Anxiety Disorders

The focus of attention on anxiety disorders within the context of this much larger topic of concern is based on the following. According to the Anxiety Disorders Association of America (ADAA, 2011), anxiety disorders are the most common mental illness in the United States. It is estimated that approximately 40 million adults, age 18 and older are affected by this type of

disorder; which is 18% of the general population. It was revealed in a study conducted by the Anxiety and Depression Association of America (ADAA) in 1999 entitled “The Economic Burden of Anxiety Disorders” that anxiety disorders costs the United States more than \$42 billion per year (ADAA, 2011). This is approximately one-third of the annual cost of mental health.

According to ADAA (2011), when an individual experiences an anxiety disorder she or he is three to five times as likely to visit a physician. Moreover, they are six times as likely to be hospitalized for other psychiatric disorders, than individuals without an anxiety disorder. The Association also indicated that many individuals who experience an anxiety disorder also experience a co-occurring/comorbid disorder or physical illness, other than depression. Interestingly, though the National Comorbid Survey (as cited in Pigott, 2003) revealed that the most common psychiatric disorders in the U.S. were major depression, alcohol dependence, and simple phobia. It was also found that one in four of the national sample, met lifetime criteria for at least one anxiety disorder. In addition, Pigott (2003) highlighted that one in four individuals will experience an anxiety disorder in their lifetimes. In addition, 12 month prevalence of anxiety disorders was 17% which is higher than for substance use (11%) or affective disorders (11%).

Hence, it becomes more difficult to deal with such a diagnosis because symptoms tend to become exacerbated in such cases. This is convincing given the nature of identified co-occurring diagnoses by the ADAA as follows: Bipolar disorder, eating disorder, headaches, irritable bowel syndrome (IBS), sleep disorders, substance abuse, adult attention deficit/hyperactive disorder (ADHD), body dysmorphic disorder, chronic pain, fibromyalgia, and stress. To add to the complexity of this issue, older adults are just as at risk as younger individuals for anxiety; especially GAD. However, risk is typically associated with traumatic events confronted by this

population. As cited in Pigott (2003), there are also other notable consequences of a diagnosis of an anxiety disorder besides a vulnerability to depression for example. There is an increased risk for functional impairment, diminished job opportunities, impaired job performance, and elevated mobility and mortality rates.

Women and Anxiety Disorders

Within this framework of anxiety disorders, there is a more concerning picture for females. Alexander, Dennerstein, Kotz, and Richardson (2007), documented that women experience a high lifetime rate of anxiety disorders, with approximately 30.5% of women compared to men meeting diagnostic criteria from epidemiologic studies. According to Bourdon et al. (as cited in Craske, 2003) for example, studies as early as the 1980s and beyond have consistently found that females are more likely to be at risk than men for fear and anxiety. It was suggested even back then that females were twice as likely to experience anxiety disorders. Ginsberg (2004) stated that the impact of gender is profound in that it increases the likelihood of developing an anxiety disorder by 85% in women as compared to men.

The compelling statistics documented above reflect the high potential for individuals to experience an anxiety disorder and the disparity between men and women; women being twice as likely to experience anxiety disorders. However, Craske (2003) gives the topic of women and anxiety more depth and understanding by highlighting that women are vulnerable to more risk factors than men throughout their lifespans. In turn, an examination of these risk factors provides more food for thought in regard to the importance of addressing this issue for women. Especially, since some of these risk factors may emanate from a society in which women have historically been undervalued, experienced social and moral injustices, poverty, and violence that are gender based.

As suggested by Craske (2003), the notion of negative affectivity or negative emotional reactivity plays an influential role in the anxiety that women experience over the lifespan relative to men. For females, the level of negative affectivity tends to increase over the lifespan based on their interactions with others in the world. The opposite is true for males, who have the highest level of negative affectivity within the early months after they are born; and this tends to decrease over the lifespan. Craske (2003) stated that there are differences in parenting style given the early, greater emotional needs or negative affectivity of boys. As a result, mothers become more synchronized with boys than girls. The author hypothesized that this process may set the tone for several conditions which include: (a) a foundation of unpredictability and uncontrollability over the world, (b) nature of emotional responding, and (c) attentional control for females. This process has further importance because these foundational aspects are important to levels of ongoing distress and one's ability to regulate emotional arousal.

Therefore, even though the level of negative affectivity in females can be attributed to genetic factors; to a greater extent in women than men. There is greater support for the notion that females' propensity to negative affectivity is more strongly correlated to experiences and context as females mature. This is reinforced by the shift in greater susceptibility to negative affectivity for females at approximately age 2; when gender role behaviors also begin to develop. Therefore, Craske (2003) also indicated that social influences contribute to the evolution of heightened negative affectivity in females.

One of the major social influences is parents and their predisposition to reinforce gender specific behaviors throughout childhood. In most cases, the outcome for females is that they are not encouraged to explore and master skills of coping and persistence. Moreover, the perception becomes that they are less capable and inappropriate when assertive and/or independent. As a

consequence, they do not increase a sense of being in control and also revert to avoidant behaviors. To add to this dynamic, females also develop a heightened sensitivity to facial expressions. Therefore, unlike males, females are more prone to detecting threat, learning threat associations, and retaining high levels of reactivity to aversive events; especially when this is combined with heightened negative affectivity otherwise. Overall, females, unlike males, are diminished in their potential capacity to buffer themselves from current distress and future stressors (Craske, 2003).

It is such experiences and context/frameworks that females confront which in part, lead this population to be more susceptible to increased levels of anxiety. Hence, females are more prone to emotional distress following major traumas and social network crises; particularly beyond earlier developmental stages. Craske (2003) emphasized that the divergence between male and females increased post puberty for example. A female propensity to anxiety intensifies during adolescence while it remains unchanged for males. This propensity is not due to susceptibility to fear, but rather to increased levels of anxiousness and avoidant responses. Since adolescence is also a time when, compared to earlier stages of development, there are more negative life events, stronger role socialization pressures, and underlying evolutionary pressures for females to procreate for example. Hence, vulnerability factors become more prominent from this developmental stage onward. Factors that also seem to contribute to increases in generalized anxious responding by this point for females are: (a) an increase in levels of worry, (b) self-focus, (c) sensitivity to facial expressions, and (d) an awareness of internal states based on external and less reliable cueing (Craske, 2003).

Research in the area of physiology and behavior mirror this pattern of generalized anxious response in females. Unlike males, when the sympathetic adrenal medullary and the

hypothalamic-pituitary axis are activated there is then a moderation by oxytocin and other endogenous opioids. This causes the “fight-flight” system to go into a mode of down- regulation. While Taylor et al. (2000) stated that this serves a purpose in the evolutionary process by causing the parent not to flee; but tend to their off-spring, it is a disadvantage to females from the perspective of managing anxiety. It does not allow females to attain exposure to threats or trauma to the extent that males do. Hence, females do not attain mastery or learn effective threat value reappraisal; nor do females develop respective resiliency in this area of their lives (Craske, 2003). It is apparent that to underestimate this interplay of physiology and social influences for females, is to deny an understanding of the underpinning of the experience of anxiety in females that appears to be gender based to a notable extent.

Generalized Anxiety Disorder

Fostering more focused attention on generalized anxiety disorder (GAD) serves to strengthen a justification for examining this broader topic of anxiety from a gender-specific perspective. According to the ADAA (2011), GAD is the most common type of anxiety disorder. It affects approximately 6.8 million adults or 3.1 % of the United States population each year. According to Spitzer, Kroenke, Williams, and Lowe (2006), prevalence based on reports from general medical practice is 2.8 % to 8.5% and 1.6% to 5% based on the general population. Two large U.S. epidemiological surveys, the Epidemiologic Catchment Area study (ECA) and the National Comorbidity Survey (NCS) found that an estimated 5 to 6% lifetime prevalence rate for GAD (Piggott, 1999). Do and Do (2008) indicated that 90% of individuals with a lifetime prevalence for GAD also tend to have a lifetime history of at least one other psychiatric diagnosis; echoing the broader profile of anxiety disorders in general. In turn, major depression is the most common comorbid disorder for approximately 1/3 of GAD patients. This is

particularly compelling because comorbidity between GAD and depression notably increases the risk for suicide. Other comorbid conditions include: agoraphobia (27%), simple phobias (25%), social anxiety disorder (23%), panic disorder (23%), alcohol dependency (11.2%), and drug dependency (5.1%).

Furthermore, Do and Do (2008) has suggested that like other anxiety disorders, GAD is associated with notable psychosocial impairments, disability, decreased quality of life, and increased use of health care resources. It is also reflected by Ballenger et al. (2001) that GAD is the most common cause of disability in the United States workplace. Melchoir, et al. (2007) found that individuals exposed to high psychological job demands (excessive workloads and extreme time pressures) were twice as likely to develop GAD; as compared to those with low job demands. This is interesting given that it was reported in “Women in the Labor Force: A Databook, 2010” (Bureau of Labor Statistics, 2011) that 58.5 % of women were in the labor force in 2010. It is also anticipated that women’s participation in the workforce will continue to increase.

Moreover, there is some evidence to suggest that susceptibility does not diminish as individuals advance through the aging process. GAD remains both common and impairing in older adults, as cited in Lenze et al. (2011). Such research is highly relevant since women are now considered the majority in the older population (U.S. Department of Health and Human Services, 2007). Riley (2011) identified the following risk factors for GAD in general: being female; family member with an anxiety disorder; long-term exposure to abuse, poverty, or violence; low self-esteem; poor coping skills; smoking or other substance abuse; and increased stress.

Women and Generalized Anxiety Disorder

Given the context of GAD examined above and the reality that most primary care patients presenting for treatment for GAD are: (a) women, (b) report that the onset for GAD is age 25 to 45, (c) more likely to have a comorbid psychiatric diagnosis, and (d) experience a chronic clinical course (Pigott, 2003). It is warranted that licensed professional counselors acknowledge this population of women with GAD as a distinct one with possibly unique initial assessment, referral, and treatment needs. Pigott (2003) asserted that this presentation of more women than men with GAD for treatment is especially true when such women also have a comorbid psychiatric diagnosis. This researcher also indicated that women tend to have comorbid psychiatric diagnoses, along with GAD more than men. According to Pigott (2003), there tends to be a comorbid diagnosis of depressive disorders; particularly dysthymia for women with GAD. In turn, women tend to experience an even more chronic course and greater symptom severity than men.

The three Centers from the Epidemiological Catchment Area (ECA) study found that based on a 12-month prevalence rate, women experience anxiety at approximately double the rate of men for anxiety disorders; whether comorbidity exclusions are suspended or left in place (Howell, Brawman-Mintzer, Monnier, & Yonkers, 2001). When suspended the rate for men was 2.4% and women 5%. When left in place the rate for men was 1.9% and women 3.4%. Furthermore, the highest 12-month rates were in African American women (less than 32 years old) and Hispanic women age 45-64 years. In both cases, this represented more than 10%. Even when lifetime prevalence is compared to men, women are at twice the rate of men with 6.6%. This has been noted in research studies since the early 1980's.

Similar risk factors for GAD in women have been highlighted as with anxiety disorders in general. Kendler and colleagues (as cited in Pigott, 2003), suggested that a childhood history of parental marital separation or childhood history of separation from a parent in women was an indicator for GAD as adults. These researchers also found that GAD is a moderately familial disorder that is largely or totally due to genetic factors shared between relatives rather than family environment. Approximately 30% of the risk for GAD was attributed by Kendler and colleagues to genetic factors. The remaining 70% of the risk was attributed to environmental factors in regard to the pathophysiology of GAD. It is disturbances in noradrenergic, serotonergic, and GABA-ergic neuro-transmission that is implicated as a risk factor as well (as cited in Pigott, 2003). However, what is most relevant to this subject is evidence Pigott (2003) found to suggest that a risk factor that impacts more specifically symptom severity in GAD is female reproductive hormone cycles. However, this researcher qualifies this by stating that this has not yet been supported by research for pregnancy and the postpartum period specifically. Howell et al. (2001) have also implied that GAD in women is more connected to gender-specific social roles or experiences.

In turn, Howell et al. (2001) suggested that risk factors for GAD in girls are as follows: major life events, a higher level of self-consciousness, a lower level of self-esteem, higher self-rated social competence, greater emotional reliance, more social support from friends, more physical illness, poorer self-rated physical health, less obesity, less exercise, and more physical symptoms. Noted however, is that when psychosocial variables were controlled, there was no reduction in risk to the girls verses boys. Howell et al. (2001) concluded that this implied a gender-related intrinsic factor.

Statement of the Problem

There has been exploration of risk factors associated with anxiety disorders, generalized anxiety disorder, and women with GAD in a variety of areas of research. However, from a review of the research literature there appears to be only a cursory examination of the relationship between the fluctuations in reproductive hormones and GAD symptoms in women. This is despite the respective success of hormone replacement therapy (HRT) in treating hormonal imbalances experienced by adult females. It is suspected that this is partly due to how controversial the issue of HRT treatment has been; especially given a medical system that has been informed by a patriarchal society. In addition, there are so many other factors that may contribute to GAD that have traditionally been assumed to be primary or key to the manifestation of related symptoms.

Therefore, it is not surprising that there is virtually a non-existence of research devoted to this issue within the discipline of counselor education. As indicated earlier, this may be partly due to a lack of opportunity within counselor educator programs to focus more specifically on how physiology or subtle physiological problems may impact the overall well-being of individuals from a clinical counseling perspective. As a result, awareness of the need for research in this area is not raised.

It is suspected that for similar reasons, issues unique to women may not be adequately infused into most counselor education programs. It is important to qualify the above statements by indicating that it is presumed that professional counselors are trained to refer clients for a medical or psychiatric diagnosis when it is deemed beneficial to the client's overall well-being. However, it is argued that this is most probable when the client has overt medical or psychiatric symptoms. Therefore, the core challenge or problem for licensed professional counselors is

identifying the contribution that a subtle physiological risk factor can make to a client's complaint. A poignant example of this may be how the physiological issue of a hormonal imbalance is related to a woman's experience of GAD or symptomology that appear similar to GAD criteria. This is a significant problem for licensed professional counselors because the initial and on-going case assessment may be based on an incomplete picture of what is primarily contributing to the client's complaint or symptoms. Secondary consequences may then arise in turn. For example, medical, psychiatric, or other referrals may be neglected or ignored as part of the treatment planning and implementation process. Similarly, inappropriate or inadequate treatment interventions may be utilized. This can lead to compromised treatment outcomes.

Ultimately, when a client's underlying medical (physiological) problem is not identified and appropriately attended to, it may deteriorate and further negatively affect the functioning and overall well-being of the client. Otherwise, this has potential to damage the client/counselor therapeutic relationship when both the client and counselor become frustrated with the counseling process because a key piece of the puzzle remains missing over time. Also in due course, possibly leading to a depreciation in the credibility of licensed professional counselors as highly competent clinicians.

While it can be debated that the majority of cases do not involve such subtle physiological factors of concern, it does not make this a less important issue for the cases in question here. Even if there is a relative minority of women who experience GAD that appear to be primarily caused by hormonal imbalances, the subject deserves adequate attention. It could set a precedent for how licensed professional counselors will conduct treatment. Especially for other client populations with underlying physiological issues that can inform the counseling process and potential positive outcomes. Hence, a decision and commitment to study this topic of

concern for women who comprise a major population served by licensed professional counselors.

Therefore, the purpose of this study is to examine the relationships among hormonal changes or imbalances, healthy/unhealthy lifestyles, and self-efficacy and GAD among women who are receiving bio-identical hormonal treatment in a large urban area. In turn, the aim is to suggest implications for licensed professional counselors in regard to initial treatment assessment, appropriate referral, and effective treatment interventions.

Research Questions

Research question 1. What is the relationship between hormonal levels and GAD?

Research question 2. Can women's experiences with GAD be predicted from hormonal levels, a healthy or unhealthy lifestyle, and level of self-efficacy?

Research question 3. Is the relationship between women's experiences with GAD and hormonal levels mediated by a healthy or unhealthy lifestyle?

Research Question 4. Is the relationship between women's experiences with GAD and hormonal levels mediated by their level of self-efficacy?

