

**THE EFFECT OF A LEISURE EDUCATION INTERVENTION ON ANXIETY LEVELS
OF INDIVIDUALS PARTICIPATING IN A SMOKING CESSATION PROGRAM**

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**A Dissertation Submitted to the Faculty of Middle Tennessee State University
in Partial Fulfillment of the Requirement for the Degree of
Doctor of Philosophy**

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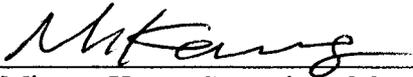
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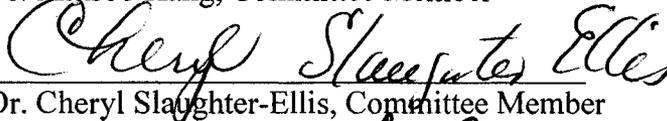
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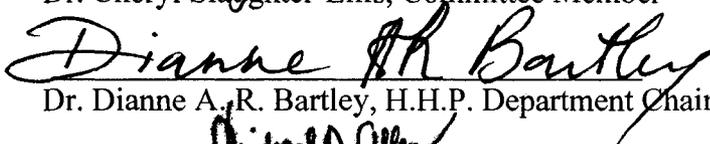
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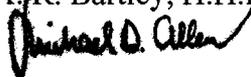
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According to the literature, anxiety levels are exacerbated in individuals attempting to overcome addiction to nicotine (NIDA, 1998). It was hypothesized that a structured leisure education intervention, when added to an existing smoking cessation program, would reduce anxiety levels in individuals participating in the program. There have been no documented studies of leisure education being utilized as an intervention with individuals in a smoking cessation program.

The existing smoking cessation program which was used for the study consists of an initial visit to the Department of Veterans Affairs Tennessee Valley Healthcare System (VATVHS) Murfreesboro Campus Preventive Medicine Clinic. The initial visit included a written intake evaluation and an educational session which includes tobacco-related health information and education, discussion between the participant and a Preventive Medicine nurse and physician and the provision of pharmaceutical aids, when indicated, to assist with the smoking cessation process. Subjects were drawn from veterans who voluntarily participated in this smoking cessation program. To obtain a treatment group (n = 25) and a control group (n = 25), a scripted consistent fifteen minute verbal leisure education session and structured consistent written leisure education information were provided to each participant in the treatment group. The participants in the control group did not receive this leisure education session or the written materials. Participants in both groups completed the previously validated Beck Anxiety Inventory (BAI) during their initial visit and during two subsequent interviews by the investigator. Mean anxiety scores from the three

administrations of the BAI to the treatment group and control group were analyzed using a 2 x 3 repeated measures analysis of variance (ANOVA) to identify interaction effects.

The results indicate no statistically significant interaction effect of the leisure education intervention on anxiety levels of the participants. However, the mean of the treatment group across time does show a significant difference.

DEDICATION

This work is dedicated with love to my parents, Nino and Marie, and my husband, Jim.

My parents spent every minute of their young lives doing everything possible to provide for me and my three brothers in every way imaginable. They not only assured that we received the best education possible by sending us to private Catholic schools, they were there to support us in earning our education and instilling in us that we had the potential to accomplish our dreams. This confidence has enabled me to believe that anything is possible if I apply myself. Daddy loved and supported me in every way until the time of his death and Mother continues the tremendous love and support. They are truly the most incredible parents a child could ever have.

Jim has always been loving and supportive beyond words during our life together. But he has displayed tremendous patience and tolerance as I have worked to complete my education. Without his understanding and constant encouragement this accomplishment would not have been possible.

I am truly blessed to have these three special individuals in my life and feel it is only appropriate that this dedication be made to them. I can't thank them enough for all they mean to me.

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I also wish to acknowledge all of my family members, friends, and co-workers who provided encouragement and support during this process. Without their expressions of pride in my work and accomplishments I would have gotten very discouraged at times during the process. They made me feel as if they were all part of the work and that together we could complete it. I am grateful for all of them.

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Without the support of these individuals and others too numerous to mention I would not have had the drive and determination to complete this work and I want to thank each and every one of them.

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CHAPTER I

INTRODUCTION

Despite the decline of smoking prevalence among adults in the United States from 42.4% in 1965 to 22.5% in 2002 (CDC, 2002), tobacco use continues to be the leading preventable cause of death in the U.S. (U.S. Department of Health and Human Services, 2001). As compared to these numbers for the general population, the prevalence of smoking among veterans of the U.S. military who utilize the Veterans Health Administration (VHA), a division of the U.S. Department of Veterans Affairs (DVA), for healthcare is much higher at 32.5% (VHA, 2001). Studies indicate that this may be attributed to the high prevalence of smokers among active personnel in the U.S. military and that those with previous military experience have a higher rate of lifelong patterns of cigarette smoking behaviors (Feigelman, 1994). The impact of cigarette smoking is extremely costly in terms of lives lost and the economic impact of treating individuals with smoking-related illnesses and disabilities is tremendous.

Studies of the mortality rate of smokers in the general U.S. population indicate that cigarette smoking causes an estimated 440,000 deaths, or about 1 of every 5 deaths each year (CDC, 2002 & CDC, 2003). Cigarette smoking kills an estimated 264,000 men and 178,000 women in the U.S. each year (CDC, 2002). More deaths are caused each year by tobacco use than by all deaths from human immunodeficiency virus (HIV), illegal drug use, alcohol use, motor vehicle injuries

suicides, and murders combined (CDC, 2002 and McGinnis and Foege, 1993). On average, adults who smoke cigarettes die 13-14 years earlier than non-smokers (CDC, 2002). Based on current cigarette smoking patterns, an estimated 25 million Americans who were alive in 1997 will die prematurely from smoking-related illnesses, including 5 million people younger than 18 (CDC, 1997). Due to their higher prevalence of smoking than compared to the general U.S. population, U.S. veterans who utilize the VHA for healthcare represent a large percentage of these statistics.

The higher prevalence of smoking among VHA patients represents a tremendous health risk for veterans and an economic burden to the VHA and is an indication for the need of effective smoking cessation programs. Therefore, the VHA has increased the availability and accessibility of smoking cessation programs and services to individuals that they serve. According to *Smoking Cessation Special Initiative for Fiscal Year 1997*, all VHA facilities were mandated to implement a strategic plan based on Agency for Health Care Policy and Research (AHCPR) recommendations (VHA, 1996).

Many smokers acknowledge the fact that smoking is a health risk and express a desire to quit. There are numerous smoking cessation programs offered by many of the 156 VHA Medical Centers and 710 Community-Based Outpatient Clinics, however, based on a report on the 1999 Large Health Survey of Veterans, these services are often not provided to veterans seeking treatment (Miller, Lee, Kalman, Spiro & Kazis, 2001a). This report also indicated that over 80% of VHA smokers who visited a VA healthcare provider in the past 12 months reported needing treatment services for their smoking, but only 17% of them indicated they usually or always received the services they needed to quit.

Traditional smoking cessation interventions offered by the VHA are composed primarily of pharmaceutical interventions such as nicotine patches, inhalers, and medications. Studies indicate that medical interventions alone are not adequate to treat all of the symptoms associated with nicotine withdrawal (U.S. Surgeon General, 2000 and Shipley, 1998). It is recommended in these studies that multi-faceted interventions which address the physical and psychological addiction symptoms associated with nicotine withdrawal be implemented. Such symptoms may include anger, anxiety, depressed mood, loss of ability to concentrate, increased appetite, and craving for nicotine (NIDA, 1998).

In an effort to reduce one of these symptoms, anxiety, this study proposes to examine the effects of incorporating a therapeutic leisure education intervention into an existing smoking cessation program. No literature exists that assesses, specifically, the effects of a leisure education intervention on anxiety during a smoking cessation program. However, there are numerous reasons to hypothesize that the addition of a leisure education intervention may assist in reducing the symptoms of nicotine withdrawal. According to the National Institute on Drug Abuse (NIDA, 1987), “Substance abuse is a multifaceted syndrome that cannot be treated as a straightforward medical problem that will respond to medical treatment only.” Duncan and Gold (1982) report that professionals, including therapeutic recreation specialists, are in a web of complex behaviors and physiological problems when they work with individuals in substance abuse recovery. There have been studies, which report the treatment outcomes of various therapeutic recreation interventions in reducing anxiety, improving coping skills, reducing boredom, managing stress, and other benefits in various patient populations (Coyle, Kinney & Shank, 1991). There also exist studies which investigate

therapeutic recreation treatment outcomes specifically for individuals recovering from addictions (Burling, Seidner, Robbins-Sisco, Krinsky & Hanser, 1992 and Carruthers & Busser, 1995). However, other than Rancourt, (1991a) there exist very few studies which specifically examine the effect of a leisure education intervention as a treatment modality when used for individuals with addictions. It has been reported that there is a need for additional descriptive and outcome research in this area (Rancourt, 1991b). Additionally, there are no studies which specifically investigate leisure education as an intervention to reduce anxiety in a smoking cessation program. This study will focus specifically on the effects of leisure education as an intervention to reduce anxiety among participants in an existing ongoing smoking cessation program.

Based on the Stages of Change Model (Prochaska, 1992), additional interventions, such as leisure education, offered in a smoking cessation program may provide assistance in motivating and encouraging the individuals to make specific plans to change their behavior. Based on the literature, it is hypothesized that leisure education offered as part of a multi-faceted smoking cessation program will reduce anxiety levels in the participants by giving the participants the skills to develop concrete plans and set goals for leisure involvement and will provide reinforcement to continue the plan and to meet the goals which are set.

Statement of the Problem

Behavioral risk factors contribute to the overall poor health and greater use of services by veterans eligible for treatment by the VHA medical centers. Lifestyle and health habits influence the risk of disease and overall health. The prevalence of smoking among individuals receiving healthcare from the VHA is 32.5% as opposed to 22.7% in the general U.S. population. Traditional smoking cessation interventions offered by the

VHA are generally pharmaceutical in nature and do not address many of the symptoms associated with nicotine withdrawal. Anxiety is one of these symptoms.

Purpose of the study

The purpose of the study is to examine the effect of a therapeutic leisure education intervention on anxiety levels of individuals participating in a smoking cessation program at the VATVHS, Murfreesboro Campus.

Hypothesis

1. The leisure education intervention will have a significant effect on reducing anxiety levels among the participants in the treatment group.

Assumptions

1. Research indicates that the symptom of anxiety is exacerbated in individuals engaged in the smoking cessation process. Research also indicates that anxiety levels may be reduced in individuals with numerous conditions and diagnoses, including addictions, when leisure education is utilized as a treatment intervention. Therefore, it may be assumed that leisure education would have positive effect in reducing anxiety levels in individuals participating in a smoking cessation program.

2. Participants in the treatment group will engage in the leisure education program.

Delimitations

This study will be delimited by the following factors:

1. Treatment and control groups will consist of veterans eligible for medical treatment by the VHA.
2. Treatment and control groups will consist of individuals who volunteer to participate in an existing smoking cessation program offered by the VATVHS Murfreesboro Campus.

3. Treatment and control groups will be composed of approximately 25 subjects each.

Definitions of terms

Recreational Therapy – A treatment service provided to restore, remediate or rehabilitate in order to improve functioning and independence as well as reduce or eliminate the effects of illness or disability. This treatment is provided by qualified recreational therapists who are trained and certified, registered and/or licensed to provide Therapeutic Recreation (American Therapeutic Recreation Association, 1987). For the purpose of this study recreational therapy is defined as the service offered by recreational therapists employed by the VHA to provide leisure education to the patients.

Leisure Education – A treatment intervention provided by recreational therapists that focuses on the development and acquisition of skills, attitudes, and knowledge related to leisure participation and leisure lifestyle development. These services utilize an educational model as opposed to a medical model and operate on the assumption that behavior can change and improve as the individual acquires new knowledge, skills, attitudes, and abilities (Peterson and Gunn, 1984). In this study leisure education is defined as the verbal and written information provided to the participants in order to educate them regarding the role leisure activities may serve during times of nicotine cravings during the nicotine withdrawal process.

Anxiety – 1a: a painful or apprehensive uneasiness of mind usually over an impending or anticipated ill b: a cause of anxiety 2: an abnormal and overwhelming sense of apprehension and fear often marked by physiological signs (as sweating, tension, and increased pulse), by doubt concerning the reality and nature of the threat, and by self-doubt about one's capacity to cope with it (Merriam-Webster, 2006). Anxiety is a

recognized symptom associated with the nicotine withdrawal process. For the purpose of this study, anxiety is defined as participants' scores on the Beck Anxiety Inventory.

Addiction – An illness in which a person seeks and consumes a substance, such as alcohol, tobacco or a drug, despite the fact that it causes harm (Mayo Clinic, 2006). For the purpose of this study addiction is defined as the participants' scores on the Fagerstrom Nicotine Dependence Scale.

CHAPTER II

REVIEW OF THE LITERATURE

Studies have shown that the prevalence of tobacco use by active duty U.S. military personnel has traditionally been much higher than that of the U.S. general population. Nicotine addiction followed these individuals from military to civilian life. Long-term use of cigarettes due to nicotine addiction leads to chronic tobacco related illnesses and conditions which are often subsequently treated by the VHA. Studies also indicate that smoking cessation produces numerous physical and psychological symptoms due to the nicotine withdrawal process. One of these symptoms is anxiety, which is a common symptom in recovery from addiction. Leisure education has been proven to be successful when utilized as a treatment intervention for individuals with addictions. There are no reports of any studies that have been conducted to examine the effect of leisure education on anxiety levels during nicotine withdrawal. However, inferences may be made from the available literature that leisure education as an additional treatment intervention may have a significant effect on anxiety levels in individuals participating in a smoking cessation program.

Historical Perspective on Smoking Prevalence in the U.S.

Tobacco use is the leading preventable cause of death in the U.S. (U.S. DHHS, 2001). Cigarette smoking causes an estimated 440,000 deaths, or about 1 of every 5 deaths, each year (CDC, 2002).

Cigarette smoking is the single most preventable cause of premature death in the U.S., killing approximately 1300 people each day (CDC, 1993; Peto, Lopez, Boreham, Thun, Heath and Doll 1996). Smokers are at a greatly increased risk of various forms of cancer, emphysema, chronic obstructive pulmonary disorders, heart disease, strokes, and other diseases and conditions. At the time of the first U.S. Surgeon General's Report in 1964, 42% of adults smoked cigarettes. Smoking prevalence declined to 29% in 1987 (U.S. DHHS, 1989) and to 25.7% in 1991 (CDC, 1993). In 1995, an estimated 47 million adults (24.7%) were current smokers (CDC, 1997). In 2002, smoking prevalence among U.S. adults 18 years of age and older was 22.5% (CDC, 2004). Based on Healthy People 2010 one of the U.S. health objectives is to reduce the prevalence of cigarette smoking among adults to $\leq 12\%$.

Historical perspective on smoking prevalence among active U.S. military personnel

The U.S. military, until the 1980s, promoted the use of tobacco by military personnel. Cigarettes were generously included in the rations provided to the soldiers during World War I and, according to Borio (1993), "virtually an entire generation returned from the war addicted to cigarettes." Also according to Borio, those opposed to sending cigarettes to the "doughboys" were accused of being traitors. World War I General John J. Pershing was quoted as saying, "You ask me what I need to win this war. I answer tobacco as much as bullets." (Borio, 1993). Borio also quoted Pershing as saying, "Tobacco is as indispensable as the daily ration; we must have thousands of tons without delay." Borio also reports that in 1918 the War Department purchased the entire output of Bull Durham tobacco to assure that U.S. soldiers would be provided cigarettes and Bull Durham advertised, "When our boys light up, the Huns will light out."