Definition of Terms

Generalized Anxiety Disorder (GAD) – According to the *Diagnostic and Statistical Manual of Mental Disorders* (4th Ed.; DSM-IV – TR; American Psychiatric Association, 2000), Generalized Anxiety Disorder is described as a mental disorder with an essential feature being excessive anxiety and worry. The anxiety and worry occurs more days than not for a period of at least 6 months, about a number of events or activities. The individual finds it difficult to control the worry. The anxiety and worry are accompanied by at least three additional symptoms from a list that includes restlessness, being easily fatigued, difficulty concentrating, irritability, muscle

tension, and disturbing sleep (difficulty falling asleep or staying asleep, or restless unsatisfying sleep).

The anxiety, worry, or physical symptoms cause clinically significant distress or impairment to social, occupational, or other important areas of functioning. The disturbance is not due to the direct physiological effects of a substance (e.g. a drug of abuse, a medication) or a general medical condition (e.g. hyperthyroidism) and does not occur exclusively during a Mood disorder, a Psychotic Disorder, or a Personality Developmental Disorder (DSM-IV – TR; American Psychiatric Association, 2000).

The International Classification of Diseases (ICD-10, 2010) has listed a number of physical symptoms that may be experienced by individuals with GAD: Palpitations or pounding heart, or accelerated heart rate, sweating, trembling or shaking, dry mouth, difficulty breathing, feeling of choking, chest pain or discomfort, nausea or abdominal distress, feeling dizzy, unsteady, faint or light headed, feelings that objects are unreal or that one's self is distant or not really here (depersonalization), fear of losing control, going crazy or passing out; fear of dying, hot flushes or cold chills, numbness or tingling sensations, muscle tension or aches and pains, restlessness and inability to relax, feeling keyed up, mental tension, a sensation of a lump in the throat, difficulty swallowing, and exaggerated responses to minor surprises or being startled. For the purposes of this endeavor/study GAD will be considered a chronic stress disorder as well. It is presumed that individuals with GAD are chronically stressed (Tafet et al., 2001).

Self-Efficacy - As defined by Bandura and cited by Wissing et al. (2011), for the purpose of this study self-efficacy was operationally defined as the levels of confidence people have in their ability to implement a course of action or attain specific performance outcomes. Bandura (as cited in Wissing et al., 2011) described self-efficacy as a sense of personal agency that builds

on an individual's cognitive evaluation and processing of availability of social, physiological, and other resources, as well as previous experiences of efficacy.

Healthy/Unhealthy Lifestyle – This term was operationally defined as the extent to which an individual has control in regard to overall health lifestyle thinking and behaviors. Health lifestyle thinking and behaviors refer to those identified on the FANTASTIC checklist which are as follows: Family, friends; activity; nutrition; tobacco, toxins; alcohol; sleep, seatbelts, stress; type of personality; insight; and career.

Hormonal Imbalance(s) - The term hormonal imbalance (s) referred to lower or higher levels of testosterone, estrogen (estrone, estradiol and estriol), progesterone, DHEA, and/or cortisol than are considered within normal ranges that may lead to negative physiological effects. At least one or more hormones identified above that are not within a normal range qualify as a hormonal imbalance. This definition excludes hormonal imbalances as a general medical condition. Instead, it will be operationally defined as an underlying or subtle physiological problem or risk factor.

Bio-identical Hormones – According to Conaway (2011), bio-identical hormones are derived from plant sources and are termed bio-identical because it is claimed that they are structurally identical to endogenous hormones, not just human hormone receptor binders. When bio-identical hormones are used for bio-identical hormone replacement therapy (BHRT) rather than traditional hormonal replacement therapy (HRT) they are typically steroid hormones including estrone sulfate, estropipate, 17B-estradiol, progesterone, testosterone, and dehydroepiandrosterone (DHEA). Such hormones are derived in a laboratory and not harvested from endogenous sources. Hence, bio-identical hormones will not be operationally defined as natural hormones within the context of this study.

Bio-Identical Hormonal Replacement Therapy (BHRT) – Bio-identical hormonal replacement therapy (BHRT) was operationally defined as the following regimen. Saliva testing of women’s hormones was used to identify whether hormones were either within ranges considered normal or higher or lower than the normal ranges. Once an imbalance in at least one or more hormones was identified (based on results that are not in the normal range), the physician then prescribed a combination of bio-identical hormones to bring hormones into balance. Bio-identical hormone prescriptions were then filled at a compounding pharmacy that used hormones derived from “natural” sources.

Saliva Test – Saliva test was operationally defined as the type of test conducted by a Canadian medical laboratory using samples of saliva collected and submitted to the laboratory by women who participated in the study. The saliva test was used to identify hormonal levels that represented within normal ranges, excesses, or deficiencies. Saliva tests results were reported in the form of a medical laboratory report that was submitted to the respective women’s medical files at the medical health spa. The medical director/primary physician then completed further comprehensive interpretation of the saliva tests in order to prescribe bio-identical hormones as needed.

Saliva Test Interpretation – Saliva test interpretation by the medical director/primary physician at the medical health spa was operationally defined as interpretation based on the clinician’s formal medical training, clinical experience, and overall medical assessment of the patient. Saliva test interpretation as defined above was used to guide the physician’s prescription of bio-identical hormones to women who participated in the study.

Assumptions of the Study

- All women in the sample were receiving bio-identical hormonal treatment after being diagnosed with a hormonal imbalance(s).
- All women in the sample were prescribed bio-identical hormones by the same physician and have continued to use this treatment since medical diagnosis.

Limitations of the Study

- The study was limited to women who are receiving bio-identical treatment from a single physician located in an urban area.
- The study was limited to women who have been in treatment for hormonal imbalances for a minimum of three months.

CHAPTER 2

LITERATURE REVIEW

Women and Anxiety Disorders

Psychosocial Factors

A three-year longitudinal study was conducted by Calkins et al. (2009) to examine psychosocial predictors of the onset of anxiety disorders in women. This included new and recurrent onset of an anxiety disorder and 643 women participated in the study. The study revealed that for women who experienced a new episode of anxiety there were three major predictors: (a) history of anxiety, (b) increased anxiety sensitivity (the fear of anxiety related sensations), and (c) increased neuroticism. Both onset and recurrence were predicted by anxiety sensitivity and neuroticism. History of an anxiety disorder predicted recurrence for this sample of women as well.

Similarly, Alexander, Dennerstein, Kotz, and Richardson (2007) indicated in a review of nomenclature, comorbidity, and epidemiology in regard to women, anxiety, and mood that early life experiences, heredity, gender, other psychiatric illness, stress, and trauma interact in dynamic ways to lead to either anxiety or mood disorders. Heim et al. (2002) examined the role of early adverse experience and adulthood stress in the prediction of neuroendocrine stress activity in women. These researchers demonstrated with the findings of their study that life stress was associated with anxiety in women. They found that a history of childhood abuse was related to increased neuroendocrine stress activity that was heightened when further trauma occurred in adulthood for women. Their underlying premise was that sensitization of stress-responsive neurobiological systems as a possible consequence of an early adverse experience was implicated in the pathophysiology of anxiety and mood disorders.

Another psychosocial factor that has been associated with anxiety in the research literature is quality of life impairment. One of the most recent respective studies was conducted by Barrera and Norton (2009) that examined the relationship between quality of life impairment and GAD, social phobia, and panic disorder. It was found that both men and women in their sample with the above disorders reported less satisfaction with their life than non-anxious adults. This study took into account that the degree of quality of life impairment was similar for the three disorders.

Female Hormonal Factors

Piggott (1999) reviewed the unique characteristics of primary anxiety disorders in women. As a result, hormonal factors was identified and examined as one of the unique characteristics of women that correlate with anxiety disorders. The author indicated that three primary neurotransmitter systems are traditionally considered to mediate anxiety: the locus ceruleus-norepinephrine system, the serotonin system, and the γ -aminobutyric acid (GABA)-benzodiazepine receptor complex.

Estrogen and Progesterone. In addition, Piggott (1999) suggested that female gonadal hormones, particularly estrogen and progesterone may have a regulatory role in the function of these neurotransmitter systems in women. Hence, it was stated that genetic differences in anxiety disorders may be explained by the effects of estrogen on serotonin; since estrogen enhances serotonin function. Piggott (1999) also highlighted that postmenopausal women who receive estrogen replacement therapy have been found to enhance their serotonin response. According to Piggott (1999), there is some evidence that elderly women tend to respond to Selective Serotonin Reuptake Inhibitor (SSRI) anti-depressant treatment more efficiently when they receive estrogen replacement therapy. The author indicated that the role of progesterone in terms of its impact on

the brain and nervous system is less clear. Nonetheless, it also was proposed that progesterone can antagonize and/or neutralize the actions of estrogen. As a result, adding progesterone to estrogen replacement therapy may neutralize the mood enhancing and stress-attenuating effects given estrogen administration. However, these statements do not account for the complexity of roles other metabolites may play.

Piggott (1999) also reflected on the role of estrogen and progesterone as it affects the female reproductive cycle. The author stated that the female reproductive cycle is shaped by notable fluctuations in estrogen and progesterone. In turn, gonadal hormonal changes that are cyclic in nature may have a key influence on the onset and course of anxiety disorders in women. As cited in Piggott (1999), it is common for anxiety disorders to worsen during the premenstrual stage of the cycle.

In addition, the menstrual cycle has a substantial influence on both the onset and course of anxiety disorders. However, the supportive evidence is linked specifically with obsessive-compulsive disorder and panic disorder. Pregnancy and the postpartum period have similar impacts on anxiety disorders; particularly obsessive-compulsive disorder and panic disorder. Both during and after pregnancy, there may be worsening of symptoms characteristic of obsessive-compulsive disorder and panic disorder.

Cortisol. Another study conducted by Wardenaar et al. (2011), focused on the dimensions of depression and anxiety and the hypothalamo-pituitary-adrenal axis. One of the reported findings was an increase in morning cortisol for patients who were currently anxious at the time the study was conducted. The main impact occurred in patients who experienced panic disorder with agoraphobia. This finding supports the observation in prior studies that the hypothalamo-pituitary-adrenal axis appeared altered in patients with anxiety. Interestingly, the

researchers emphasized that this is not only when there was the presence of a diagnosis that correlated with patients in the study. Specific symptom patterns and severity also correlated with morning increases in cortisol.

Oskis, Loveday, Hucklebridge, Thorn, and Clow (2011) examined cortisol dysregulation in female children and adolescence based on whether healthy or unhealthy attachment style was developed. Interestingly, these researchers concluded that there was the same pattern of cortisol dyregulation for female children and adolescents associated with anxiety disorders as found in previous studies for adult females. Participants exhibiting an anxious attachment style had higher cortisol levels upon awakening in the morning.

McHugh, Behar, Gutner, Geem, and Otto (2010) examined how cortisol, stress, and attentional bias toward threat are related. The underlying premise of their study is that attentional bias toward threatening stimuli is a key feature of anxiety and acute stress. The study revealed that there was a trend toward a stronger negative association between acute cortisol change and attentional bias change among women relative to men. Therefore, it was implied that gender and stress may moderate the association between cortisol and attentional bias. The results of this study support the theoretical perspective of Craske (2003) highlighted earlier which suggested a link between compromised attentional control in women and emotional dysregulation.

The topic of cortisol changes was also explored in a study that focused on women victims of physical and psychological intimate partner violence (Pico-Alfonso, Garcia-Linares, Celdan-Navarro, Herbert, & Marinez, 2004). This study revealed that intimate partner violence was the main factor that predicted the alterations in hormonal levels after controlling for age, smoking, pharmacologic treatment, and lifetime history of victimization. One the alterations found in hormonal levels was with evening cortisol. Women who were victims of intimate partner

violence had more severe symptoms of anxiety; as well as depression and incidence of post-traumatic stress disorder.

Bremner, Vermetten, and Kelley (2007) measured the cortisol levels (as well as DHEA and Estradiol) of women who experienced childhood sexual abuse-related post-traumatic stress disorder. The study showed that abused women with PTSD had lower concentrations of cortisol during the afternoon hours (12 to 8 p.m.) than women who experienced abuse without later symptoms of PTSD. Inclusion of this study is relevant though it does not address anxiety, since it is assumed in this context that anxiety is a severe form of stress, like post-traumatic stress.

Testosterone. As cited in Hermans et al. (2007), testosterone is the end product of the hypothalamic-pituitary-gonadal axis that down regulates the stress response at multiple levels. Hermans et al. (2007) asserted that androgens, primarily testosterone, promote dynamic regulation of the stress system by acting upon central neuropeptidergic pathways that control corticotropin releasing hormones and arginine vasopressin expression. This assertion was the thrust for their study of exogenous testosterone's attenuation role in the integrated central stress response in healthy young women. The results of the study indicated that the administration of testosterone led to a decreased responsiveness of the stress system in the healthy women who were described as anxiety prone participants.

Another study conducted by Giltay et al. (2012) focused on the association between testosterone and depression, anxiety disorders, and antidepressant use. The study showed that salivary testosterone was lower in female patients with a depressive disorder, generalized anxiety disorder, social phobia, and agoraphobia as compared to female controls. It was also found that SSRIs may increase salivary testosterone in women and men.

Interestingly, at least one study highlighted that testosterone may reduce fear but not consciously experienced anxiety in women. Van Honk, Peper, and Schutter (2005) concluded that this was the first study that provided evidence for fear-reducing properties of testosterone in humans. According to Van Honk et al. (2005), animal studies indicated that the effects of testosterone on motivation and emotion are of subcortical origin and of an unconscious nature. These researchers also suggested that implications of the study may be relevant to the topic of both disorders of fear and disorders of anxiety.

Dehydroepiandrosterone (DHEA). Strous et al. (2003) found that DHEA is a major circulating corticosteroid in humans and serves as a precursor for both androgenic and estrogenic steroids. Its sulfated form (DHEA-S) is the most abundant steroid in the body. As indicated earlier, Pico-Alfonso et al. (2004) examined the impact of intimate partner violence on women's hormonal levels. In addition to finding that women who were victims of intimate partner violence experienced higher levels of evening cortisol, there was evidence that these women also had higher levels of morning and evening DHEA. Furthermore, the researchers indicated that there was also a correlation between higher levels of anxiety (as well as depression and incidence of post-traumatic stress disorder) and higher levels of morning and evening DHEA. Rasmusson et al. (2004) also investigated the potential relationship between DHEA and symptoms associated with PTSD in women. However, participants in the study were at a premenopausal stage in their reproductive lives. These researchers conducted this study because they questioned whether endogenous, peripherally released steroids with antigluco-corticoid activity might play a role in enhancing the pituitary and adrenal responsiveness in female subjects who were premenopausal and experiencing symptoms of PTSD. The outcomes of the study suggested that an increase in the capacity of DHEA release in response to extreme adrenal activation could

shape the pattern of HPA axis adaptation to extreme stress, as well as mitigate the severity of PTSD and negative mood symptoms in premenopausal women with PTSD.

In a similar study, DHEA was measured (as well as cortisol and estradiol) over 24 hours in women with childhood sexual abuse-related post-traumatic stress disorder (Bremner et al., 2007). Results suggested that DHEA was not associated with childhood sexual abuse-related PTSD in women. The relevance of the above studies that focus on PTSD is based on an earlier assumption that anxiety can be considered a severe form of stress; as is post-traumatic stress within this context.

Strous et al. (2003) investigated the efficacy of DHEA in the management of the negative symptoms, depressive, and anxiety in schizophrenia. Their exploration was based on past research that demonstrated administration of DHEA improved mood, a sense of well-being, interest, activity, and energy in several subpopulations. The results indicated significant improvements in negative symptoms, depression, and anxiety in participants who received DHEA. It was highlighted that the effects were most notable in women with schizophrenia. It was stated in this study that the increases found in DHEA and DHEA-S after its administration did not have an impact on the levels of cortisol. The study gives attention to the issue of comorbid diagnoses with anxiety and the relationship in this context to hormonal imbalances in women.

Women and Generalized Anxiety Disorder (GAD)

Psychosocial Factors

Fewer studies have had a pointed focus on GAD in women and related psychosocial factors. When psychosocial factors were examined, study samples were comprised of both women and men. Otherwise, researchers appeared to have examined several anxiety disorders at

once in relation to women and psychosocial factors. Such studies are included in other relevant sections.