As a part of the war effort during World War II (1939-1945), U.S. President Roosevelt declared tobacco a protected crop. General Douglas McArthur made the cornucopia pipe his trademark by posing with it on dramatic occasions such as wading ashore during the invasion and reconquest of the Philippines. Cigarettes were included in the U.S. soldiers' C-Rations. Tobacco companies sent millions of free cigarettes to U.S. soldiers, mostly popular brands. Civilians in the U.S. resorted to smoking off-brands such as Rameses and Pacayunes. Cigarette sales reached an all-time high and a fierce shortage developed (Borio, 1993).

High prevalence of tobacco use among the soldiers in the U.S. military continued for many years. It was not until 1980 that the Department of Defense (DoD) Military Health System began to address the health risks of the active-duty military personnel, many of which were attributed to tobacco use, and began to conduct surveys to assess the prevalence of substance use (alcohol, illicit drugs, and tobacco) among military personnel (Research Triangle Institute, 2005). Additional studies were conducted by DoD in 1982, 1985, 1988, 1992, 1995, and 1998 with the broad goals of assessing the health of persons in the military against selected Healthy People 2000 targeted objectives and to continue to assess the prevalence of substance abuse among military personnel. According to the results of these surveys, the percentage of active U.S. military personnel who smoked worldwide decreased from 51.0% in 1980 to 29.9% in 1998. However, when the survey was conducted in 2002 to assess military personnel health against selected Healthy People 2010 targeted objectives, the number of active military personnel who smoked increased to 33.8%. This increase, along with other indicators of stress and mental health, were attributed to the military's role in worldwide events during the previous two

years according to Dr. William Winkenwerder, Jr., Assistant Secretary of Defense for Health Affairs (Research Triangle Institute, 2005).

The high prevalence of tobacco use by active duty Air Force personnel resulted in smoking-attributable direct medical care costs of \$20,098,339.00 in 1997 (CDC, 2000). The same study reported the smoking-attributable productivity costs of time lost spent on breaks, days sent in the hospital, and time away from duty station for outpatient clinic visits for 1997 totaled \$87,142,716.00 (CDC, 2000).

Tobacco smoking doesn't only affect those military personnel who smoke. Children of military personnel who are routinely exposed to environmental tobacco smoke (ETS) are at increased risk for respiratory diseases, and older children with asthma may experience exacerbation of their asthma, accounting for \$661 million in increased annual healthcare costs nationally (Lee, 1998).

Historical perspective on smoking prevalence among U.S. military veterans who utilize the Veterans Health Administration for healthcare

Studies show that the prevalence of tobacco use among veterans is much higher than that in the general population. According to a VHA study in 1997 approximately 30% of males and 27% of females treated by the VHA currently smoked cigarettes (VHA, 1997). In a report on a more recent study, the 1999 Large Health Survey of Veterans, it was found that 36.7% of male patients and 28.6% of female VHA patients smoked as compared to 25.2% and 20.5% respectively in the general population (Miller, Spiro, Kalman, Lee, and Kazis, 2001b).

According to Robert Sullivan, MD, Director of the VA National Center for Health Promotion, surveys in 1997 and in 1998 of 43,000 veterans enrolled in VA primary care

clinics found that 30% of the patients treated by the VHA used tobacco. Based on the results of the National Medical Expenditure Survey (NMES) conducted in 1987, prevalence of smoking in U.S. veterans was 26% higher than in non-veterans, and smoking prevalence in veterans seeking healthcare within the VA System was 52% higher than in veterans using other sources for their health care (McKinney, McIntire, Carmody, and Joseph, 1997). A report by Miller based on the 1999 Large Health Survey of Veterans indicates that due to the historic promotion of cigarette smoking in the military, tobacco use accounts for a substantial proportion of the diseases and illnesses, which require healthcare services for eligible veterans who are treated by the VHA (Miller, et al., 2001b). The same report states that 36.7% of VHA patients smoke compared to 25.2% of the general population. It was concluded that more and better smoking cessation services should be offered by the VHA due to the tremendous health benefits which could be derived from effective smoking cessation programs.

Impact of tobacco-related illnesses in the general U.S. population

Smoking-related illnesses, conditions, and disabilities create an enormous national economic burden in terms of health care costs and lost productivity. A 1993 study estimated the national cost of care provided for conditions related to smoking was \$50 billion and the loss of productivity was \$47 billion (Burdick, 1998). A more recent study reported that national costs to treat smokers who suffer from smoking-related diseases totaled \$72.7 billion a year (Rice, 1998). Lightwood and Glantz (1997) report that a 1% drop in the smoking prevalence in the U.S. would result in 924 fewer hospitalizations for heart attack and 538 fewer hospitalizations for stroke each year, which would save over \$44 million annually. Also reported, (Lightwood, Phibbs and Glantz, 1999) a drop of

1% in the smoking prevalence among pregnant smokers in the U.S. would result in 1,300 less low birth weight live births per year and save \$21 million annually in direct medical costs.

The largest numbers of smoking-related deaths annually are a result of lung cancer (124,000), heart disease (111,000), and the chronic lung diseases of emphysema, bronchitis, and chronic airways obstruction (82,000) (CDC, 2002). The risk of dying from lung cancer is more than 22 times higher among men who smoke cigarettes and approximately 12 times higher among women who smoke cigarettes compared with those individuals who never smoked (Novotny and Giovino, 1998). Since 1950, lung cancer deaths among women have increased by more than 600% and since 1987, lung cancer has been the leading cause of cancer-related deaths in women (U.S. DHHS, 2001). Cigarette smokers are two to three times as likely to die from coronary artery disease (Novotny and Giovino, 1998). Cigarette smoking is associated with a ten-fold risk of dying from chronic obstructive lung disease (Novotny and Giovino, 1998). Approximately 90% of all deaths from chronic obstructive lung diseases are attributable to cigarette smoking (U.S. DHHS, 2001; Novotny and Giovino, 1998).

Impact of tobacco-related illnesses in veterans receiving healthcare from the Veterans Health Administration

There have been numerous studies by the VHA to examine the health risks of tobacco use and the health care costs associated with smoking in the veteran population. In a study by Sherman, et al., (2001b) patients from 18 VHA facilities were surveyed using questions adapted from the California Tobacco Survey, the Medical Outcomes Study and other previously validated sources. It was determined that current smokers

who utilize the services of VHA have higher outpatient mental health use, social work visits, and more nursing home admissions than former smokers and those who never smoked. There were no significant differences in the uses of emergency room or general medicine visits between current smokers and those who were former smokers and those who never smoked. Results suggest that current smokers have a higher prevalence of utilizing VHA services for chronic conditions which require repeated episodes of care or continuous long-term care. Costs for these services are higher than periodic emergency room visits or general medicine visits for acute conditions.