Female Hormonal Levels and GAD

One of the few studies to address the effects of female reproductive hormones on women with an anxiety disorder was conducted by Van Veen, Jonker, Van Vliet, and Zitman (2009). The study examined generalized social anxiety disorder (gSAD) and not GAD. However, it did focus on the influence of female reproductive hormones on this anxiety disorder (gSAD). The study is relevant given that both GAD and gSAD are more prevalent in women. The researchers included as one of their premises that gonadal hormones estrogen and progesterone regulate the female hormonal cycle (menarche, menstrual cycle, pregnancy, postpartum period, lactation, and menopause). It was hypothesized that premenstrually and in the last trimester of the pregnancy the levels of anxiety were higher. Overall, it was found that most of the study's participants did not report an influence of the female hormonal cycle on gSAD symptoms. However, there was a sub-group of women who reported more severe social anxiety and avoidance in the premenstrual period and less severe symptoms during pregnancy. A similar result was found by Hsiao, Hsiao, and Lui (2004) in their study of premenstrual symptoms and premenstrual exacerbation in patients with psychiatric disorders. Patients with GAD reported higher rates of premenstrual syndrome and premenstrual exacerbation. It was suggested that this phenomenon appeared to be linked to a decrease in estrogen levels.

Reimold et al. (2011) investigated whether central serotonin transporter levels are associated with stress hormone response and anxiety. Their objective was to assess the interrelation of cortisol response, thalamic 5-HTT levels, and anxiety in one group of healthy subjects and 2 other samples of patients with unipolar major depression (UMD) and obsessive-

compulsive disorder (OCD). Their rationale was based on the principle that negative mood states are characterized by both stress hormone dysregulation and serotonergic dysfunction, reflected in the altered levels of thalamic serotonin transporter (5-HTT). The study concluded that there was an association between stress hormone response, thalamic 5-HTT levels, and anxiety. It was also suggested that a reduction in 5-HTT levels contributed to an increase in anxiety. However, these researchers also highlighted that there was a link between 5-HTT levels and stress hormone (cortisol) responses.

In an earlier study, Tafet et al. (2001) investigated whether there was a correlation between cortisol level and serotonin uptake in patients with chronic stress and depression. This study is considered relevant for the purpose of this endeavor because women who experience GAD are also considered chronically stressed. These researchers reported that there was a substantial increase in the level of afternoon cortisol in the blood of patients with GAD and Major Depressive Disorder (MDD).

Two studies reinforced the notion that anxiety disorders affected individuals across the lifespan; including in the later years of life. The first study was conducted by Mantella et al. (2008). These researchers based their study on the assertion that age associated alterations in hypothalamic-pituitary-adrenal (HPA) axis functioning may make individuals more susceptible to HPA dysregulation in the context of mood and anxiety disorders. Therefore, they studied the association between salivary cortisol and a diagnosis/severity of late-life generalized anxiety disorder. It was found that late-life GAD was characterized by elevated basal salivary cortisol levels and severity of GAD was positively correlated with cortisol levels. Hence, HPS axis dysfunction in late-life GAD was demonstrated. Consequentially, a potential negative impact of aging on HPA axis function in anxiety disorders was identified in this study.

Another study that examined cortisol levels and GAD also focused on elevated cortisol levels in older adults with GAD. Lenze et al. (2011) explored the treatment of adults (60 years and older) with GAD by administering escitalopram (an SSRI) to one group and a placebo to another group within the sample. There were also collections of salivary cortisol at six daily time points for two consecutive days. The study revealed that when there were reductions in cortisol due to the application of the SSRI, anxiety levels decreased. It was concluded that SSRI treatment of GAD in older adults reduces HPA axis hyperactivity.

In a similar study, the treatment applied was cognitive therapy rather than medication. Tafet, Feder, Abulafia, and Roffman (2005) investigated the regulation of hypothalamic-pituitary-adrenal activity in response to cognitive therapy in patients with generalized anxiety disorder. They utilized both psychological and psycho-neuro-endocrinological parameters to evaluate the efficacy of cognitive therapy. Anxiety symptoms were assessed using the Hamilton Anxiety Rating Scale (HAM-A) and the hypothalamic- pituitary-adrenal (HPA) function was determined by assessing circulating cortisol levels. These researchers found that there was a significant decrease in the HAM-A scores, along with significant changes in plasma cortisol levels, after the completion of cognitive therapy. This implied an indirect link again between cortisol levels and the symptoms of GAD.

Otherwise, a study conducted by Steude et al. (2011) measured cortisol levels differently and gained results contrary to other studies mentioned above. Results suggested that under naturalistic conditions GAD is associated with hypercortisolism. Unlike other studies, this study used measures of hair cortisol rather than salivary plasma or urinary assessments. Unlike some other studies, the goal was to attain a retrospective index of cortisol secretion over a prolonged

period of time. The study reflected implications of long-term cortisol secretion as a marker for psychiatric disorders associated with hypo- or hypercortisolism.

Self-efficacy and Anxiety in Women

There is some evidence to support the notion that self-efficacy has a positive impact on the overall well-being in women. Srimathi and Kiran Kumar (2010) examined the relationship between self-efficacy and overall well-being in a study with a sample of 325 employed women, who worked in one of five different organizational sectors (hospitals, banks, educational institutions and call centers). The results demonstrated that there was a significant and positive correlation between all dimensions of psychological well-being (autonomy, environmental mastery, personal growth, positive relations with others, purpose in life, and self- acceptance) and self-efficacy scores. Self-acceptance and environmental mastery correlated highly with self-efficacy; and purpose of life and autonomy correlated least with self-efficacy. Teaching and banking were areas in which there was a specific lack of correlation between psychological well-being and self-efficacy.

A more explicit link between anxiety in women and level of self-efficacy was explored in a study conducted by Jones et al. (2010). These researchers investigated self-efficacy and distress in women with AIDS. The results revealed that women given a combination of cognitive behavioral stress management and expressive supportive therapy (which led to an increase in cognitive behavioral self-efficacy) experienced significant decreases in both anxiety and depression. This applied both to the time immediately post intervention and follow up long term. The sample comprised predominantly minority women living with AIDS in a low income, urban environment.

Stanley et al. (2002) measured self-efficacy and optimism in older adults with GAD. These researchers were interested in the predictive utility and theoretical significance of self-efficacy and outcome beliefs for understanding anxiety in late life; especially since this population had not been highlighted in related research on the topic. It was found that self-efficacy and outcome expectations were lower in older adults with GAD relative to published data from younger and older community samples.

Another study demonstrates that there is research that indirectly addresses the potential relationship between GAD and self-efficacy. As with the study above that concentrated on a specific population of older adults with GAD; the study in focus here examined a sample of 794 adults with asthma. The researchers in exploring the relationship between GAD and asthma morbidity examined cross sectional associations between GAD and asthma control, quality of life, and self-efficacy. The study found that GAD was associated with worse asthma morbidity independent of age, sex, smoking, and asthma severity. Low asthma self-efficacy and comorbid major depression were identified as being accountable for the associations. It was suggested in discussion of the study that self-efficacy plays an important role in determining asthma outcomes in relation to GAD. Therefore, an individual's confidence in his or her ability to control or manage asthma symptoms within different contexts was impactful (Lavoie, Boudeau, Plourde, Campbell, & Bacon, 2011).

Healthy/Unhealthy Lifestyle and Anxiety in Women

A review of the literature on this topic of interest suggested that few studies have addressed healthy/unhealthy lifestyle inclusive of several factors with a focus specifically on women. An exception to this trend is a recent study conducted in Australia (Xu, Anderson, & Courtney, 2010). The researchers implemented a longitudinal study of the relationship between

lifestyle and mental health among women at midlife and older women. Mental health measures used were: anxiety, depression, and mental well-being. Lifestyle measures included body mass index, exercise, smoking, alcohol use, and caffeine consumption.

In regard to anxiety, the study revealed that women who had been past alcohol drinkers had lower anxiety scores when compared with nondrinkers. No effect was found for occasional drinkers. Other lifestyle factors were associated with lower mental well-being such as caffeine consumption and smoking. Only when exercise was participated in five to six times a week was there a limited reduction in anxiety. Overall, even alcohol was not significantly correlated with anxiety in this study. It is important to note that the sample in the study in question was made up of both post and peri-menopausal women that limit the findings.

It appears from the review of the literature there has not been a standard or pattern of factors that are associated with healthy/unhealthy lifestyle in women. Therefore, recent studies that highlight at least one factor in relationship to either women and anxiety or a specific anxiety disorder will be given attention as follows.

Exercise/Physical Activity. Salmon (2001) completed a meta-analysis that reflected on the effects of physical exercise on anxiety, depression, and sensitivity to stress. This researcher suggested the following in regard to exercise as an intervention for anxiety. Exercise has non-specific benefits that assist in the reduction of anxiety; as with depression. Exercise training has reduced anxious mood by comparison with strength and flexibility training. In addition, Salmon (2001) asserted that there is research that implies exercise has anxiolytic and antidepressant effects on more disturbed patients as well. The researcher also suggested that exercise training continues to offer clinicians a modality for non-specific therapeutic social and psychological processes. It also may offer a specific psychological treatment that may be particularly effective

for patients where conventional psychological intervention is not acceptable. In a reviewed article, Strohle (2009) critically examined the literature in regard to the association of physical exercise and the prevalence and incidence of depression and anxiety. The author also concluded that recent well-controlled studies suggest that exercise training may be effective in addressing panic disorder.

An interesting study was conducted in the Netherlands by Moor, Beem, Stubbe, Boomsma, and Geus (2006). Regular exercise, anxiety, depression and personality were studied using a sample of 19,288 adolescent and adult twins with their families. It was found that older females exercised more than males, whereas adolescent males exercised more than their female peers. In addition, the researchers concluded that exercisers were on average less anxious and depressed, less neurotic, more extroverted, higher in thrill and adventure seeking and higher in dis-inhibition. The article in question also noted with interest that the study corroborates and extends previous findings in this manner.

Gutiérrez et al. (2011) explored the influence of exercise on mood in postmenopausal women age 60 to 70 years. In the exercise group studied, there were statistically significant improvements in subjects with moderate and severe symptoms of anxiety. It was concluded that a controlled program of exercise for postmenopausal women may alleviate symptoms of anxiety. It was also indicated that exercise might attenuate the effects of physiological and psychological changes associated with menopause and prevent pathologic changes. Another study that addressed this topic in a sample of older individuals was conducted by Pasco et al. (2011). These researchers investigated the relationship between habitual physical activity and the risk of depressive and anxiety disorders among older men and women. The main conclusion was that high levels of habitual physical activity that included household activities, sporting activities, and

other physically active leisure-time activities are protective against subsequent risk of development of anxiety disorders.

Another notable study addressed the effects of short-term exercise training on signs and symptoms of GAD. Herring, Jacob, Suveg, and O'Conner (2011) examined the relationship between exercise and anxiety with a sample of younger women between the ages of 18 and 37 years, unlike the studies above that focused on samples of older women. The study showed that resistance and aerobic exercise both led to improvements in signs and symptoms associated with GAD; especially in regard to irritability, anxiety, low vigor, and pain.

In 2012, Herring, Jacob, Suvey, Dishman, and O'Connor conducted a similar study. They focused on the feasibility of exercise training for the short-term treatment of GAD using a randomized controlled trial. Thirty sedentary women between the ages of 18 and 37 were randomly allocated to resistance exercise training, aerobic exercise training, or a waiting list. The women had a DSM-IV diagnosis of GAD prior to the study and were receiving no other forms of treatment besides pharmacotherapy. It was concluded that exercise training, including resistance exercise training is a feasible, low risk treatment that can potentially reduce worry symptoms among GAD patients. The researchers also suggested that exercise can be an effective adjunct or augmented with other forms of short-term treatment for GAD.

Diet/Nutrition. Few studies have explored the potential relationship between anxiety and overall dietary patterns. However, a recent study was conducted in Greece addressing eating habits in relation to anxiety symptoms among healthy adults (Yannakoulia et al., 2008). The sample included both women (400) and men (453) randomly selected from different areas of the Attica region of Greece. Less anxious men and women were found to have a different pattern of a *light* diet than more anxious women and men. Less anxious women had a vegetarian pattern

with the lowest consumption of red meat and sweets. The study did not define what was considered a *light* diet. A *western-type* diet was associated with higher levels of anxiety in women.

A comparable study was conducted by Jacka et al. (2010). These researchers studied the association of western and traditional diets with depression and anxiety as part of a longitudinal Geelong Osteoporosis study. The Geelong Osteoporosis study used a sample of women from the Australian compulsory commonwealth electoral rolls for the Barwon Statistical Division. There were 1,046 women between ages 20-93 in the sample by the 10th year of the study. Results demonstrated that a *traditional* diet that consisted of vegetables, fruit, meat, fish, and whole grains was associated with a lower probability for anxiety disorders, as well as, major depression. A *western* diet of processed or fried foods, refined grains, sugary products, and beer was associated with depression.

Kacka, Mykletun, Berk, Bjelland, and Tell, (2011) later studied the association between habitual diet quality and the common health disorders in community dwelling adults in Norway. The sample included 5,731 women and men ages 46 to 49 and 70 to 74 years. A traditional Norwegian diet comprised vegetable, fruit, low-fat dairy, whole grains, fish, and non-processed red meat. Adjustments were made for variables such as age, education, income, physical activity, smoking, and alcohol consumption in the study. The results showed that a healthy diet was associated with both lower levels of anxiety and depression for women. A traditional Norwegian diet was associated with reduced depression in women and anxiety in men. A western type diet was associated with increased anxiety and depression for both women and men. Researchers concluded that those with better quality diets were less likely to be depressed, whereas a higher intake of processed and unhealthy foods was associated with increased anxiety.

Smoking (Tobacco). McGee and Williams (2006) conducted research in New Zealand to examine the predictors of persistent smoking and quitting among women smokers. At the time of follow up, the sample was comprised of 575 women. Follow up was conducted 13 years after the original study was conducted. The average age of women at baseline was 34 years. High levels of anxiety, poor maternal education, being young at birth of first child, having a partner who smoked, and high tea/coffee consumption were associated with smoking for women at baseline. Subsequent persistent smoking was predicted by being a young mother and the number of cigarettes smoked at baseline. Higher levels of anxiety significantly predicted subsequent quitting. Researchers also suggested that there was a strong correlation between anxiety and both smoking and quitting. They found that women who were more anxious at baseline were twice as likely to report current smoking, than those with low anxiety. However, women with high anxiety were surprisingly three times as likely to report quitting 13 years later.

Anxiety sensitivity as it correlated with smoking motives and outcome expectancies among adult daily smokers was investigated by Leyro, Zvolensky, Vujanovic, and Bernstein (2007). Results of the study demonstrated that anxiety sensitivity significantly and incrementally predicted habitual, addictive, negative affect reduction motives to smoke, and negative reinforcement outcome expectations. Anxiety sensitivity was notably more influential than factors such as discomfort intolerance, Axis I diagnosis, gender, volume of alcohol consumed and average number of cigarettes smoked per day. Anxiety sensitivity also was examined as a moderator of the relationship between smoking level and post- traumatic stress symptoms among trauma-exposed adults (Feldner et al., 2008). A majority of the sample utilized was female, 59 of a total of 78 adults exposed to trauma. The researcher outcomes indicated that the combination of high levels of anxiety sensitivity and greater number of cigarettes per day was correlated with

higher symptom levels than any other combination of these factors. A test of specificity was conducted as well and affirmed that the three aspects of anxiety sensitivity did not moderate the relationship between smoking level and depressive smoking symptoms. The researchers suggested that the findings of the study provide greater understanding of the relationship between smoking and posttraumatic symptoms by integrating cognitive factors such as anxiety sensitivity.

The role of anxiety sensitivity as it related to smoking was explored even further in another study conducted by Gonzalez, Zvolensky, Vujanovic, Leyro, and Marshall (2009). These researchers focused on an evaluation of anxiety sensitivity, emotional dysregulation, and negative affectivity among daily cigarette smokers. This was also in relation to smoking motives and barriers to quitting. The study revealed that anxiety sensitivity was significantly related to coping, addictive, and habitual smoking motives, as well as greater perceived barriers to quitting. This was despite variances that were accounted for by concurrent tobacco, alcohol, and marijuana use and discernible from shared variance with negative affectivity and emotional dysregulation. Hence, reinforcing the notion that anxiety sensitivity (as a cognitive factor) is important to a deeper understanding of psychological processes involved with cigarette smoking.

Sleep. A potential relationship between sleep and psychiatric disorders has been explored in the research domain. One study examined this topic in regard to depressive and anxiety disorders. More specifically, researchers focused on insomnia and sleep disturbance as correlates with major depressive disorder and anxiety disorders (van Mill, Hoogendijk, Vogelzangs, van Dyck, & Penninx, 2010). These researchers used a sample of 2,619 individuals from the Netherland Study of Depression and Anxiety. It was revealed in the study that both depressive and anxiety disorder were strongly associated with sleep disturbances. In addition, insomnia and

short sleep duration persisted after remittance of both disorders. Long sleep duration was associated with current depressive and anxiety disorders.