Symptoms associated with nicotine withdrawal

Before effective smoking cessation programs may be offered, it is imperative that nicotine addiction and withdrawal be understood. Smoking cigarettes is not merely a habit that may be broken. It is an addiction, much like an addiction to alcohol, heroin, cocaine, or any other addictive drug. In 1988, the 20th Report of the Surgeon General concluded that cigarettes and other forms of tobacco are addicting (Windom, 1988). It also concluded that nicotine is the drug in tobacco that causes addiction and that the pharmacological and behavioral processes that determine tobacco addiction are similar to those that determine addiction to such drugs as heroin and cocaine. A study funded by the National Institute on Drug Abuse (NIDA) has confirmed that nicotine affects the same brain mechanisms in rats as other drugs of abuse and increases brain levels of dopamine (Pidoplichko, DeBiasi, Williams and Dani, 1997). In another NIDA-funded study (Epping-Jordan, Watkins, Koob and Markou, 1998), researchers studied the effects of nicotine abstinence on the brain's sensitivity to pleasure by systematically inducing electric pulses. Nicotine was administered to rats until their nicotine blood levels equaled

that of a human who smoked thirty cigarettes per day. While nicotine was administered, the animals' sensitivity to brain reward remained stable. When the rats' nicotine was removed, the scientists had to increase the intensity of electrical current by more than 40% before the rats showed through their behavior that electrical pulses to the brain were again pleasurable. Stephenson (1998) reported, "These results are comparable to the altered brain reward sensitivity found during withdrawal from many other addictive drugs." Also in this report Allen I. Leshner, M.D., Director of NIDA was noted as stating, "This understanding may also help in the development of better treatments to address the withdrawal symptoms depression, anxiety, irritability, and craving that interfere with people's attempt to quit." It is important to understand the chemical aspects of nicotine addiction if effective smoking cessation treatment interventions are to be designed. However, nicotine addiction must be addressed in a similar fashion as addiction to other drugs that are commonly used and abused. This means that the treatment must be comprehensive, multi-faceted and address behavioral and environmental issues, as well as the physical addiction (U.S. Surgeon General, 2000).

Smoking is an addiction much like that of alcohol, heroin, and cocaine (Cohen, Pickworth and Henningfield, 1991). With this being the case, smoking cessation results in many symptoms due to the process of nicotine withdrawal. Benowitz (1992) stated that symptoms of acute smoking cessation include restlessness, irritability, anxiety, drowsiness, impatience, confusion and impaired concentration. It is also reported that nicotine withdrawal involves symptoms such as anger, anxiety, depressed mood, difficulty concentrating, increased appetite, and a craving for nicotine (NIDA, 1998). The Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV)

designates Diagnostic Criteria for 292.0 Nicotine Withdrawal to include the following signs following abrupt cessation after the daily use of nicotine for at least several weeks: (1)dysphoric or depressed mood, (2)insomnia, (3)irritability, frustration, or anger (4)anxiety, (5)difficulty concentrating, (6)restlessness, (7)decreased heart rate, (8)increased appetite or weight gain (American Psychiatric Association, 2000). For purposes of this study, the symptom of anxiety during nicotine withdrawal will be further explored.

Anxiety as a symptom of nicotine withdrawal

In a pilot study conducted to assess the acute effects of smoking cessation on health-related quality of life (HRQoL) and perceived work performance results indicated that from baseline to one week post-quit there was a significant increase of anxiety in the participants (Erickson, Thomas, Blitz, Pontius, 2003). Another study reports that there was no evidence of an increase in anxiety following smoking cessation (West and Hajek, 1997). The DSM-IV, which identifies anxiety as a symptom of nicotine withdrawal, states “Withdrawal symptoms can begin within a few hours of cessation, typically peak in 1-4 days, and last for 3-4 weeks.” In this context it is implied that anxiety may fluctuate over time and can vary in intensity. This type of anxiety is best described as “state anxiety” according to Spielberger (1980). Spielberger describes “state anxiety” as a “transitory emotional state of the human organism that is characterized by subjective, consciously perceived feelings of tension and apprehension, and heightened autonomic nervous system activity.” When increased anxiety remains at a relatively stable level in an individual, Spielberger describes the condition as “trait anxiety.” Trait anxiety is

manifested as an anxiety disorder and causes an individual to possess a general tendency to perceive a general level of threat in their environment

Using the Beck Anxiety Inventory (BAI) this study will measure the anxiety levels of participants prior to engaging in smoking cessation which would indicate a baseline measure of their existing anxiety levels. The BAI was chosen as the measurement instrument because it is designed to have the participants indicate the prevalence of various physiological symptoms of anxiety during the past week. Anxiety levels will again be measured in the participants when they are 7 to 10 days into the smoking cessation process and then again 21 to 25 days later. It is anticipated that the anxiety levels will fluctuate among the 3 measures and therefore indicate that the participants are experiencing state anxiety.

Current smoking cessation treatment interventions offered by the Veterans Health Administration

In the late 1980s recognition of the high prevalence of tobacco use among active-duty military personnel, which subsequently resulted in the high prevalence among veterans treated by the VHA, caused the VHA to actively pursue smoking cessation promotion. This was done in an effort to reduce tobacco-related illnesses and conditions in the veterans treated and the subsequent health care costs associated with the treatment. Prior to this time, the VHA had few policies and no health program initiatives regarding cigarette smoking among the veterans treated by the VHA. Preventive medicine was not addressed. The VHA primarily treated existing diseases, illnesses, and conditions, which were presented by the patients. Many changes in policies and treatment delivery began to occur during the early 1990's. Preventive medicine began to be addressed in an effort to

meet healthcare needs of the veterans in regards to preventing illnesses, diseases, and conditions instead of treating those which had already occurred.

The VHA National Center for Health Promotion (NCHP) has, as one of its responsibilities, oversight of the VHA Preventive Medicine Programs "Special Initiatives." Each year the NCHP selects a significant preventable health problem and emphasizes it through the implementation of Special Initiative Guidelines in all VA Primary Care Clinics. The NCHP collects data on these special initiatives from all VA Primary Care Clinics and reports to clinicians on how to further improve preventive measures in health care which address these identified high-profile potentially preventable health problems. Smoking cessation was chosen in 1996 as the Special Initiative for FY 1997. This called for all VHA facilities to implement a strategic plan based on the Agency for Health Care Policy and Research (AHCPR) recommendations. VHA Directive 96-006 dated October 16, 1996 and titled, *Smoking Cessation Special Initiative for FY 1997* provided a worksheet which was completed by 147 VA Medical Centers (VAMCs) providing primary care services. The NCHP staff compiled the data from the worksheets submitted by the 147 VAMCs. Some of the responses were estimated where data were unavailable. Therefore the findings must be viewed with this limitation in mind. Findings show that veterans were being screened for the use of tobacco, but that few of them were referred to comprehensive effective smoking cessation programs. The findings of the Special Initiative included the consideration that coordinated multidisciplinary strategies are needed to substantially lower rates of veterans who smoke (Burdick, 1998).

In an effort to improve the health of the veterans treated by the VHA and to reduce healthcare utilization and healthcare costs associated with cigarette smoking, the VHA has implemented programs and services which address those veterans who smoke cigarettes. These efforts are not only designed to address medical treatment for those veterans who present themselves to the VAMCs with already manifested smoking-related illnesses and conditions, but those who currently smoke and desire to stop in an effort to prevent further and future health-related problems.

In an effort to assess the number of veterans who smoke and their healthcare needs, including smoking cessation programs, the VHA has initiated many surveys and screening tools which are administered to veterans being treated by the VHA. Lifestyle and health habits influence the risk of disease and overall health. Behavioral risk factors of veteran patients treated at VAMCs have been studied by the VHA in such studies as the 1999 Large Health Survey of Veterans. Behavioral risk factors determined by these results were stratified with comparable estimates from the Behavioral Risk Factor Surveillance System (BRFSS) and National Health Interview Survey (NHIS) for the general population (U.S. sex/age standardized for VHA vs. U.S. population) where available. Results indicated that less than 30% of VHA enrollees exercised regularly and 32.5% smoked tobacco. According to the results of this survey, 45.7% of the respondents reported that a VA provider had inquired about amount of physical activity and 71.8% reported they had been asked about smoking. Over 80% reported that they did not get the services required to make the lifestyle changes (Miller, Lee, Kalman, Spiro, and Kazis, 2001a). In another report based on the same survey it was stated that most smokers said that, in the past year, VHA providers had asked about their smoking (76%) and advised

them to quit (69%), but only 27% had been referred for cessation, and only 15% said they were given the services they needed to quit (Miller, Kazis, & Spiro, 2000). In another report by Miller, et al., (2001b), it was concluded that the impact of this interpretation of the data from the 1999 Large Health Survey of Veterans should lead to more and better services and programs to promote smoking cessation. The authors also concluded that tobacco use accounts for a tremendous proportion of disease, illness burden, and health care costs for the VHA and there would be substantial benefits in its reduction.

Another report on the study by Sherman, Yano, Lanto, Simon & Rubenstein (2001a) reported that of the 7,706 patients contacted, 1,457 (19%) were current smokers. A majority (85%) of those smokers felt that smoking was harmful to their health and a comparable number felt they were addicted to nicotine. Approximately half of those surveyed who currently smoked were interested in quitting in the near future. Even though most of those surveyed reported a VA provider asked them about their smoking habits, few were referred to a smoking cessation program. This report concluded that the VHA is missing opportunities to refer patients to smoking cessation programs and that better smoking cessation programs should be developed.

Historically, smoking cessation programs have included pharmaceutical interventions such as nicotine replacement therapy (NRT) in the form of patches, inhalers, or gum, antidepressants such as Zyban or Wellbutrin, hypnosis, group and individual counseling, and various other interventions such as recommendations on behavior changes which may be made by the participants to assist in coping with the symptoms of nicotine withdrawal.

It has been determined that a combination of pharmaceutical and behavioral therapies are the best methods for overcoming nicotine addiction. In a study, which examined the complementary effects of nicotine replacement therapy (NRT) and behavior therapy, it was shown that a single therapy has a 20 to 25 percent effectiveness rate. But, when a combination of the two therapies was used, the success rates for long-term abstinence were as high as 35 to 40 percent (Stitzer, 1998). According to Stitzer, there are three reasons why combined pharmaceutical and behavioral treatment is most effective in nicotine addiction treatment: 1) enhanced compliance with treatment interventions, 2) independent effects on different outcome targets (withdrawal relief producing better initial abstinence versus new coping skills producing better long-term outcomes), and 3) independent effects on different populations such that some people benefit from pharmacotherapy and others from behavior therapy. However, Stitzer goes on to say that with the exception of craving, symptom suppression has not been reliably related to abstinence success. A report by the Surgeon General also recommends combining pharmacological and behavioral counseling when treating smoking cessation (U.S. Surgeon General, 2000). This report states that up to 25% of quitters can remain abstinent for at least one year when they participate in a program which combines pharmacological and behavioral counseling techniques.

Leisure education

Leisure education is a treatment intervention commonly used by recreation therapists to change and improve behavior based on the client's acquisition of knowledge skills, attitudes, and abilities. It is utilized as an educational model as opposed to a medical model (Peterson and Gunn, 1984). It is imperative that clients possess an

understanding of leisure as well as have a variety of leisure interests and abilities in order to effectively develop and manage their leisure lifestyle. Leisure awareness involves a cognitive awareness of leisure and its benefits. In addition to the awareness of leisure and its benefits, individuals must have a personal awareness of leisure which includes knowledge of their own personal leisure values, attitudes, and skills. Another component of leisure awareness is related participatory and decision making skills. With these skills an individual possesses the capacity for decision-making skills, leisure planning, and problem-solving techniques (Peterson and Gunn, 1984). Leisure education is based on a model of self-determination which allows an individual to determine what they need through leisure experiences in his/her life (Bullock & Mahon, 1997; Mundy & Odom, 1979). According to the Clinical Practice Guideline for Treating Tobacco Use and Dependence, these skills are essential for individuals participating in smoking cessation to be successful. The Guidelines state that three types of counseling and behavioral therapies were found to be especially effective and should be used with all patients attempting tobacco cessation. One of these therapies is “provision of practical counseling (problem solving/skills training)” (Fiore, et al., 2000). According to George and Dustin (1988) individuals who have been chemical dependent need to learn to positively structure their time and learn to cope with feelings and situations which were previously addressed by abusing drugs.

When an individual engages in smoking cessation it is essential that they develop a personal plan for action. Leisure education may assist by providing the individual the skills needed to develop the plan by providing them with needed information through

specific and predetermined content as related to smoking cessation issues brought on by symptoms of nicotine withdrawal, specifically anxiety.

Leisure education as a treatment intervention for individuals with addictions

Yoder (1990) and Annis (1986) contend that individuals in treatment for addiction should be taught skills, which will enhance their ability to identify and confront aversive problems. These skills will enable those individuals to effectively cope with situations, which may otherwise cause relapse. According to Duncan and Gold (1982), professionals who are working with individuals recovering from drug abuse are involved in a web of complex behaviors and physiological problems. There are many theories of drug use, abuse, and dependency. Gold (1980) contends that drug abuse theories which address coping mechanisms are related to theories that address self-esteem and learning. An individual's perception of anxiety and their perceived ability or inability to cope with the anxiety is correlated with their level of self-esteem. Gold states that drugs do for the abuser what they feel they cannot do. This includes reducing anxiety, giving them a feeling of control, and a feeling that they can control their environment.

Although there are no studies in the literature involving the effects of leisure education on anxiety during nicotine withdrawal, there are numerous studies which cite recreation therapy as an effective intervention in anxiety reduction and stress management associated with substance abuse and other illnesses and disabilities. Rancourt (1991a and 1991b) studied the effects of a leisure education program on stress reduction for women who were in treatment for substance abuse. McAuliffe and Ch'ien (1986) also reported that recreational activities were effective in reducing stress among individuals with addictions. Several studies have shown that exercise, which is an

enjoyable leisure pursuit for many individuals, may reduce anxiety associated with stress (Berger 1983 and 1986, Long, 1984 and Sachs, 1982). The inclusion of a leisure education intervention offers an addition to smoking cessation programs which may reduce the participants' anxiety symptoms associated with nicotine withdrawal.

Summary

Tobacco use is the leading preventable cause of death in the U.S. Smoking prevalence among U.S. military veterans is higher than that of the general U.S. population. Smoking prevalence among U.S. military veterans utilizing the VHA for health-related services is higher than the general U.S. military veteran population. The VHA continues to strive to provide more effective smoking cessation services to the veterans they serve.

Increased anxiety is a symptom of nicotine withdrawal. There have been no studies to examine the effects of leisure education on anxiety levels in individuals participating in a smoking cessation program. Leisure education has been proven to reduce anxiety in individuals undergoing treatment for chemical dependence. This study will examine the effects of leisure education as an added intervention on anxiety levels in participants utilizing an existing smoking cessation program.

It is hypothesized that there will be a significant effect on anxiety levels among the participants in the treatment group.

CHAPTER III

METHODOLOGY

Participants

The participants in the study were drawn from individuals enrolled in a smoking cessation program at the VATVHS Murfreesboro Campus. The participants consisted of U.S. military veterans who are eligible for medical treatment by the VATVHS. Due to the fact that the patient population served by the VHA is predominantly male, the same was true for this study. The age range of the participants was 25 – 68 years of age.

Procedures

This study was approved by the Institutional Review Board at Middle Tennessee State University (see Appendix A), the VA Tennessee Valley Healthcare System Institutional Review Board (see Appendices B and C), and the VA Tennessee Valley Healthcare System Research and Development Committee (see Appendix D).