Spira, Stone, Beaudreau, Ancoli-Israel, and Yaffe (2009) examined anxiety symptoms and objectively measured sleep quality with a study sample of 3040 older women. All participants were 65 and older and were living in the community at the time of the study. The researchers suggested in their conclusion that elevated anxiety symptoms were independently associated with poor objectively measured sleep efficiency and elevated sleep fragmentation in very old women. This was given that the study accounted for significant depressive symptoms, medical comorbidities, and use of antianxiety medications.

Otherwise, the issue of sleep patterns and psychological distress was explored by Caldwell and Redeker (2009) with younger female research participants. Their study sample was comprised of 115 women living in the inner city; who were between the ages of 18 and 40 years. These participants were either enrolled in the Special Supplemental Nutrition Program for Women, Infants, and Children or received gynecological care at the clinic of a northwestern urban academic medical center. The findings revealed that high levels of life stress, sleep pattern disturbance, and psychological distress were common with selected populations. Psychological stress included symptoms of anxiety, depression, and psychological trauma.

Prenatal women were also studied in regard to the relationship between depression, anxiety and insomnia symptoms by Swanson, Pickett, Flynn, and Armitage (2011). The sample of 257 pregnant or postpartum women was drawn from a clinical management database and they were all seeking outpatient psychiatric treatment. This was one of the few studies that measured generalized anxiety. Fifty-two percent of women reported symptoms of insomnia, 75% reported

symptoms of depression, and 61% reported symptoms of generalized anxiety. It was concluded that symptoms of insomnia were linked to symptoms of anxiety, as well as, depression.

Another study examined sleep symptoms in women from another perspective. Woods and Sullivan Mitchell (2010) investigated sleep symptoms during the menopausal transition (MT) and early post-menopause (PM) stages in women's reproductive cycles. The sample comprised 286 women from the Seattle Midlife Women's Health Study. A longitudinal study was conducted between 1990 and 2007. The results indicated that the women's problems of not being able to go to sleep was associated with perceived stress, history of sexual abuse, perceived health, alcohol use, and lower cortisol. Severity of nighttime awakening was significantly associated with age, late MT stage, and early PM, hot flashes, depressed mood, joint pain, backache, perceived stress, history of sexual abuse, perceived health, alcohol, and anxiety. Severity of early morning awakening was associated with age, hot flashes, depressed mood, joint pain, backache, perceived stress, history of sexual abuse, perceived health, and anxiety. Therefore, though anxiety was one of the factors linked to sleep patterns there were many others that were also impactful.

Little attention has been paid to a specific relationship between anxiety in women and caffeine or anxiety in women and alcohol. Keogh and Chaloner (2002) indicated that it appears that anxiety sensitivity status in women influenced the analgesic effects of caffeine on pain management. Cited in the above article was a literature review conducted by Fredholm, Battig, Holmen, Nehlig, and Zvartau, (1999). These reviewers reported that apart from caffeine leading to increases in cardiovascular activity, aroused mood, and at times panic; caffeine had the effect of provoking anxiety. However, this finding was not unique to women. A review of the literature revealed a sole study that highlighted a possible relationship between middle-aged and older

adult women and binge drinking. It was concluded that women in these respective age groups, who occasionally binge drink also had an increased risk for panic disorder without agoraphobia and post- traumatic stress disorder. Furthermore, it was a challenge to find any studies that focused on the remaining lifestyle factors included in the Fantastic Lifestyle Assessment.

CHAPTER 3

METHODOLOGY

Introduction

The methods used to collect and analyze the data needed to address the research questions are presented in this chapter. The topics included in this discussion are: restatement of the purpose, research design, setting for the study, participants, instrumentation, data collection procedures and data analysis. Each of these sections will be discussed separately.

Restatement of the Purpose

The purpose of this study was to examine the relationships between hormonal changes or imbalances, healthy/unhealthy lifestyles, and self-efficacy and GAD among women who receiving bio-identical hormonal treatment in a large urban area.

Research Design

A non-experimental, correlational research design was used in this study. This type of research design is useful when attempting to determine the extent to which a relationship exists between variables. According to Gay, Mills, and Airasian (2008), correlational research designs cannot be used to imply causation, however, this type of research can be used to determine the magnitude and direction of the relationships among variables. This type of research design is appropriate when the independent variable is not being manipulated and no treatment or intervention is being provided to the participants.

While experimental research can be affected by threats to internal and external validity, non-experimental research generally does not have the same concerns. As the participants in the present study were asked to complete a set of instruments once, the treat of instrumentation,

regression to the mean, and maturation did not affect this study. However, the researcher was aware of uncontrolled extraneous variables that may have influenced the outcomes of the study.

Setting for the Study

The study was conducted in a large urban city located in Ontario, Canada. The sample of women who participated in the study was clients of a Medical Health Spa that had one site within this region. The Medical Health Spa provides women's health services for an annual fee as a membership-based clinic. Related services are as follows: hormonal replacement therapy, comprehensive health history and physical exam, personal health status reports, breast exams and instruction, pap smear for cervical cancer screening, menstrual disorders, peri and post-menopausal issues, pre-conceptual counseling, pregnancy counseling and testing, STD testing and counseling, birth control counseling, prevention and treatment of osteoporosis, nutrition and weight management, and smoking cessation. The type of hormonal replacement treatment provided is bio-identical hormonal replacement therapy (BHRT). Other uninsured services provided include: school/work notes due to illness, certificate of health verification, prescription repeats by phone/fax, photocopies/faxes.

All services are performed/provided by licensed and board certified health professionals that include the primary care of one Medical Director/Physician. The Medical Director and founder specialized in Internal Medicine, Radiology, Endocrinology, Women's Health, Family Practice, and Cosmetic Medicine. In addition, to being a board certified physician, the medical director is board certified in Anti-Aging Medicine.

The founder's mission is to optimize the health potential of women through health promotion, disease prevention, and continued preservation of overall health, with close regular follow-ups providing education and counseling for matters concerning health, sexuality and

treatment of chronic disease. When women initially become members, they begin with a complete initial physical examination and lab tests as needed. Once the results are attained, members are automatically scheduled for a health promotion consultation and medical treatment required is determined by the medical director/physician. Women are advised to also schedule follow-up consultations every 6-12 weeks depending on the course of treatment recommended.

Participants

The participants in this study are women who have been members of the Medical Health Spa and have been receiving bio-identical hormone replacement therapy for a minimum of three months at the clinic. The participants were at least 18 years of age, with no upper limit on the age of the women in the study. The women in the study were able to read and comprehend English to complete the surveys.

Sample size

To determine the appropriate sample size for the study, a power analysis using G*Power 3.1 was used (Faul, Erdfelder, Lang, & Buchner, 2007). A sample of 34 women was needed to obtain a power of .80 for a multiple linear regression analysis using a two-tailed test, with an effect size of .25, an alpha level of .05, for seven predictors. Increasing the number of participants provides an increase in the power of the analysis to make a correct decision based on the results of the inferential statistical test. Figure 1 presents a graphical representation of the effects of sample size on power for this study.

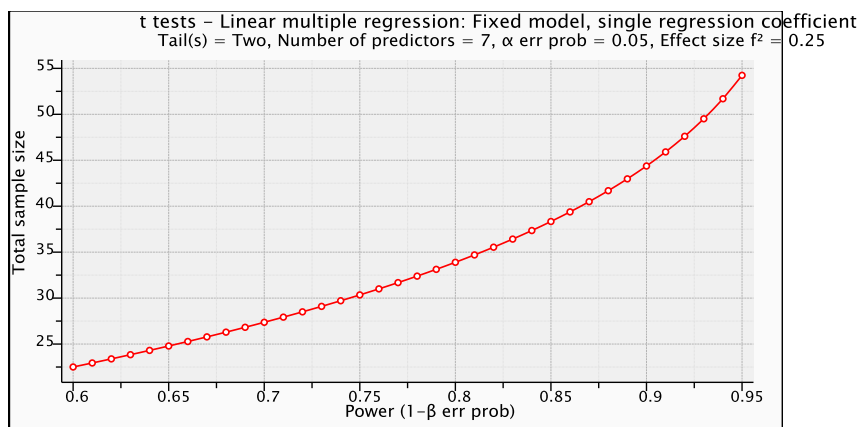


Figure 1 - Sample Size Calculation

Note: Faul et al., 2007

Instrumentation

Four instruments have been used in the study. These instruments include: Generalized Anxiety Disorder Scale (Spitzer, Kroenke, Williams, & Lowe, 2006), The General Self-Efficacy Scale (Schwarzer & Jerusalem, 1995), FANTASTIC Lifestyle Checklist (Ciliska & Wilson, 1984; Wilson, Nielsen, & Ciliska, 1984), and a researcher-developed demographic survey.

Generalized Anxiety Disorder Scale (GAD-7; Spitzer, et al., 2006).

The GAD-7 is a 7-item self-report scale was developed to measure the extent of generalized anxiety in the general population. The GAD-7 assesses the diagnostic criteria of the *Diagnostic and Statistical Manual of Mental Disorders* (4th Ed.; DSM-IV – TR; American Psychiatric Association, 2000) diagnostic criteria A, B, and C for GAD. Participants indicate the number of times during the past two weeks that they have experienced the seven symptoms that are considered central to GAD. Response options range from not at all (0) to nearly every day (3).

Scoring. The numeric values associated with the ratings are summed to obtain a total score. Possible scores could range from 0 to 21, with higher scores indicating higher levels of generalized anxiety. The scores greater than 5, but less than 10 indicate mild anxiety, with scores 10 or greater and less than 15 indicating moderate anxiety. Scores 15 or greater are indicative of severe anxiety symptoms. As the purpose of this study is not to diagnose anxiety, the raw scores will be used in the data analysis.

Validity and reliability. A confirmatory factor analysis provided support that the 7 items on the scale were measuring a single construct (Löwe et al., 2008). The results were the same when tested by gender and ethnicity. Statistically significant relationships were obtained for the GAD-7 when correlated with the Patient Health Questionnaire -2 ($r = .64, p < .001$) and the Rosenberg Self-Esteem Scale ($p = -.43, p < .001$). The resultant correlations were in the anticipated directions. Discriminant validity was used to determine if the scale could discriminate between men and women. Women had significantly higher scores when compared to men.

Cronbach alpha coefficients were used to determine the internal consistency of the items (Löwe et al., 2008). Results of this testing provided an alpha coefficient of .89, which reflects good internal consistency. No tests were reported on the stability of the instrument over time.

Norm scores. Normative scores were obtained for a sample of 5,030 participants, including men (46.4%) and women (57.6%) with a mean age of 48.4 ($sd = 18.0$) years. The Approximately 5% of the participants had GAD-7 scores 10 or higher (moderate to severe generalized anxiety) and 1% had scores 15 or greater (severe generalized anxiety; Löwe et al., 2008).

The General Self-Efficacy Scale (Schwarzer & Jerusalem, 1995).

The General Self-Efficacy Scale (GSE; Schwarzer & Jerusalem, 1995) was developed in 1979 to measure general self-efficacy, focusing on being able to predict the ability to cope with daily hassles and ability to adapt following experiences with stressful life events. According to Bandura (as cited in Scholz, Doña, Sud, & Schwarzer, 2002), most self-efficacy scales should be domain-specific (e.g., ability to complete algebra problems, ability to run a marathon). The scale consists of 10 items that were based on the premise that generalized self-efficacy is related to the confidence that a person has in his/her ability to manage stressful experiences effectively.

Scoring. The participants will be asked to rate each of the 10 items using a 4-point scale ranging from 1 for not at all true to 4 for exactly true. The numeric ratings for each of the 10 items are summed to obtain a total score that ranges from 10 to 40. Higher scores on this scale are indicative of higher levels of general self-efficacy.

Validity and reliability. A principal components factor analysis was used to determine the homogeneity of the instruments. Separate studies with a German, Spanish, and Chinese sample produced results that indicated a single factor construct (Schwarzer, Bäßler, Kwiatek, & Schröder, 1997). When self-efficacy scores were correlated with depression ($r = -.52$), anxiety ($r = -.60$), and optimism ($r = .55$), the results were statistically significant and in the anticipated directions indicating good discriminant validity. Schwarzer et al. (1997) asserted that these results also were aligned with Bandura's self-efficacy theory.

The internal consistency of the scale was assessed using Cronbach alpha coefficients. The resultant alpha coefficients were .91 for the Chinese scale, .84 and .81 for the German and Spanish scale respectively. These results indicate that good internal consistency. The German version of the scale was tested for stability by having a group of cardiac surgery patients

complete the scale prior to surgery and again six months later. The correlation coefficient of .67 provided support that the instrument had good stability as a measure of reliability. Tests of reliability for the American version of the instrument provided similar outcomes.

FANTASTIC Lifestyle Checklist

The FANTASTIC Lifestyle checklist (Wilson & Ciliska, 1984) was developed as a lifestyle assessment for physicians to use in learning about their patients' lifestyles and environmental factors. The checklist uses 25 items to measure 9 lifestyle factors: family and friends; activity; nutrition; tobacco and toxins; alcohol; sleep, seatbelts, and stress; type of personality; insight; and career.

Scoring. The items are rated using 3-point scales, with the measurements depending on the items being measured. The 3-point scales range from 0 to 2, with higher scores indicating greater adoption of the lifestyle. The numeric values associated with the items under each lifestyle factors will be summed to obtain a total score. This score will be divided by the number of items to obtain a score that reflects the original measurement scale.

Validity. The instrument has been tested for validity by correlating the physicians' assessment with scores from the FANTASTIC (Kason & Ylanko, 1984). The correlation was low, but statistically significant between patients' and doctors' rating of the lifestyles of the patients ($r = .22$, $p < .001$, $DF = .97$).

Reliability. The stability of the FANTASTIC Lifestyle Checklist was tested using test/retest correlations (Kason & Ylanko, 1984). The obtained correlations between the two ratings was .60 ($p < .001$, $DF = 98$). The correlations for the individual items ranged from .64 (competition and aggression) to .89 (ideal weight). The overall correlation was .60, with the factor correlations ranging from .37 for alcohol and driving to .59 for emotional support. All of

the correlations were statistically significant. Wilson, Nielsen, and Ciliska (1984) tested the checklist for reliability. The test-retest correlations for people under 65 years of age ranged from .62 for career to .87 for tobacco/toxins. No reports were provided for internal consistency, possible because of the limited number of items on lifestyle factor.

Demographic Survey

The researcher-developed demographic survey was used to collect personal characteristics of the women who will be included in the study. The items on this survey included age, ethnicity, educational level, marital status, number of children, and work status. The items used a combination of forced-choice and fill-in-the-blank response formats. The women were assured that all information is confidential and that no person will be identifiable in the study.

Data Collection Methods

After obtaining approval from the Human Subjects Committee at Wayne State University to conduct the study, the researcher met with the physician who agreed to allow her to ask patients in her practice to participate in the study. At this meeting, the researcher and the physician determined a coding technique that was used to link data from the physician regarding the number and type of hormonal levels for which her patients are being treated and the survey responses from the patients. Using this code, the researcher developed survey packets that included a copy of the informed consent form, a letter from the physician indicating her support for the study (invitation letter), and copies of the four surveys that were then used in the study, and one preaddressed, postage paid envelope for confidential return of the completed survey and signed informed consent form. The informed consent form was used to explain the purpose of

the study, provide assurances of confidentiality, and ask permission for the physician to release medical information regarding the patient's hormonal imbalances.

After coding the surveys, the researcher gave the survey packets to the nurse practitioner to address the envelopes to the selected patients. The nurse practitioner was also given a coding sheet that was used to match the patients' hormonal levels with the returned surveys. Only the nurse practitioner and physician knew the identities of the participants. The researcher has only the numeric code that was assigned, and remains unaware of the patients' names or addresses. This provides assurances of confidentiality.