Clinical data were gathered from the standard TVHS Department of Preventive Medicine Smoking Cessation Intake Evaluation (see Appendix E) currently being utilized in the smoking cessation program. The intake evaluation solicits demographic information and information regarding the smoking habits of the smoking cessation program participant. For the purposes of this study, the Beck Anxiety Inventory (BAI) (see Appendix F) was self-administered by the participants who agreed to participate in the study. Participants in the study consisted of veterans eligible for treatment by the

VHA who voluntarily enrolled in the smoking cessation program. The smoking cessation program has an average of 8 participants who enroll into the program each month. The study continued for a total of six months until a total of 50 participants representing the treatment group (n=25) and the control group (n=25) agreed to participate and completed the study. This sample size was deemed adequate based on the power analysis which was performed prior to initiating the study. Each patient who voluntarily presented themselves for evaluation to be included in the smoking cessation program during the timeframe of the study was asked to voluntarily participate in the study. Those who agreed to participate completed and signed the VA Research Consent Form (see Appendix B) and the VA Authorization to Use/Disclose Protected Health Information Form (see Appendix C). In addition to the intake evaluation interview by a Preventive Medicine Clinic physician, each participant was individually provided education on the smoking cessation process by the physician.

The investigator personally met with each participant in the treatment group and control group following the completion of their initial interview and evaluation by the physician. Interventions for the treatment group included verbal scripted leisure education from this investigator (see Appendix G) and written educational information to be taken home with them following the session (Appendix H). The leisure education sessions conducted with the treatment group participants by this investigator lasted approximately 15 minutes and the administration of the BAI to participants in each group took approximately 10 minutes. Participants in the control group did not receive verbal or written leisure education information.

The BAI was also administered to all participants in the treatment and control groups during either a follow-up interview in person or by phone within 7-10 days after the initial interview and again approximately 3 weeks (21-25 days) after the second completion of the BAI to assess the anxiety levels of the participants. Following the completion of the BAI during this contact the participants were asked if they were currently smoking cigarettes and if they were using any antidepressant medication which is commonly prescribed by a physician to assist in the smoking cessation process.

Data Collection

During the timeframe of data collection a total of 112 appointments were made for outpatients to be enrolled in the Preventive Medicine Clinic smoking cessation program. Of the 112 patients scheduled 44 (39%) either did not show up for their appointment or rescheduled their appointment for a later date. Of those reporting to the clinic for their appointment (n=68) eight patients declined to participate in the study. Six patients were deemed inappropriate for the study either due to complicated medical or mental health diagnoses or due to the fact that they smoked only cigars or used smokeless tobacco and did not smoke cigarettes. The investigator was not available to request participation from two eligible participants and two patients were dropped from the study due to the inability of the investigator to contact them by telephone to collect needed data following their initial visit.

The participants were assigned to the treatment group (n=25) or control group (n=25) using an adapted randomization method based on a coin toss prior to assignment of the first subject (Hedden, Woolson, & Malcolm, 2006). The coin toss determined that

the first participant would be assigned to the control group and future participants were assigned alternately to the treatment or control group as they were enrolled into the study.

All patients enrolled in the smoking cessation program complete a self-administered Department of Preventive Medicine and Health Smoking Cessation Intake Evaluation (see Appendix E), Beck Depression Inventory (see Appendix J), and Fagerstrom Test for Nicotine Dependence, which is incorporated into the Intake Evaluation as items 29 - 34, prior to being evaluated by a physician to determine if the patient is appropriate for enrollment in the program. The patients deemed appropriate by the physician for the smoking cessation program were seen by the investigator immediately following their evaluation to explain the study and request the patients' participation.

Those participants who volunteered to participate in this study also completed a self-administered BAI (see Appendix F) and signed a VA Research Consent Form 10-1086 (see Appendix B) as well as a VA Research Consent Form 10-1086 Authorization for Release of Protected Health Information for Research Purposes (see Appendix C). Those participants assigned to the treatment group then received the verbal leisure education intervention (see Appendix G) and review of written leisure educational materials given to them to be taken home for use (see Appendix H). Those assigned to the control group did not receive the intervention or the written educational materials. Follow-up telephone calls or personal contact were made by the investigator to all treatment group and control group participants 7-10 days following their initial visit to the Preventive Medicine Clinic and again 21-25 days following the first follow-up call or personal contact. During the two follow-up calls or contacts the participants were asked

by the investigator to complete a BAI by responding to the investigator during the call or completing the BAI during the personal contact. At the conclusion of the second follow-up completion of the BAI the participants were asked to report if they were smoking equally as much as prior to their enrollment in the smoking cessation program, not smoking at all or if they had reduced the amount of cigarettes they were smoking prior to enrolling in the program. They were also asked to report whether or not they were taking any type of prescribed antidepressant medication.

Instrumentation

Demographic/Descriptive data.

Instruments utilized to collect the demographic/descriptive data consisted of the TVHS Department of Preventive Medicine and Health Alvin C. York VA Medical Center Smoking Cessation Intake Evaluation (see Appendix E), which includes the Fagerstrom Test for Nicotine Dependence, and the Beck Depression Inventory (BDI) (see Appendix I). Demographic and descriptive data from these instruments which was included in the analysis consisted of a variety of variables including age, gender, ethnicity and smoking habits of the participants.

Anxiety measurements.

Data from the BAI, which was administered to each participant on three occasions, was analyzed as results from this instrument indicate measures of anxiety which was the dependent variable being investigated by this study. The BAI consists of 21 items which each describe a common symptom of anxiety. It was designed to discriminate anxiety from depression in individuals and is recommended for use in

assessing anxiety in clinical and research settings. The respondents are asked to rate how much they have been affected by each symptom over the past week, including that day, using a 4-point scale ranging from 0 – 3. The items are summed to obtain a total score which can range from 0 to 63 to indicate the level of anxiety they have been experiencing. The BAI has proven reliability with internal consistency using item-total correlation ranging from .31 to .71 (median=.60). Validity of the BAI has been confirmed as the correlations of the BAI with a set of self-report and clinician-rated scales were all significant. The correlation of the BAI with the Beck's Depression Inventory (BDI) is .48. The correlation of the BAI with the Hamilton Anxiety Rating Scale – Revised (HARS-R) and Hamilton Rating Scale for Depression – Revised (HRSD-R) are .51 and .25, respectively.

Data collected during the three administrations of the BAI were analyzed to assess the difference in anxiety levels between the control group and the treatment group at the beginning, approximately a week after the beginning, and approximately a month after the beginning of the study. The differences in the data reflect the effect of leisure education on anxiety levels between the two groups. It was hypothesized that results would indicate a significantly lower level of anxiety in the treatment group as compared to that of the control group.

Statistical Analyses

The power analysis conducted prior to the study indicated that a total of 50 participants would be needed to ensure that the number of participants in the sample would be sufficient to produce differences in the anxiety levels of the treatment group

and control group if in fact there were differences. Descriptive statistics were calculated in order to describe the sample being tested. A 2 x 3 repeated measures ANOVA was used to identify the interaction effect of the leisure education intervention on anxiety levels between the two groups. This type of statistical analysis is appropriate because the study consisted of two groups and the same participants appear in all three conditions of the study. The dependent factor, anxiety, was measured in each participant under three conditions of time. This analysis was conducted from data collected during the intake evaluation, at the interview between 7-10 days later and from a subsequent interview between 21-25 days following the second interview. This analysis was conducted using the Statistical Package for the Social Sciences (SPSS) software package. The level of statistical significance was set at .05.

CHAPTER IV

RESULTS

The purpose of this study was to examine the effect of a therapeutic leisure education intervention on anxiety levels of individuals participating in an existing smoking cessation program in the Preventive Medicine Clinic at the VATVHS Murfreesboro Campus. Participants in the study consisted of veterans eligible for treatment by VHA who voluntarily enrolled in the smoking cessation program.

Participants in the study were assigned to the treatment or control group using an adapted randomization method. The treatment group participants received a leisure education intervention. Three Beck Anxiety Inventory (BAI) measures were collected from all participants in the treatment and control groups. Statistical analyses were performed using the mean BAI scores for each measure from the two groups to identify interaction effects.