The women who received the survey packets were asked to read the informed consent form, sign and place it in the envelope addressed to the physician's office, along with the completed survey. The informed consent form and the completed survey were then mailed to the physician's office. When each participant's signed consent form and completed survey was received, the physician's nurse practitioner then retrieved respective saliva test results for that participant indicating hormonal levels at initial and most recent testing. Saliva tests results were copied, coded, and all identifiers were blocked out. The researcher was then provided each participant's completed coded survey and saliva tests. All signed consent forms received from participants in this study remain stored at the medical health spa. The above process provided assurances that confidential medical information were not disclosed for any participant who did not agree to be in the study and maintained the confidentiality of the women who did participate in the study.

The participants completed the surveys in their homes. They were instructed not to provide any identifying information on the surveys (e.g., name, address). They were also asked

to place the survey (in addition to the consent form) in the envelope with the physician's address and place them in the mail.

One week following initial distribution of the surveys, the nurse practitioner sent a reminder to the non-responders. In this notice, she thanked those who had completed and returned their surveys and asked those who did not respond to return their completed surveys. The data collection was considered complete four weeks following the initial distribution of the surveys.

Data Analysis

The data from the surveys were entered into a computer file for analysis using SPSS – Windows, ver. 20.0. The data analysis was divided into three sections. The first section used frequency distributions and measures of central tendency and dispersion to provide a profile of the participants. The second section used descriptive statistics to summarize the responses on the scaled variables, including levels of hormones, GAD scores, scores on the healthy/unhealthy lifestyle survey, and levels of self-efficacy. The third section of the data analysis used inferential statistical analyses to address the research questions developed for the study. The statistical analyses used in this section included pearson product moment correlations, stepwise multiple linear regression analysis, and mediation analysis. All decisions on the statistical significance of the findings were made using a criterion alpha level of .05. Table 1 presents the statistical analyses used in this study.

Table 1

Statistical Analysis

Research Questions	Variables	Statistical Analysis
1. What is the relationship between hormonal levels and GAD.	Hormonal levels Severity of GAD Symptoms	Pearson product moment correlations will be used to determine the strength and direction of the relationship between hormonal levels and the severity of GAD symptoms
2. Can women's experiences with GAD be predicted from hormonal levels, a healthy or unhealthy lifestyle, and level of self-efficacy?	<u>Dependent Variable</u> Severity of GAD Symptoms <u>Independent Variable</u> Hormonal Levels Healthy/unhealthy lifestyle Level of self-efficacy	Stepwise multiple linear regression analysis will be used to determine which of the independent variables can be used to predict the severity of GAD symptoms.
3. Is the relationship between women's experiences with GAD and hormonal levels mediated by a healthy or unhealthy lifestyle?	<u>Dependent Variable</u> Severity of GAD symptoms <u>Independent Variable</u> Hormonal Levels <u>Mediating Variable</u> Healthy/unhealthy lifestyle	Barron and Kenney's four-step mediation analysis will be used to determine if a healthy/unhealthy lifestyle mediates the relationship between severity of GAD symptoms and level of hormones. The four steps that are used in the mediating analysis are: <i>Step 1:</i> Show that the initial variable is correlated with the outcome. Use Y as the criterion variable in a regression equation and X as a predictor (estimate and test path <i>c</i> in the above figure). This step establishes that there is an effect that may be mediated. <i>Step 2:</i> Show that the initial variable is correlated with the mediator. Use M as the criterion variable in the regression equation and X as a predictor (estimate and test path <i>a</i>). This step essentially involves treating the mediator as if it were an outcome variable. <i>Step 3:</i> Show that the mediator affects the outcome variable. Use Y as the criterion variable in a regression equation and X and M as predictors (estimate and test path <i>b</i>). It is not sufficient just to correlate the mediator with the outcome; the mediator and the outcome may be correlated because they are both caused by the initial variable X.

Research Questions	Variables	Statistical Analysis
<p>4. Is the relationship between women's experiences with GAD and hormonal levels mediated by their level of self-efficacy?</p>	<p><u>Dependent Variable</u> Severity of GAD symptoms</p> <p><u>Independent Variable</u> Hormonal Levels</p> <p><u>Mediating Variable</u> Level of Self-efficacy</p>	<p>Thus, the initial variable must be controlled in establishing the effect of the mediator on the outcome.</p> <p><i>Step 4:</i> To establish that M completely mediates the X-Y relationship, the effect of X on Y controlling for M (path c') should be zero. The effects in both Steps 3 and 4 are estimated in the same equation. If all four of these steps are met, then the data are consistent with the hypothesis that variable M <i>completely</i> mediates the X-Y relationship, and if the first three steps are met but the Step 4 is not, then <i>partial</i> mediation is indicated. (Barron & Kenny, 2012, p. 2)</p> <p>Barron and Kenney's four-step mediation analysis will be used to determine if the level of self-efficacy mediates the relationship between severity of GAD symptoms and number of hormonal levels.</p>

CHAPTER 4

RESULTS OF DATA ANALYSIS

The results of the data analyses were used to provide a description of the sample and address the research questions developed for the study. The chapter is divided into three sections. The first section provides a profile of the participants, with baseline data on the scaled variables presented in the second section of the chapter. Results of inferential statistical analyses that were used to address the research questions posed for the study are presented in the third section of the chapter.

The purpose of this study is to examine the relationships among changes in hormonal levels, healthy/unhealthy lifestyles, and self-efficacy and GAD among women who are receiving bio-identical hormonal treatment in a large urban area. In turn, the aim is to suggest implications for licensed professional counselors regarding initial treatment assessment, appropriate referral, and effective treatment interventions.

A total of 266 surveys were distributed to women being seen at a medical health spa in a large urban area. Of this number, 55 were completed and returned for a response rate of 20.7%. Data on the hormonal levels of the women when first seen at the medical health spa and at their latest visit were obtained from their medical records.

Description of the Sample

The women completed a short demographic survey to provide information on their personal characteristics. The ages of the women were summarized using descriptive statistics. Table 2 presents results of this analysis.

Table 2

Descriptive Statistics – Ages of the Participants

Number	Mean	SD	Median	Range	
				Minimum	Maximum
50	54.74	7.06	54.50	37	71
Missing	5				

The mean age of the women was 54.74 (SD = 7.06) years, with a median age of 54.50 years. The women ranged in age from 37 to 71. Five women did not provide their ages on the survey.

The women provided their ethnic group on the survey. Frequency distributions were used to summarize their responses. Table 3 presents results of this analysis.

Table 3

Descriptive Statistics – Ethnic Group

Ethnic Group	Number	Percent
African Canadian	2	3.7
Asian/Pacific Islander	1	1.8
Caucasian	50	90.9
Multi-ethnic	1	1.8
Other	1	1.8
Total	55	100.0

The majority of the women in the study reported they are Caucasian (n = 50, 90.0%), with 2 (3.7%) indicating their ethnicity as African Canadian. One (1.8%) participant each reported Asian/Pacific Islander, multi-ethnic, or other.

The women were asked to report their marital status. Their responses were summarized using frequency distributions for presentation in Table 4.

Table 4

Descriptive Statistics – Marital Status

Marital Status	Number	Percent
Single/Never married	1	1.8
Married	45	81.8
Divorced	5	9.2
Living with Partner	2	3.6
Other	2	3.6
Total	55	100.0

The largest group of participants ($n = 45$, 81.8%) reported their marital status as married. Five (9.2%) women indicated their marital status as divorced. One (1.8%) woman was single/never married, and 2 (3.6%) each reported their marital statuses as living with partner and other.

The women reported their employment status on the survey. Frequency distributions were used to summarize their responses. Table 5 presents the results of this analysis.

Table 5

Descriptive Statistics – Employment Status

Employment Status	Number	Percent
Working full-time	29	53.7
Working part-time	11	20.4
Retired	12	22.2
Currently not working, not looking for employment	2	3.7
Total	54	100.0
Missing	1	

The majority of the women (n = 29, 53.7%) reported they were working full-time, with 11 (20.4%) indicating their employment status was working part-time. Twelve (22.2%) women were retired, with 2 (3.7%) indicating that they were currently not working and not looking for employment. One participant did not provide a response to this question.

The women were asked to indicate the number of dependent children living at home. Their responses were summarized using frequency distributions for presentation in Table 6.

Table 6

Descriptive Statistics – Number of Dependent Children

Number of Dependent Children	Number	Percent
0	32	62.7
1	10	19.6
2	7	13.7
3	1	2.0
4	1	2.0
Total	51	100.0
Missing	4	

The largest group of women (n = 32, 62.7%) reported no dependent children, with 10 (19.6%) indicating they had one dependent child. Seven (13.7%) of the women had two dependent children and 1 (2.0%) each reported 3 and 4 dependent children. Four of the participants did not provide a response to this question.

The length of time since the women's first treatment was obtained from their records. These dates have been summarized in six month increments. Table 7 presents the frequency distribution summarizing the length of time since first treatment.

Table 7

Descriptive Statistics – Length of Time since First Treatment

Length of Time Since First Treatment	Number	Percent
0 to 6 months	6	11.3
7 to 12 months	7	13.2
13 to 18 months	2	3.8
19 to 24 months	2	3.8
25 to 30 months	4	7.5
31 to 36 months	1	1.9
37 to 42 months	3	5.7
43 to 48 months	3	5.7
49 to 60 months	4	7.5
61 to 72 months	1	1.9
72 to 84 months	4	7.5
84 to 96 months	2	3.8
96 to 108 months	5	9.4
108 to 120 months	7	13.2
More than 120 months	2	3.8
Total	53	100.0

The greatest number of women (n = 7, 13.2%) had started treatment either 6 to 12 months ago or 108 to 120 months ago. The time since beginning treatment ranged from 0 to 6 months or more than 120 months prior to the study.

Description of the Variables

The scaled variables, generalized anxiety, self-efficacy, and healthy/unhealthy lifestyle factors, were scored using the authors' protocols. The hormonal levels at the last office visit were obtained from the physician's records. The scores on the surveys and the hormonal levels were summarized using descriptive statistics. Table 8 presents results of this analysis.

Table 8

Descriptive Statistics – Hormonal Levels and Scaled Variables

Variable	Number	Mean	SD	Median	Range	
					Minimum	Maximum
Hormones						
Estrone	55	4.89	8.18	2.00	.10	50.00
Estradiol	55	12.03	17.21	4.40	.10	80.00
Estriol	55	31.62	21.21	46.60	.10	50.00
Progesterone	55	333.99	968.74	17.00	1.00	5000.00
Testosterone	55	26.00	50.79	11.00	1.00	318.00
Cortisol	55	2.26	1.41	1.87	.58	8.11
DHEA	55	.11	.11	.08	.01	.66
Self-efficacy	55	3.22	.46	3.30	1.60	3.90
Anxiety	55	1.91	.69	1.80	1.00	3.86
Healthy Lifestyles						
Family/friends	55	4.36	.70	4.67	2.00	5.00
Activity	55	3.65	1.04	4.00	1.00	5.00
Nutrition	55	3.96	.68	4.00	2.25	5.00
Tobacco/toxins	55	4.51	.34	4.67	3.33	5.00
Alcohol	55	4.75	.48	5.00	3.00	5.00
Sleep/Seatbelt/Stress	55	3.81	.64	3.67	2.33	5.00
Personality	55	3.42	.81	3.33	1.67	5.00
Insight	55	3.75	.81	3.67	2.00	5.00
Career	55	4.41	.70	4.50	2.00	5.00

Hormones. The mean estrone level was 4.89 (sd = 8.18), with a median of 2.00. The range of actual levels was from less than .10 to 50.00. The normal range for estrone was <16. Estradiol had a mean score of 12.03 (sd = 17.21), with a median of 4.40. The range of actual levels for estradiol was .10 to 80.00. The normal range for estradiol is from 0.2 to 5.2. The range of actual levels for estriol was from .10 to 50.00, with a median of 46.60. The mean estriol level was 31.62 (sd = 21.21). The normal range for estriol was < 32.00. The mean score for progesterone was 333.99 (sd = 968.74), with a median of 17. The range of actual levels of progesterone was from 1.00 to 5000.00. Normal range for progesterone was 80 to 270. The mean level of testosterone was 26.00 (sd = 50.79), with a median of 11.00. The actual range of testosterone levels was from 1.00 to 318.00. The normal range for testosterone was 4 to 33. The mean level of cortisol was 2.26 (sd = 1.41), with a median of 1.87. The range of actual levels of cortisol was from .58 to 8.11. The normal range for cortisol was from 1.80 to 3.80. The mean level of DHEA was .11 (sd = .11). The median level for DHEA was .08, with a range from .01 to .66. Normal range for DHEA was from .10 to 1.30.

The mean score for self-efficacy was 3.22 (sd = .46), with a median score of 3.30. The actual range of scores was 1.60 to 3.90. Possible scores on this scale could range from 1.00 to 4.00, with higher scores indicating higher levels of self-efficacy.

The mean score for general anxiety was 1.91 (sd = .69). The median score for anxiety was 1.80, with actual scores ranging from 1.00 to 3.86. Possible scores could range from 1.00 to 4.00, with higher scores indicating greater anxiety. The raw scores for GAD were summarized using the cut-points developed by Spitzer, Kroenke, Williams, and Lowe (2006). Mild anxiety was found in 18 (32.7%) of the participants, with 22 (40.0%) of the women reporting moderate levels of anxiety. Fifteen (27.3%) women in the study reported severe anxiety.

The healthy/unhealthy lifestyle subscales were rated using a 5-point scale, with higher scores indicating a healthier lifestyle. The mean score for family/friends was 4.36 (sd = .70), with a median of 4.67. The actual scores on this subscale ranged from 2.00 to 5.00. The mean score for activity was 3.65 (sd = 1.04), with a median score of 4.00. Actual scores for activity ranged from 1.00 to 5.00. The mean score for nutrition was 3.96 (sd = .68), with a median score of .68. The range of actual scores for nutrition was from 2.25 to 5.00. The mean score for tobacco/toxins was 4.51 (sd = .34), with a median score of 4.67. Actual scores for tobacco/toxins ranged from 3.33 to 5.00. The range of actual scores for alcohol ranged from 3.00 to 5.00, with a median score of 5.00. The mean score for alcohol was 4.75 (sd = .48). The mean score for sleep/seatbelt/stress was 3.81 (sd = .64), with a median of 3.67. The range of actual scores for sleep/seatbelt/stress was from 2.33 to 5.00. The mean score for personality was 3.42 (sd = .81), with a median score of 3.33. The range of actual scores was from 1.67 to 5.00. The range of actual scores for insight was from 2.00 to 5.00, with a median score of 3.67. The mean score for insight was 3.75 (sd = .81). The mean score for career was 4.41 (sd = .70), with a median score of 4.50. The range of actual scores for career was from 2.00 to 5.00.

Research Questions

Four research questions were posed for this study. Each of these questions were addressed using inferential statistical analyses, with all decisions on the statistical significance of the findings made using a criterion alpha level of .05.

Research question 1. What is the relationship between hormonal levels and GAD?

Pearson product moment correlations were used to determine the strength and direction of the relationships between hormonal levels and GAD. The results of this analysis are presented in Table 9.

Table 9

Pearson Product Moment Correlations – Hormonal Levels and Generalized Anxiety Disorders

Hormones	Number	r	p
Estrone	55	-.17	.225
Estradiol	55	-.10	.449
Estriol	55	-.33	.014
Progesterone	55	.10	.478
Testosterone	55	-.04	.757
Cortisol	55	.12	.401
DHEA	55	-.11	.412

One hormone, estriol, was statistically significant related to GAD, $r(55) = -.33, p = .014$. The negative relationship between estriol and GAD indicated that women who had lower levels of estriol tended to report higher GAD. The remaining correlations between the hormone levels and GAD were not statistically significant.

Research question 2. Can women's experiences with GAD be predicted from hormonal levels, a healthy or unhealthy lifestyle, and level of self-efficacy?

A stepwise multiple linear regression analysis was used to determine which of the hormone levels, levels of self-efficacy, and healthy or unhealthy lifestyles could be used to predict GAD. The results of this analysis are presented in Table 10.