Demographic/Descriptive Data

The 50 participants in the study were predominantly male ($n = 45$). Ethnicity of the participants included 44 (88%) Caucasian and 6 (12%) African American. Ages ranged from 25-68 years with a mean age of 53.2. A summary of the following descriptive data appears in Table 1. Participants reported a history of years smoking from 12-53 with a mean of 36.2 years. Scores on the Beck Depression Inventory ranged from 0-34 with a mean score of 13.6 which indicates mild to moderate depression (Beck et al., 1961). Results from the Fagerstrom Test for Nicotine Dependence (Heatherton et

al., 1991) indicated that dependence levels ranged from 2-9 with a mean level of 5.9 which indicates most participants had a medium to high nicotine dependence score.

The mean baseline BAI measure for the treatment group was 14.3. It decreased at the second measure to 11.8 and again at the third measure to 10.1. The control group mean baseline measure of 11.8 decreased at the second measure to 10.60 but increased slightly to 10.64 at the third measure (see Table 1).

Analysis of Anxiety Levels

The primary objective of this study was to examine the effect of the leisure education intervention on anxiety levels of the participants. The BAI scores were used in a 2 x 3 [two groups by three measures] repeated measures ANOVA to determine the interaction effect of the intervention over time between the treatment group and control group. Mauchly's Test of Sphericity did not indicate a within-subjects statistical significance ($p = .453$). The assumption of sphericity was proven to be correct.

There was no statistically significant interaction effect of the leisure education intervention on anxiety levels ($F(2,96) = 1.382$, $p = .256$ (see Table 2).

Table 1

Descriptive Data of the Participants (N = 50)

Variable	$M \pm SD$	N
History of Years Smoking	36.2 ± 10.4	50
Beck Depression Inventory	13.6 ± 8.7	50
Fagerstrom Nicotine Dependence	5.9 ± 1.7	50
Beck Anxiety Inventory		
Baseline Measure		
Treatment Group	14.3 ± 11.5	25
Control Group	11.8 ± 10.4	25
Second Measure		
Treatment Group	11.8 ± 11.0	25
Control Group	10.6 ± 8.2	25
Third Measure		
Treatment Group	10.1 ± 9.3	25
Control Group	10.6 ± 10.0	25

Table 2

Tests of Within-Subjects Effects

Source of Variation	Type III Sum of Squares	<i>df</i>	Mean Square	<i>F</i>	<i>Sig</i>
Sphericity Assumed					
Time	187.893	2	93.947	4.459	.014
Time * TXCONTGR	58.240	2	29.120	1.382	.256
Error	2022.533	96	21.068		

Table 3

Characteristics Between Groups

Variable	Tx Group (N=25)	Control Group (N=25)
Mean Years Smoked	36.6	35.7
Mean Fagerstrom Dependence Score	6.1	5.8
No Longer Smoking	7	8
Smoking Same Amount	5	8
Smoking Less	13	9
Taking Antidepressants	15	10
Mean Beck Depression Score	14.7	12.6

Summary of Results

Based on the literature it was anticipated that the anxiety levels of the participants would increase as the participants experienced nicotine withdrawal during the smoking cessation process and then return to baseline levels within 21-25 days of cessation. This did not occur. The mean BAI scores decreased in both groups from baseline to the second measure 7-10 days later (see Figure 1). The mean BAI score of the treatment group decreased again from the second measure to the third measure (see Figure 2). The mean BAI score of the control group increased very slightly from the second measure to the third measure (see Figure 3).

It was assumed based on the literature that the mean BAI scores would increase for both groups from the baseline measure to the second measure and that the mean BAI scores for the treatment group would increase at a lower rate than the control group. The results of the 2 x 3 repeated measures ANOVA, however, indicate that the interaction effect between group and time on anxiety levels was not significant ($p=.256$).

Effect was not significant due to the discrepancy between the means used from a prior study to perform the power analysis and the means obtained from the present study.