Table 10

Stepwise Multiple Linear Regression Analysis – Generalized Anxiety Disorder, Hormone Levels, Self-Efficacy, and Healthy and Unhealthy Lifestyles

Predictor	Constant	b- Weight	β	Δr^2	T	p
Included Variables						
Insight	3.94	-.54	-.63	.40	-5.88	<.001
Excluded Variables						
Estrone			-.07		-.62	.541
Estradiol			-.08		-.76	.451
Estriol			-.17		-1.57	.123
Progesterone			.20		1.86	.068
Testosterone			.05		.49	.626
Cortisol			.01		.10	.924
DHEA			-.10		-.10	.349
Self-efficacy			-.08		-.08	.528
Family/friends			.21		.21	.088
Activity			-.06		-.06	.599
Nutrition			-.13		-.13	.230
Tobacco/Toxins			-.06		-.06	.584
Alcohol			.03		.03	.770
Sleep/Seatbelts/Stress			-.21		-.21	.080
Personality			-.24		-.24	.129
Career			-.10		-.10	.515
Multiple R	.63					
Multiple R ²	.40					
F Ratio	34.60					
DF	1, 53					
Sig of F	<.001					

One predictor variable, insight, was a statistically significant predictor of GAD, $F(1, 53) = 34.60$, $p < .001$. The negative relationship between insight and GAD indicated that women who had higher levels of insight were less likely to have GAD. The remaining predictor variables did not enter the stepwise multiple linear regression equation, indicating they were not statistically significant predictors of GAD.

Research question 3. Is the relationship between women's experiences with GAD and hormonal levels mediated by a healthy or unhealthy lifestyle?

The Baron and Kenny's (2012) four-step mediation analysis was used to determine if healthy or unhealthy lifestyle elements were mediating the relationship between GAD and hormonal levels. As insight was the only healthy or unhealthy lifestyle element that was a statistically significant predictor of GAD, the mediation analysis was limited to this variable. Table 11 presents results of the mediation analysis for GAD and estriol.

Table 11

Mediation Analysis – Insight as a Mediator in the Relationship between GAD and Estriol

Predictor Variable	Criterion Variable	R ²	F ratio	β
Estriol	GAD	.11	6.53	-.33*
Estriol	Insight	.08	4.31	.27*
Insight	GAD	.40	34.60	-.63**
Insight	GAD	.40	34.60	-.63**
Estriol		.03	19.01	-.17

*p < .05; **p < .01

On the first step of the mediation analysis, a statistically significant relationship was found between estriol (predictor variable) and GAD (criterion variable), $R^2 = .11$, $F(2, 52) = 6.53$, $\beta = -.33$. The relationship between estriol and the mediator, insight, tested on the second step of the analysis was statistically significant, $R^2 = .08$, $F(2, 52) = 4.31$, $\beta = .27$. The third step of the mediation analysis tested the relationship between estriol and GAD. The results of this analysis was statistically significant, $R^2 = .40$, $F(2, 52) = 34.60$, $\beta = -.63$. In Step 4, when holding insight constant, the standardized beta weight for GAD was reduced from $-.33$ (step 1) to

-.17 (step 4), $R^2 = .03$, $p > .01$. Based on this finding, insight appears to be mediating the relationship between estriol and GAD.

Research question 4. Is the relationship between women's experiences with GAD and hormonal levels mediated by their level of self-efficacy?

A mediation analysis was planned using GAD as the criterion variable and hormonal levels as the predictor variable. Level of self-efficacy was to be used as the mediating variable. Because self-efficacy was not related to GAD, mediation analysis was not completed.

Summary

The results of the statistical analyses that were used to describe the sample and address the research questions have been presented in this chapter. A discussion of the findings and recommendations for practitioners and further research are included in Chapter 5.

CHAPTER 5

SUMMARY AND DISCUSSION

Summary

The intent of the study was to conduct a preliminary enquiry into the relationship between Generalized Anxiety Disorder (GAD) in women and hormonal imbalances, self-efficacy, and lifestyle. Key consideration was also given to the outcomes of the study as it points to implications for licensed professional counselors and counselor educators. This chapter features a summary of the statement of the problem, literature, study methods and procedures, and findings of the study. In turn, included is a discussion of findings, implications of the study, limitations of the study, and recommendations for further study.

Restatement of the Problem

Risk factors associated with anxiety disorders, GAD, and women with GAD have been researched in a number of study domains. Yet based on a review of the literature, there has been a perfunctory investigation of the relationship between hormonal imbalances and GAD symptoms in women. A lack of attention to this topic may be attributed, at least in part, to the controversial nature of hormone replacement therapy (HRT) within a patriarchal medical system and an on-going primary interest in other factors traditionally associated with GAD.

The absence of literature on the topic in question is only heightening within the discipline of counselor education. It is postulated that the non-existence of such studies is the result of understandable limitations of counselor education programs. Such programs have not had the latitude to focus on how physiological or subtle physiological problems may impact the overall well-being of individuals from a clinical counseling prospective. As a result, an interest in pursuing research in this area has not been sparked. Therefore, the core challenge or problem for

licensed professional counselors is to identify the contribution that a subtle physiological risk factor can make to a client's complaint. Given that licensed professional counselors are predominantly trained to assess if a referral is merited for a medical or psychiatric diagnosis based on overt medical and psychiatric symptoms. It was argued in this study that a poignant example of such a potential challenge for counselors may be how the physiological issue of a hormonal imbalance is related to a woman's experience of GAD.

The significance of the problem for licensed professional counselors resides in the potential for the initial and on-going assessment to be based on an incomplete picture of what is primarily contributing to the client's complaint or symptoms. Furthermore, assessments of that nature can have secondary consequences that are just as important to consider. For instance, medical, psychiatric, or other referrals may be neglected or ignored as part of the treatment and implementation process. Likewise, compromised treatment outcomes also can result when inappropriate or inadequate treatment interventions may be utilized.

Literature Summary

The relevance attached to addressing women and GAD is steeped in the literature reviewed. The literature reflects the mental health landscape in the United States with regard to anxiety disorders in the general population and anxiety disorders as experienced by women. It is within this mental health context that women's experience of GAD is conceptualized. According to the Anxiety Disorders Association of America (ADAA, 2011), approximately 40 million adults, age 18 and older are affected by anxiety disorders (18 % of the general population). The association has also stated that anxiety disorders are the most common mental illness in the United States. The ADAA (2011) also indicated that anxiety disorders account for a third of the total cost of mental health in the United States. Such notable costs are related to the following

according to the ADAA (2011): (a) physician visits that are five times more likely for individuals with an anxiety disorder, and (b) hospitalizations for other psychiatric disorders that are six times more likely than for individuals without an anxiety disorder.

Furthermore, according to Piggott (2003), one in four individuals will experience an anxiety disorder in their lifetimes. What confounds this finding is that older adults are just as at risk as younger individuals for anxiety; particularly GAD (ADAA, 2011). Piggott (2003) also identified related consequences of being diagnosed with an anxiety disorder that includes a vulnerability to depression, increased risk for functional impairments, diminished job opportunities, impaired job performance, and elevated mobility and mortality rates.

There is an even more disconcerting picture that has developed based on the literature in regard to anxiety disorders and women. Since the early 1980s and beyond, studies have consistently shown that females are more at risk than males for fear and anxiety and have at least twice the risk for anxiety disorders (Bourdon et. al 1988 as cited in Craske, 2003). Alexander et al. (2007) found that women experience a high lifetime rate of anxiety disorders, with approximately 30.5% of women meeting diagnostic criteria from epidemiologic studies. Moreover, Ginsberg (2004) highlighted how profound gender is in regard to anxiety disorders with a statement that gender increases the likelihood of developing an anxiety disorder by 85% for women as opposed to men.

Otherwise, Craske (2003) provided more depth and understanding of the topic of anxiety disorders related specifically to women. The author focused extensively on women's unique vulnerability to certain risk factors for anxiety disorders throughout their lives; as opposed to men. Craske (2003) noted that unlike men, women confront increases in negative affectivity (emotional reactivity) over the lifespan as their gender roles continue to inform their functioning.

Craske (2003) detailed that social influences predominate as contributors to growing negative affectivity in females over time. These social influences include parents and their predisposition to reinforce gender specific behavior, sensitivity to facial expressions and related heightened threat detection, exposure to major trauma, and social network crises. These social factors are influential within a context of women's lives that exclude learning or mastery of effective threat re-appraisals due to the lack of exposure to their world unlike men (Taylor et al., 2000).

The following is a summary of other studies that have focused on either psychosocial factors or female hormonal factors as they relate to women and anxiety disorders. Calkin et al. (2009) found that the major predictors of anxiety for women were a history of anxiety, increased anxiety sensitivity (the fear of anxiety related sensations), and increased neuroticism when it was the first episode of anxiety. Otherwise, the onset and recurrence of anxiety were predicted by anxiety sensitivity and neuroticism. Recurrence for women was predicted by history of anxiety disorder.

According to Alexander, Dennerstein, Kotz, and Richardson (2007), anxiety and mood disorders were related to the dynamic interaction of factors, such as early life experiences, heredity, gender, other psychiatric illness, stress, and trauma. Based on the findings of Heim et al. (2002), life stress, including a history of childhood abuse and further trauma in adulthood for women, was correlated with anxiety in women. The study's underlying premise was that the pathophysiology of anxiety and mood disorders was associated with a sensitization of stress-responsive neurobiological systems that were impacted by early adverse experiences. Barrera and Norton (2009) found that individuals with GAD, social phobia, and panic disorder reported being less satisfied with their lives than non-anxious individuals. Therefore, quality of life impairment was related to anxiety in both women and men.

Piggott (1999) was one of the few researchers who highlighted more unique characteristics of anxiety disorders rather than psychosocial factors. One of those unique characteristics was hormonal factors in women. This author's underlying premise was that three primary neurotransmitter systems mediate anxiety: the locus ceruleus-norepinephrine system, the serotonin system, and the γ -aminobutyric acid (GABA) – benzodiazepine receptor complex. It was also postulated that estrogen and progesterone might serve to regulate the function of the neurotransmitter systems mentioned above. The author suggested that estrogen enhances serotonin function and in turn may account for genetic differences in anxiety disorders. It was also proposed that progesterone can antagonize and/or neutralize the actions of estrogen. Hence, the mood enhancing and stress-attenuating effects of estrogen may be neutralized by the administration of progesterone as well. Piggott (1999) also underscored that:

1. enhanced serotonin response was found in postmenopausal women who received estrogen replacement therapy,
2. there was some evidence that elderly women tend to respond to SSRI anti-depressant treatment more efficiently when they receive estrogen replacement therapy,
3. anxiety disorders tend to worsen during the premenstrual stage of the cycle due to cyclic gonadal hormonal changes in women, and
4. the menstrual cycle, pregnancy, and the post-partum period has an influence on the onset and course of specific anxiety disorders (specifically) obsessive-compulsive disorder and panic disorder.

Other studies have provided findings regarding the relationship between cortisol and anxiety disorders. Wardenaar et al. (2011) found that there were increases in levels of cortisol in patients who were anxious at the time of their study and more specifically in patients who

experienced panic disorder and agoraphobia. It was noted in the study that morning increases in cortisol correlated with specific symptom patterns and severity, rather than only when there was a presence of a patient diagnosis. Oskis, Loveday, Hucklebridge, Thorn, and Clow (2011) found that participants who were either female children or adolescents had higher level of morning cortisol when they exhibited an anxious attachment style. The pattern of cortisol dysregulation identified was concluded to be similar to the cortisol dysregulation patterns previously found in studies of adult females with anxiety disorders.

McHugh, Behar, Gutner, Geem, and Otto (2010) found that there was a trend towards a stronger negative association between acute cortisol change and attentional bias change among women relative to men. The underlying premise of the study was that attentional bias (toward threatening stimuli) is a key feature of anxiety and acute stress. The study supported the theoretical perspective of Craske (2003) that suggested there is a relationship between compromised attentional control in women and emotional dysregulation. Pico-Alfonso, Garcia-Linares, Celda-Navarro, Herbert, and Martinez (2004) found that there were alterations in evening levels of cortisol for women who experienced intimate partner violence. These women were also experiencing severe symptoms of anxiety, as well as, depression and posttraumatic disorder.

Relevant to a summary of the studies that addressed the topic of testosterone and anxiety disorders in women is the notion that testosterone is the end product of the hypo-thalamic-pituitary-gonadal axis that down regulates the stress response at multiple levels (Hermans et al., 2007). In their study, Hermans et al. (2007) revealed that the administration of testosterone led to a decreased responsiveness of the stress system in healthy women described as anxiety-prone participants. Giltay et al. (2012) found that saliva testosterone was lower in female patients

diagnosed with depressive disorders, GAD, social phobia, and agoraphobia. Van Honk, Peper, and Schutter (2005) showed that testosterone might reduce fear but not consciously experienced anxiety in women.

A summation of studies related to the relationship between DHEA and anxiety disorder in women is introduced with the following statement. DHEA is a major circulating corticosteroid in humans and serves as a precursor for both androgenic and estrogenic steroids. Pico-Alfonso et al. (2004) found that apart from having higher levels of morning cortisol, women who were victims of intimate partner violence had higher levels of morning and evening DHEA. Higher levels of anxiety, depression, and incidence of PTSD also were associated with higher levels of morning and evening DHEA. One of Strous et al. (2003) findings was improvements in negative symptoms, depression, and anxiety in study participants who received DHEA; particularly with regard to women with schizophrenia.

A summary of the reviewed literature has focused on research in the areas of anxiety disorders in the general population and anxiety disorders in women. Consequently, research more specific to the subject of GAD and women's experience of GAD will be summarized at this juncture. According to ADAA (2011), approximately 6.8 million adults or 3.1 % of the United States population is affected by GAD each year. Hence, GAD is the most common type of anxiety disorder. Approximately 90% of individuals with a lifetime prevalence rate for GAD also are likely to have a lifetime history of at least one other psychiatric diagnosis (Do & Do, 2008). It was estimated that approximately one third of GAD patients also have a comorbid diagnosis of depression that increases the risk for suicide. Other comorbid diagnoses are agoraphobia, simple phobias, social anxiety disorder, panic disorder, alcohol dependency, and drug dependency (Do & Do, 2008). These researchers have indicated that GAD correlates with psychosocial

impairments, disability, decreased quality of life, and increased use of health care resources. According to Ballenger et al. (2001), GAD is the most common cause of disability in the United States workplace. Melchoir et al. (2007) found that individuals exposed to high psychological job demands were also twice as likely to develop GAD. Furthermore, older individuals were just as susceptible to experiencing GAD as younger people (Lenze et al., 2011). These findings are compelling since women are now considered the majority of the older population (US Department of Health and Human Services, 2007). Riley (2011) identified the following risk factors for GAD in general: being female; family member with an anxiety disorder; long-term exposure to abuse, poverty, or violence; low self-esteem; poor coping skills; smoking or other substance abuse; and increased stress.

According to Piggott (2003), most primary care patients who present for treatment for GAD: (a) are women, (b) report that the onset for GAD is age 25 to 45 years, (c) are more likely to have a comorbid psychiatric diagnosis, and (d) experience a chronic clinical course with greater symptom severity in women than men. Kendel and colleagues (as cited in Piggott, 2003) have stated that a childhood history of parental marital separation or childhood history of separation from a parent in women was an indicator of GAD as adults. According to Piggott (2003), female reproductive hormone cycles are a risk factor for GAD symptom severity for women. Howell, Brawman-Mintzer, Monnier, and Yonkers (2001) suggested a connection between gender-specific social roles or experiences and GAD in women.

According to Hsiao, Hsiao, & Liu (2004), higher rates of premenstrual exacerbations and premenstrual syndrome (with related decreases in estrogen levels) were reported by patients with GAD. Tafet et al. (2001) found that there was a notable increase in the level of afternoon cortisol in the blood of patients with GAD and Major Depressive Disorder (MDD). A study conducted by

Mantella et al. (2008) revealed that late life GAD was characterized by elevated basal saliva cortisol levels and severity of GAD was positively correlated with cortisol levels. The study suggested that HPA axis dysfunction was implicated in late life GAD as well. Lenze et al. (2011) concluded that SSRI treatment of GAD in older adults reduced HPA axis hyperactivity. These researchers suggested that application of SSRIs correlated with reductions in cortisol. Otherwise, Tafet et al. (2005) found a significant decrease in HAM-A scores for anxiety and changes in plasma cortisol levels after the administration of cognitive therapy. These researchers implied that there was an indirect link between cortisol levels and symptoms of GAD. Steude et al. (2011) suggested that under naturalistic conditions, GAD is associated with hypercortisolism. The results of this study were contrary to other similar studies mentioned above. At least, in part due to a different measure of cortisol from hair samples, rather than saliva plasma or urinary assessments. Several of the studies highlighted above included samples of both male and female participants.

Some research focused on self-efficacy as it relates to the experience of anxiety and GAD in women. Srimathi and Kiran Kumar (2010) found a significant and positive correlation between all dimensions of psychological well-being (autonomy, environmental mastery, personal growth, positive relations with others, purpose in life, and self- acceptance) and self-efficacy scores. Self-acceptance and environmental mastery correlated highly with self-efficacy; and purpose of life and autonomy correlated least with self-efficacy.

Jones et al. (2010) revealed that women given a combination of cognitive behavioral stress management and expressive supportive therapy (which led to an increase in cognitive behavioral self-efficacy) experienced significant decreases in both anxiety and depression. Stanley, Back, and Swann (2002) found that self-efficacy and outcome expectations were lower

in older adults with GAD relative to published data from younger and older community samples. According to Lavoie, Boudeau, Plourde, Campbell, and Bacon (2011) self-efficacy played an important role in determining asthma outcomes in relation to GAD.

It was a challenge to discover research that highlighted a relationship between a healthy/unhealthy lifestyle and GAD in women. However, there was literature that spoke to relationships between some to the lifestyle factors included in the FANTASTIC Lifestyle checklist and the experience of anxiety. Xu, Alexander, and Courtney (2010) found that of the lifestyle measures examined (body mass index, exercise, smoking, alcohol use, and caffeine consumption) only exercise correlated with anxiety. Exercise participated in five to six times per week led to a limited reduction in anxiety. Likewise, Salmon (2001) revealed that exercise has non-specific benefits that assist in the reduction of anxiety. Exercise training has reduced anxious mood by comparison with strength and flexibility training. Strohle (2009) also concluded that well controlled recent studies suggest that exercise training may be effective in addressing panic attacks. De Moor, Beem, Stubble, Boomsma, and De Geus (2006) found that exercisers were on average less anxious. Gutierrez et al. (2011) revealed that postmenopausal women with moderate to severe symptoms of anxiety showed significant improvements when they exercised. Similarly, Pasco et al. (2011) concluded that high levels of habitual physical activity that included household activities, sporting activities, and other physically active leisure-time activities are protective against subsequent risk of development of anxiety disorders.

One study that focused on GAD and exercise revealed that resistance and aerobic exercise both led to improvements in signs and symptoms associated with GAD (Herring, Jacob, Suveg, and O'Conner (2011). According to Herring, Jacob, Suvey, Dishman, and O'Conner

(2012), exercise training is a feasible, low risk treatment that can potentially reduce the worry symptoms associated with anxiety.

Several studies showed diet and nutrition impact anxiety. These studies revealed a connection between a light diet (Yannakoulia et al., 2008), traditional diet (Jacka et al., 2010) and healthy diet (Kacka et al. 2011) and lower levels of anxiety. Several studies (Felder et al., 2008; Gonzalez, Zvolensky, Vujanovic Leyro, & Marshall, 2009; Leyro, Zvolensky, Vujanovic, & Bernstein, 2007) have found an association between anxiety sensitivity and smoking. According to McGee and Williams (2006), there was a strong correlation between anxiety and both smoking and quitting for women.

With regard to sleep as a lifestyle factor, several studies found an association between different forms of disturbed pattern of sleep and anxiety in women (Caldwell & Redeker, 2008; Spira, Stone, Beaudreau, Ancoli-Israel, & Yaffe, 2009; Swanson, Pickett, Flynn, & Armitage, 2011). According to van Mill, Hoogendijk, Vogelzangs, van Dyke, & Penninx (2010) anxiety disorders, as well as, depressive disorders were strongly associated with sleep disturbances in the general population.

Review of Methods and Procedures

A nonexperimental, correlational research design was used in the study conducted in a large urban city in Ontario, Canada. Participants in the study were female clients at a Medical Health Spa who had been receiving bio-identical hormonal replacement therapy (BHRT) for a minimum of three months. The participants were at least 18 years of age, with no upper limit on the age of the women in the study.

A demographic survey, including age, ethnicity, educational level, marital status, number of children, and work status, was developed by the researcher to collect personal characteristics

of the women who participated in the study. The Generalized Anxiety Disorder Scale (GAD-7; Spitzer et al., 2006) was used to measure the extent of generalized anxiety experienced by women in the sample. The General Self-Efficacy Scale (Schwarzer & Jerusalem, 1995) was used to measure general self-efficacy in women who participated in the study with a focus on being able to predict their ability to cope with daily hassles and adapt after experiences with stressful life events. The FANTASTIC Checklist served as a lifestyle assessment tool that measured nine healthy/unhealthy lifestyle factors for participants in the study.

Survey packets included: (a) the Medical Health Spa's invitation that demonstrated the physician's support for completion the survey, (b) an informed consent form, (c) copies of the surveys, and (d) postage-paid envelope for confidential return of the completed surveys. Each informed consent form, survey, and preaddressed, postage-paid envelope for return of completed surveys was coded by the researcher to correspond with the coding system developed with the Medical Health Spa. The coding sheet was used by the nurse practitioner to document matching codes for each participant's respective consent form, surveys, and medical report that indicated saliva test results of hormonal levels.

A total of 266 survey packets were prepared by the researcher and were then addressed and mailed to clients by the nurse practitioner assisting in the study. The goal was to maintain the confidentiality of the women in the study by providing no identifiers to the researcher including names and addresses of participants. Of the 266 surveys mailed, 55 were completed and returned with a response rate of 20.7%.

Survey packets returned by women who participated in the study included their signed consent form and completed surveys. The nurse practitioner assisting in the study matched completed surveys with each respective woman's initial and most recent saliva test that recorded

hormonal levels. All returned and signed informed consent forms are stored at the Medical Health Spa to ensure that no personal identifiers for participants in the study are shared with the researcher. In addition to completed surveys, respectively matched initial and most recent saliva tests of participants were delivered to the researcher for statistical analysis.

Statistical analysis included the following. Pearson product moment correlations were used to determine the strength and direction of the relationship between hormonal changes and severity of GAD symptoms. Stepwise multiple linear regression analysis was used to determine which of the independent variables (hormonal levels, healthy/unhealthy lifestyle, and level of self-efficacy) could be used to predict the severity of GAD symptoms. Baron and Kenney's (2012) four-step mediation analysis was used to determine if a healthy/unhealthy lifestyle mediated the relationship between severity of GAD and hormonal levels. Baron and Kenney's four step mediation analysis was also used to determine if self-efficacy mediated the relationship between severity of GAD and hormonal levels.

Summary of Findings

The age of the women who completed the surveys ranged from 37 to 71 years, with a mean age of 54.74 (SD = 7.06) years. Ages were provided by 50 of the 55 women in the sample. Fifty (90.9%) of women who completed the survey were Caucasian, 3.7% (n=2) identified as African Canadian, and 1.8% (n=1) identified as Asian/Pacific Islander, multi-ethnic, or other. Forty-five (81.8%) of the participants reported that they were married, with 9.2% (n=5) indicated that their marital status was divorced, 3.6% (n=2) indicated they were living with partner and other. One (1.8%) reported she was single/never married. Twenty-nine (53.7%) of the women in the study reported working full-time, 20.4% (n=11) were working part-time, 22.2% (n=12) were retired, and 3.7% (n=2) indicated that they were currently not working and not looking for

employment. One participant did not respond to the question of her employment status at the time of the study. Thirty-two (62.7%) participants reported no dependent children, 10 (19.6%) had one dependent child, 7 (13.7%) reported two dependent child and 1 (2.0%) indicated 3 and 4 dependent children. Four of the participants in the study did not response to this question.

Based on the primary care physician's report, 66.7 % of the women initially assessed for hormonal imbalances reported experiencing mild to moderate levels of anxiety at the time. One third (33.3%) of the women initially assessed for hormonal imbalances reported experiencing severe levels of anxiety at the time. The primary care physician recorded the level of severity in regard to anxiety as part of an initial medical assessment when women presented with related health concerns. The present study found that 32.7% of the participants reported mild levels of generalized anxiety, 40% reported moderate levels of generalized anxiety, and 27.3% reported severe levels of anxiety. The percentages represent the levels of anxiety the participants experienced over the last two weeks prior to completing the GAD-7.

Research Questions

Four research questions were developed for this study. Each of these questions were addressed using inferential statistical analyses, with all decisions on the significance of the findings made using a criterion alpha level of .05.

Research question 1. What is the relationship between hormonal levels and GAD?

Pearson product moment correlations were used to determine the strength and direction of the relationships between GAD and hormonal levels. The results of this analysis provided evidence that estriol was significantly related to GAD ($r = -.33$, $p = .014$). The negative direction of this relationship indicated that lower levels of estriol were associated with higher levels of GAD. The other hormones were not significantly related to GAD.

Research question 2. Can women's experiences with GAD be predicted from hormonal levels, a healthy or unhealthy lifestyle, and level of self-efficacy?

A stepwise multiple linear regression analysis was used to determine which of the hormone levels, levels of self-efficacy, and healthy or unhealthy lifestyles could be used to predict GAD. Insight, a subscale of healthy and unhealthy lifestyles, entered the stepwise multiple linear regression equation, accounting for 40% of the variance in GAD ($R^2 = .40$, $F [1, 53] = 34.60$, $p < .001$). The negative relationship between insight and GAD provided evidence that women who had higher scores for insight were likely to have lower scores for GAD. The remaining independent variables did not enter the stepwise multiple linear regression equation, indicating they were not statistically significant predictors of GAD.

Research question 3. Is the relationship between women's experiences with GAD and hormonal levels mediated by a healthy or unhealthy lifestyle?

The Baron and Kenny (2012) four-step mediation analysis was used to determine if the relationship between hormonal levels and GAD was mediated by insight, a subscale of healthy and unhealthy lifestyles. One hormone was used in this analysis because estriol was the only hormone that was significantly related to GAD. The results indicated that when holding insight constant on the fourth step of the mediation, the amount of variance in GAD explained by estriol decreased from .11 on the first step to .03. The relationship between estriol and GAD also became nonsignificant, indicating that insight was a statistically significant mediator in the relationship between estriol and GAD.

Research Question 4. Is the relationship between women's experiences with GAD and hormonal levels mediated by their level of self-efficacy?

A mediation analysis was planned using GAD as the criterion variable and hormonal levels as the predictor variable. Level of self-efficacy was to be used as the mediating variable. Because self-efficacy was not related to GAD, the mediation analysis was not completed.

Discussion of Findings

The findings of the study are instrumental in bolstering the research conducted in regard to the impact hormone imbalances have on women's overall well-being. All women in the sample, at the time of their most recent saliva test, had hormonal levels within identified normal ranges. However, with the exception of estriol, hormonal levels were towards the minimal end of each respective normal range. Levels of estriol for women in the study were towards the maximum of the normal range. This seems to confirm what has been reported in some of the research literature that (a) when estrogen decreases, women's level of anxiety tend to be higher or (b) when estrogen treatment is administered anxiety levels in women decrease.

Based on the literature reviewed, studies that found correlations between anxiety disorders and levels of estrogen in women lacked attention more specifically to GAD. The present study suggests that there is a similar negative relationship between estrogen and GAD; like the negative relationship between estrogen and anxiety in women. It is interesting that the study found no significant relationships between GAD and testosterone, progesterone, cortisol, and DHEA. Particularly, since women in the sample had levels of these hormones in the lower end of the normal range. This result leads to a curiosity about the potential relationship between a pattern of lower levels of testosterone, progesterone, cortisol, and DHEA (within normal ranges) combined with higher levels of estriol (within the normal range) and lower levels of generalized anxiety.

The finding that insight (a subscale of healthy/unhealthy lifestyles) accounted for 40 % of the variance in GAD is noteworthy. Since the study showed that there was a negative relationship between insight and GAD, it seems to imply that women may potentially be able to manage symptoms of generalized anxiety by increasing their level of insight. The additional finding that insight was a significant mediator in the relationship between estriol and GAD appears to reinforce the importance of insight as a factor that impact generalized anxiety in women.

Implications of the Study

The literature reviewed and the results of the present study suggest that this is a subject that is worthy of further attention by licensed professional counselors. It provides credence to the notion that subtle physiological factors may influence the emotional and psychological well-being of our clients, particularly women. However, the present study resonates that though significant, such subtle physiological factors would not be beneficial to overestimate; relative to the backdrop of a plethora of other confounding factors that have also been well documented in the research examined. Otherwise, the major finding of the present study that lower levels of estriol were associated with higher levels of GAD is consistent with the findings of several other studies in regard to the relationship between estrogen and anxiety in women. As a result, such a finding indirectly supports the need for counselors to inquire more specifically about women's hormonal levels and related medical conditions when treating mood disorders.

Hence implicitly, the necessity to complete a thorough medical/psychosocial history at the time of intake gains added validation. It may no longer be sufficient to document the major medical conditions that women may experience. Instead, specific questions may need to be asked in regard to the subject of hormonal health. Particularly for women, documentation of such an

inclusive medical history can serve to (a) heighten the awareness of hormonal health for women, (b) open the door to psycho-education about how a woman's overall well-being may be impacted by levels of sex/reproductive hormones at different stages of their lives and (c) influence medical referral decisions and treatment planning from a holistic perspective; to include complementary traditional and/or non-traditional medical treatment.

Interestingly, an unexpected outcome of the study was the light brought to the relevance of counseling as a potential primary treatment modality for GAD. This unexpected outcome was revealed given the other major finding in the study that there is a negative relationship between insight and GAD. Hence, evidence indicating that women who had higher scores for insight were likely to have lower levels for GAD. The finding that insight was a statistically significant mediator in the relation between estriol and GAD also strengthened what was brought to light in regard to counseling as a primary treatment modality for GAD.

Therefore, the evidence that insight was key to the management of the symptoms of GAD seems to speak indirectly to the role of the licensed professional counselor. It can be argued that one of the primary roles of counselors is to facilitate the client's development of personal insight or perceptiveness when navigating through the world. For instance, Gastonguay and Hill (2006) describe insight as the acquisition of a new understanding that is recognized as an important vehicle of change for several approaches to psychotherapy. Therefore, it is postulated that without an individual's growth in insight, positive shifts in thinking, feeling, and behavior may be a challenge; even with exposure to appropriate coping skills with the counseling process. Hence, the outcome of the study in regard to insight underlines the key role that counseling can continue to play in the effective management of generalized anxiety for women. It is acknowledged that within the context of the FANTASTIC Checklist insight is defined as the way

in which one construes the world (Sherk, Thomas, Wilson, & Evans, 1985). While this definition of insight can be developed further with future research, it seems in keeping with how insight appears to be generally defined within the context of counseling.

The significant negative relationship between estriol and GAD found in the present study highlights the relevance of understanding hormones as a subtle physiological factor that relates to women's mental health. As more research is conducted in this area, it may become compelling to raise awareness of the subject within counselor education. Counselor educator programs can infuse learning about this issue, as it impacts the lives of women, into related course curriculum. For example, curriculum that focuses on medical psychosocial issues impacting this population, an understanding of the DSM, cultural diversity issues in regard to women, and seminars that include women's issues. Furthermore, such infusions of learning into the established curriculum can be enriched by inviting experts from other disciplines to present as well within counselor education programs.

Educating faculty and clinical supervisors about hormonal imbalances in women and potential impacts on their mental health would also be beneficial. Working together faculty and clinical supervisors can be instrumental in teaching counselors in training how to complete an intake process that is sensitive to female client needs in regard to mental health issues that may be related to subtle physiological factors. Part of the teaching process should include (a) sensitizing students to the medical signs and symptoms that suggest a possible hormonal underlying issue and (b) when it is deemed merited, facilitate more specific medical history questioning in regard to hormones and related health conditions as part of an initial holistic assessment of the client. In turn, counselors in training may then learn how to make appropriate medical referrals for medical treatment that may enrich counseling outcomes in general.

Limitations of the Study

The timing of the study may have been an issue. Since participants were requested to complete survey during December (the holiday season) this may in part have led to a lower participant response rate of 20.7%. In turn, the study is limited in its generalizability due to a small sample of 55 women. More specifically, the sample may not be representative of the general population in terms of ethnicity; the majority of women (90.9%) indicated Caucasian.

The presence of stress/anxiety related to the pending holidays could have been a confounding variable that may have influenced levels of generalized anxiety for women in the sample. The use of two different measures for collecting (a) baseline levels of anxiety and (b) levels of anxiety later in BHRT treatment was a major limitation as well. Further inferences may have been made if a consistent measure of generalized anxiety disorder was used at baseline (during the assessment phase prior to beginning BHRT) and later in the BHRT treatment process. Social desirability bias may also have influenced the manner in which participants chose to answer questions on the self-reported instruments of the present study.

Recommendations for Further Research

The findings of this study are arguably notable to the extent that it warrants additional related research. It is encouraged that further research be engaged in by counselor educators and/or professional counselors in collaboration with researchers in other disciplines who have similar interests. Such collaborative research will foster more thorough examination of such issues from different highly informed respective perspectives. For instance, researchers who are also professional counseling clinicians may make unique contributions. It is also strongly suggested that the study be replicated with (a) a larger sample size and (b) use of the same or an even more suitable measure of GAD with pre- and post-tests and (c) if possible be longitudinal in

nature. The inclusion of a valid/reliable social desirability scale may also be an asset in similar future research.

APPENDIX A

SURVEY

Please place a check mark in the column that most closely matches how true each of the following statements are true about you.

1	2	3	4			
Not at all true	Hardly true	Moderately true	Exactly true			
Place a check mark in the column that matches how true each of the following statements are about you:			1	2	3	4
1. I can always manage to solve difficult problems if I try hard enough.						
2. If someone opposes me, I can find the means and ways to get what I want.						
3. It is easy for me to stick to my aims and accomplish my goals.						
4. I am confident that I could deal efficiently with unexpected events.						
5. Thanks to my resourcefulness, I know how to handle unforeseen situations.						
6. I can solve most problems if I invest the necessary effort.						
7. I can remain calm when facing difficulties because I can rely on my coping abilities.						
8. When I am confronted with a problem, I can usually find several solutions.						
9. If I am in trouble, I can usually think of a solution.						
10. I can usually handle whatever comes my way.						
1	2	3	4			
Not at all	Several days	More than half the days	Nearly every day			
Over the last 2 weeks, how often have you been bothered by the following problems? (Check the column to indicate your answer)			1	2	3	4
1. Feeling nervous, anxious, or on edge.						
2. Not being able to stop or control worrying.						
3. Worrying too much about different things.						
4. Trouble relaxing.						

5. Being so restless that it is hard to sit still.					
6. Becoming easily annoyed or irritable.					
7. Feeling afraid as if something awful might happen.					
Circle the answer in each column that best describes your behavior or condition in the past month.					
My communication with others is open, honest, and clear	Almost Always	Fairly Often	Some of the time	Seldom	Almost never
I give and receive affection.	Almost Always	Fairly Often	Some of the time	Seldom	Almost never
A get the emotional support I need.	Almost Always	Fairly Often	Some of the time	Seldom	Almost never
Active exercise – 30 minutes (e.g., running, cycling, fast walk)	Almost daily	3-5 times a week	2 times a week	Less than once a week	Almost never
Relaxation and enjoyment of leisure time	Almost daily	3-5 times a week	2 times a week	Less than once a week	Almost never
Balanced meals	Almost Always	Fairly Often	Some of the time	Seldom	Almost never
Breakfast daily	Almost Always	Fairly Often	Some of the time	Seldom	Almost never
Excess sugar, salt, animal fats, or junk foods	Almost Always	Fairly Often	Some of the time	Seldom	Almost never
Ideal weight	Within 5 lbs.	Within 10 lbs.	Within 15 lbs.	Within 20 lbs.	Over 20 lbs.
Tobacco use	None in the past 5 years	None in the past year	None in the past 6 months	1 to 10 times/week	More than 10 times/week
Abuse of drugs, prescribed and unprescribed	Almost never	Seldom	Some of the time	Fairly often	Almost daily
Coffee, tea, cola	Never	1-2 daily	3-6 daily	7-10 daily	More than 10 daily
Average intake of alcohol per week	0-7 drinks	8-10 drinks	11-13 drinks	14-20 drinks	More than 20 drinks
Alcohol and driving	Never	Almost	Only	Once a	Often

		never	occasionally	month	
7-9 hours sleep per night	Almost always	Fairly often	Some of the time	Seldom	Almost never
Frequency of seat belt use	Always	Most of the time	Some of the time	Seldom	Never
Major stressful events in past year	None	1	2-3	4-5	More than 5
Sense of time urgency, impatience	Almost never	Seldom	Some of the time	Fairly often	Almost always
Competitive and aggressive	Almost never	Seldom	Some of the time	Fairly often	Almost always
Feelings of anger and hostility	Almost never	Seldom	Some of the time	Fairly often	Almost always
Positive thinker	Almost always	Fairly often	Some of the time	Seldom	Never
Anxiety, worry	Almost never	Seldom	Some of the time	Fairly often	Almost always
Depression	Almost never	Seldom	Some of the time	Fairly often	Almost always
Satisfied in job or role	Almost always	Fairly often	Some of the time	Seldom	Never
Good relationships with those around	Almost always	Fairly often	Some of the time	Seldom	Never

Please answer the following questions as they relate to you. There are no right or wrong answers. All information that you provide will remain confidential.

Age

Ethnic Group

- African Canadian
 Arabic
 Asian/Pacific Islander
 Caucasian
 Hispanic
 Multi-ethnic
 Other _____

Marital Status

- Single, never married
 Married
 Divorced
 Living with partner
 Widowed
 Other _____

- Employment Status Working full-time
 Working part-time
 Retired
 Student
 Currently not working, looking for employment
 Currently not working, not looking for employment

Number of dependent children _____

APPENDIX B

INVITATION LETTER

As a valued patient of the _____ Medical Health Spa and a female who would be eligible to participate in this activity, it is with great pleasure and appreciation that we invite you to participate in the enclosed study.

The study is the foundation of the dissertation being completed by a Ph.D. Candidate from Wayne State University – Gillian Robbins. As a licensed professional counselor who specializes in women’s issues, this student has a strong interest in further understanding what enhances the overall health and well-being of women. Therefore, the focus of her study is an examination of how women’s imbalances in hormones, level of self-efficacy, and lifestyle factors impact their experience of anxiety; and in turn their quality of life.

At _____, we are highly aware and sensitive to the negative impact anxiety has on the lives of our female patients; including those who receive bio-identical hormonal replacement therapy. Hence, we view the focus of this study as important to getting closer to effectively addressing anxiety as an obstacle in the lives of women. As a result, we welcome your support by becoming a participant in the study because it may also provide valuable information that affirms and enhances the quality to services we provide to women affected by this issue of concern.

Your participation is completely voluntary. The treatment and care you receive at the _____ Medical Health Spa will remain of the highest quality, even if you choose not to participate at any point in the study.

Your participation will be completely anonymous in nature and no one outside of the staff here at _____ will have any means of identifying who you are.

If you choose to participate in the study by completing the enclosed informed consent form and survey, then your baseline and most recent saliva test results will also be included as data in the study. The primary investigator will have access to saliva test results and surveys with no personal identifiers.

If you have any questions about the study during the period in which it is being conducted, kindly contact the primary investigator - Gillian Robbins, MA, LPC, CRC, CCC at _____.

Incentive: Participants names will be included in a draw for 1 of 5 _____ Spa package entitled “Le Petit Spa”, valued at _____. Kindly return your signed consent form and survey by December/17/2012.

Sincerely,

APPENDIX C

Research Informed Consent

Title of Study: THE RELATIONSHIP BETWEEN GENERALIZED ANXIETY DISORDER IN WOMEN AND HORMONAL IMBALANCES, SELF-EFFICACY, AND LIFESTYLE: IMPLICATIONS FOR LICENCED PROFESSIONAL COUNSELORS AND COUNSELOR EDUCATORS

Principal Investigator (PI): Gillian Robbins, Doctoral Candidate
College of Education
Department of Theoretical and Behavioral Foundations

Purpose

You are being asked to be in a research study examining the relationship between generalized anxiety disorder (GAD) in women and hormonal imbalances, self-efficacy, and lifestyle. As a female patient of Dr. Sherman's, who is at least 18 years old and has received bio-identical hormone replacement therapy you qualify to participate in this study. The estimated number of participants to be enrolled is 100.

The purpose of the study is to look at how hormonal imbalances, a healthy or unhealthy lifestyle, and the level of confidence women beyond age 18 have in their ability to function/perform with preferred outcomes (self-efficacy) impact the level of anxiety they experience.

Study Procedures

If you agree to take part in this research study, you will be asked to complete a survey with three parts.

The survey will take approximately 15 minutes to complete and there is will be no personal identifying information anywhere on the survey. Therefore, you will be asked not to write/print your name or any other form of personal identification on the survey to be submitted.

In the survey you will be asked to provide demographic information and answer questions about your experiences with symptoms of anxiety, your lifestyle in regard to health, and personal self-efficacy.

To protect your identity, you will be assigned a code number that will be the only identifier on your survey or any other data collected for the study.

In addition to the information on the survey, your medical records will be accessed to obtain your hormonal levels from your saliva tests taken at baseline and the most current saliva test. Care will be taken not to use any other information from your medical records. The code number

assigned to you will be used as the identifier and only the office staff will know the code numbers assigned to each potential participant in the study.

Research Informed Consent

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After completing the survey as per instructions included, kindly enclose the completed survey in the preaddressed, postage paid envelope that is included in the survey packet.

Benefits

As a participant in this research study, there will be no direct benefit for you; however, information from this study may benefit other people in the future.

Risks

By taking part in this study, you may experience the following risks:

Psychological/Emotional Risks: Study participants may experience feelings of anxiety, sadness, or other negative emotions. Referrals for professional counseling services will be provided in the event that a participant makes the primary investigator aware of the need for counseling.

Study Costs

Participation in this study will be of no cost to you.

Compensation

You will not be paid for taking part in this study. However, you will qualify to be part of a drawing for a Spa package in the amount of \$.00 when you complete and return the survey to

Research Related Injuries

The risks to the study are no more than minimal. In the unlikely event that you are injured, no reimbursement, compensation, or medical care is offered by Wayne State University, Medical Health Spa, or the researcher.

Confidentiality

All information collected about you during the course of this study will be kept confidential to the extent permitted by law. You will be identified in the research records by a code number. Information that identifies you personally will not be released without your written permission. However, the study sponsor, the Institutional Review Board (IRB) at Wayne State University, or federal agencies with appropriate regulatory oversight [e.g., Food and Drug Administration

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(FDA), Office for Human Research Protections (OHRP), Office of Civil Rights (OCR), etc.) may review your records.

When the results of this research are published or discussed in conferences, no information will be included that would reveal your identity.

Voluntary Participation/Withdrawal

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you decide to take part in the study you can later change your mind and withdraw from the study. You are free to answer only questions that you want to answer. You are free to withdraw from participation in this study at any time. Your decisions will not change any present or future relationship with Wayne State University or its affiliates, or other services you are entitled to receive.

The PI may stop your participation in this study without your consent. The PI will make the decision and let you know if it is not possible for you to continue. The decision that is made is to protect your health and safety, or because you did not follow the instructions to take part in the study

Questions

If you have any questions about this study now or in the future, you may contact Gillian Robbins at the following phone number . If you have questions or concerns about your rights as a research participant, the Chair of the Institutional Review Board can be contacted at

If you are unable to contact the research staff, or if you want to talk to someone other than the research staff, you may also call to ask questions or voice concerns or complaints.

Research Informed Consent

Title of Study: THE RELATIONSHIP BETWEEN GENERALIZED ANXIETY DISORDER IN WOMEN AND HORMONAL IMBALANCES, SELF-EFFICACY, AND LIFESTYLE: IMPLICATIONS FOR LICENCED PROFESSIONAL COUNSELORS AND COUNSELOR EDUCATORS

Consent to Participate in a Research Study

To voluntarily agree to take part in this study, you must sign on the line below. If you choose to take part in this study you may withdraw at any time. You are not giving up any of your legal rights by signing this form. Your signature below indicates that you have read, or had read to you, this entire consent form, including the risks and benefits, and have had all of your questions answered. You will be given a copy of this consent form.

_____	_____
Signature of participant	Date
_____	_____
Printed name of participant	Time
_____	_____
Signature of person obtaining consent	Date
_____	_____
Printed name of person obtaining consent	Time

[

APPENDIX D

WAYNE STATE UNIVERSITY INSTITUTIONAL REVIEW BOARD APPROVAL

WAYNE STATE
UNIVERSITY

IRB Administration Office
87 East Canfield, Second Floor
Detroit, Michigan 48201
Phone: (313) 577-1628
FAX: (313) 993-7122
<http://irb.wayne.edu>

NOTICE OF EXPEDITED APPROVAL

To: Gillian Robbins
College of Education

From: Dr. Scott Millis S. Millis, PhD
Chairperson, Behavioral Institutional Review Board (B3) [Signature]

Date: November 16, 2012

RE: IRB #: 114312B3E

Protocol Title: The Relationship Between Generalized Anxiety Disorder in Women and Hormonal Imbalances, Self-Efficacy and Lifestyle: Implications for Licensed Professional Counselors and Counselor Educators

Funding Source:

Protocol #: 1211011460

Expiration Date: November 15, 2013

Risk Level / Category: Research not involving greater than minimal risk

The above-referenced protocol and items listed below (if applicable) were **APPROVED** following *Expedited Review* Category (#7) * by the Chairperson/designee for the Wayne State University Institutional Review Board (B3) for the period of 11/16/2012 through 11/15/2013. This approval does not replace any departmental or other approvals that may be required.

- The IRB has determined that all applicable criteria for expedited approval have been satisfied.
 - This research meets the criteria for Expedited Review per Category #7.
 - Protocol Summary Form and Protocol (received in the IRB office on 11/13/12).
 - Research Informed Consent, dated 10/15/2012.
 - Medical Health Spa Invitation Letter
 - Data Collection Tools: General Self-Efficacy Scale, PHQ and GAD-7
-

- Federal regulations require that all research be reviewed at least annually. You may receive a "Continuation Renewal Reminder" approximately two months prior to the expiration date; however, it is the Principal Investigator's responsibility to obtain review and continued approval **before** the expiration date. Data collected during a period of lapsed approval is unapproved research and can never be reported or published as research data.
- All changes or amendments to the above-referenced protocol require review and approval by the IRB **BEFORE** implementation.
- Adverse Reactions/Unexpected Events (AR/UE) must be submitted on the appropriate form within the timeframe specified in the IRB Administration Office Policy (<http://www.irb.wayne.edu/policies-human-research.php>).

NOTE:

1. Upon notification of an impending regulatory site visit, hold notification, and/or external audit the IRB Administration Office must be contacted immediately.
2. Forms should be downloaded from the IRB website at **each** use.

*Based on the Expedited Review List, revised November 1998

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ABSTRACT**THE RELATIONSHIP BETWEEN GENERALIZED ANXIETY DISORDER IN WOMEN AND HORMONAL IMBALANCES, SELF-EFFICACY AND LIFESTYLE: IMPLICATIONS FOR LICENSED PROFESSIONAL COUNSELORS AND COUNSELOR EDUCATORS**

by

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May 2013

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The intent of the study was to conduct a preliminary enquiry of the relationship between Generalized Anxiety Disorder (GAD) in women and hormonal imbalances, self-efficacy, and lifestyle. Key consideration was given to the study as it points to implications for licensed professional counselors and counselor educators. A nonexperimental, correlation design was used in the study and conducted in a large urban city in Ontario, Canada. Participants in the study were female clients receiving bio-identical hormone replacement therapy (BHRT) for a minimum of three month at a Medical Health Spa.

A total of 55 participants completed a demographical survey, the Generalized Anxiety Disorder Scale (GAD-7), the General Self-Efficacy Scale, and the FANTASTIC checklist. Pearson product moment correlations were used to determine the strength and direction of the relationships between GAD and hormonal levels. Estriol was significantly related to GAD ($r = -.33, p = .014$). The negative direction of this relationship indicated that lower levels of estriol were associated with higher levels of GAD. A stepwise multiple linear regression analysis was used to determine which of the hormone levels, levels of self-efficacy, and healthy or unhealthy

lifestyles could be used to predict GAD. Insight, a subscale of healthy and unhealthy lifestyles, entered the stepwise multiple linear regression equation, accounting for 40% of the variance in GAD ($R^2 = .40$, $F [1, 53] = 34.60$, $p < .001$). The negative relationship between insight and GAD provided evidence that women who had higher scores for insight were likely to have lower scores for GAD. The Baron and Kenny (2012) four-step mediation analysis was used to determine if the relationship between hormonal levels and GAD was mediated by insight. One hormone was used in this analysis because estriol was the only hormone that was significantly related to GAD. Insight was a statistically significant mediator in the relationship between estriol and GAD. Implications for licensed professional counselors and counselor educators, as well as, recommendations for further research were included.

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