Figure 1

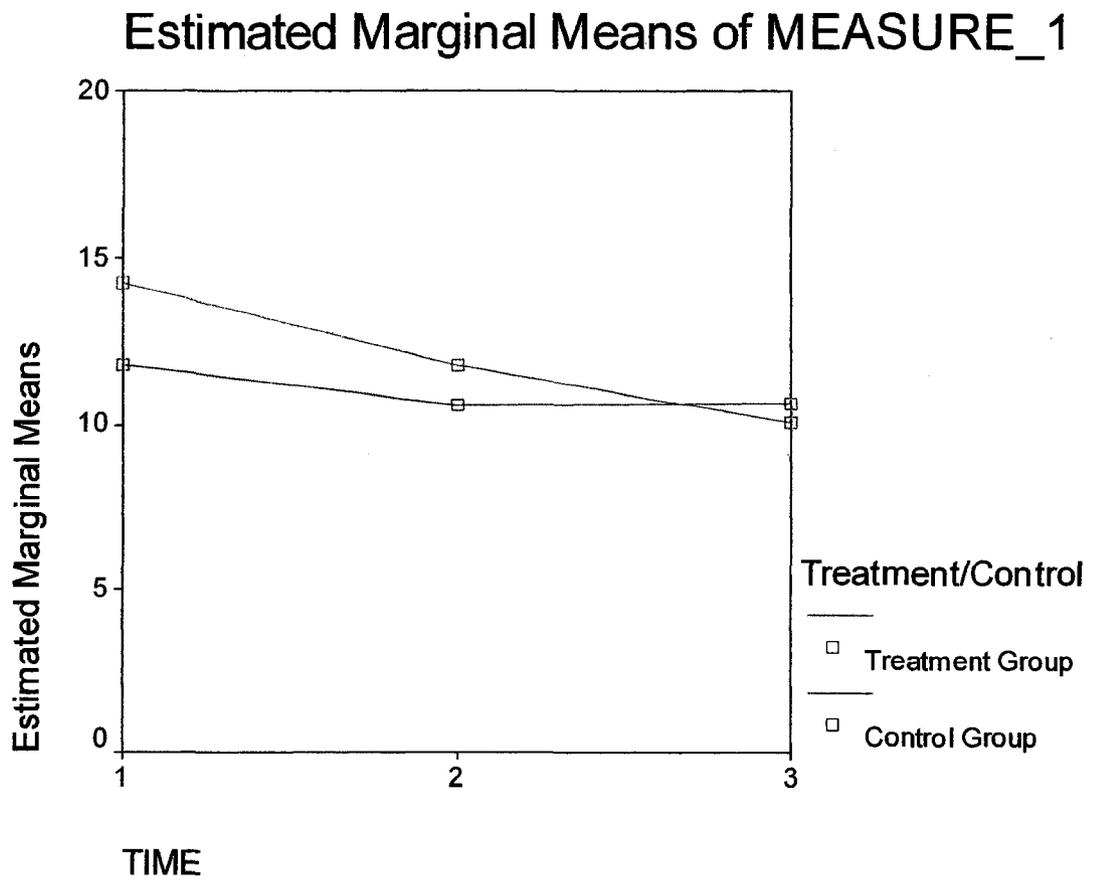


Figure 2

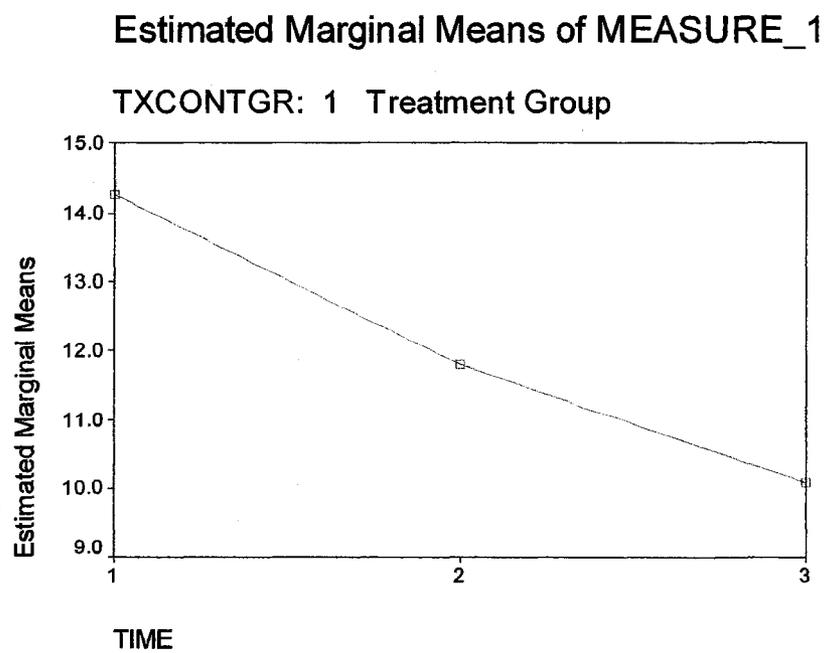
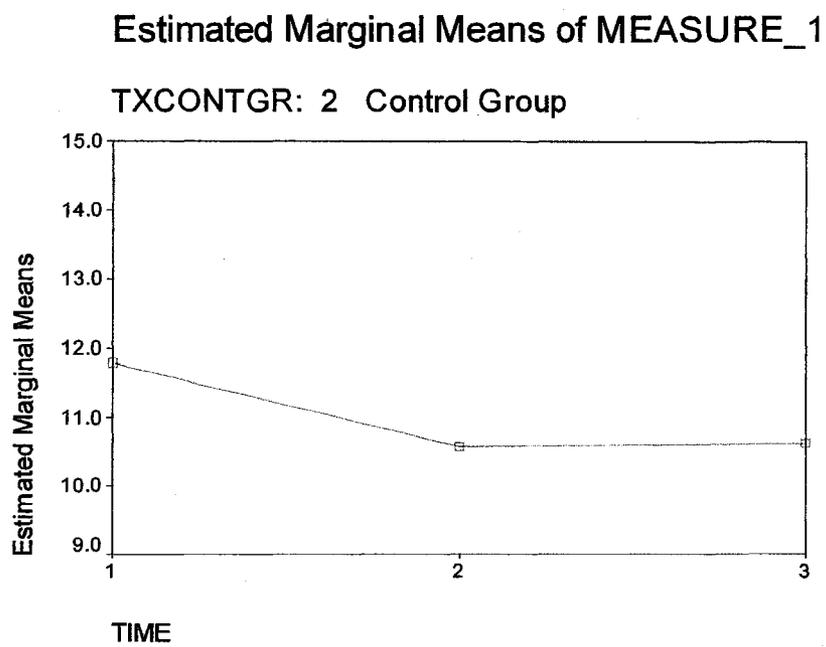


Figure 3



CHAPTER V

CONCLUSIONS AND RECOMMENDATIONS

The purpose of this study was to examine the effect of a leisure education intervention on anxiety levels of individuals participating in a smoking cessation program. A total of 52 participants began the study. Two participants did not complete the study. Analysis was conducted on data collected from the 50 participants who completed the study. The independent variable was a leisure education intervention provided to the participants in the treatment group ($n = 25$) but not provided to participants in the control group ($n = 25$). The dependent variable was anxiety level measures obtained at three different times by the investigator from all participants in the treatment and control groups. All participants were patients eligible for treatment by the VATVHS and voluntarily participating in a smoking cessation program provided by the Preventive Medicine Clinic at this facility. The 50 participants (males = 45, females = 5) had a combined mean age of 53.2 and a combined mean of 36.2 years reported history of smoking cigarettes.

Comparison of Sample to the General Population

Smoking prevalence has declined among adults in the United States from 42.4% in 1965 to 22.5% in 2002 (CDC, 2002). However, tobacco use among veterans of the U.S. military who utilize the VHA, for healthcare is much higher at 32.5% (VHA, 2001). According to Feigelman (1994) the history of high prevalence of smoking among active

personnel in the U.S. military has contributed to the higher rate of lifelong patterns of cigarette smoking among this population. Therefore, the cost of lives lost among U.S. veterans and the economic impact of treating these individuals for smoking-related illnesses and disabilities by VHA is higher than that of the general population.

Background Information

Many smokers treated by VHA express a desire to quit and/or the knowledge that smoking is a health risk. VHA facilities have increased the availability and accessibility of smoking cessation programs and services to the individuals that they serve. However, only 17% of veterans seeking treatment indicated that they usually or always received the services they needed to quit (Miller, et al., 2001a).

The traditional smoking cessation interventions offered by the VHA are composed primarily of pharmaceutical interventions such as nicotine patches, inhalers, and medications. Studies indicate that medical interventions alone are not adequate to treat all of the symptoms associated with nicotine withdrawal (U.S. Surgeon General, 2000 and Shipley, 1998). The results of these studies suggest that multi-faceted interventions which address the physical and psychological addiction symptoms such as anger, anxiety, depressed mood, loss of ability to concentrate, increased appetite, and craving for nicotine associated with nicotine withdrawal should be implemented (NIDA, 1998).

Based on the literature, there are reasons to hypothesize that the addition of a leisure education intervention may assist in reducing the symptoms of nicotine withdrawal. Studies exist which investigate therapeutic recreation treatment outcomes specifically for individuals recovering from addictions (Burling, Seidner, Robbins-Sisco,

Krinsky & Hanser, 1992 and Carruthers & Busser, 1995). Rancourt (1991a) examined the effect of a leisure education intervention as a treatment modality for individuals with addictions and reported that there is a need for additional studies in this area (Rancourt, 1991b). Unlike any previous studies, this one specifically investigated the effects of leisure education as an intervention to reduce anxiety among participants in an existing ongoing smoking cessation program.

Discussion of Anxiety Level Findings

Based on findings of previous studies identified in the literature, it was expected that anxiety levels of individuals would increase from baseline for 7-10 days as they experienced nicotine withdrawal during the smoking cessation process. Anxiety levels would then begin decreasing until returning to their baseline anxiety level 21-25 days after cessation (Erickson, Thomas, Blitz, Pontius, 2003). Similar findings are reported in the DSM-IV, which identifies anxiety as a symptom of nicotine withdrawal and states "Withdrawal symptoms can begin within a few hours of cessation, typically peak in 1-4 days, and last for 3-4 weeks." However, the results of this study did not reflect the stated expectations as based on the literature.

The mean BAI scores for the treatment and control groups decreased instead of increasing from baseline to the second measure. The mean treatment group BAI score decreased again between the second and third measures while the mean BAI score of the control group increased very slightly. The mean BAI score of the treatment group baseline measure was 14.3 and decreased to 10.1 at the third measure. The mean BAI score of the control group decreased from a baseline measure of 11.8 to 10.6 on the third measure. While the treatment group baseline mean BAI score was 2.48 points higher

than that of the control group, the treatment group third measure decreased to .56 less than that of the control group. The results indicate that the mean BAI scores of the treatment group across time shows a statistically significant difference ($F(1,48) = 5.685$, $p = .006$) (see Table 4).

This decrease instead of increase in the mean BAI scores for both groups from baseline to the second measure could possibly be attributed to the pharmaceutical interventions prescribed for the participants by the Preventive Medicine Clinic physicians to aid in reducing the symptoms of nicotine withdrawal due to the smoking cessation process. During the second follow up contact with the participants each participant was asked if they were taking any antidepressants prescribed by physicians to decrease the symptoms of nicotine withdrawal. At the time of the second follow up 25 (50%) of the participants responded that they were taking prescription antidepressants.

Assuming that the participants taking prescription antidepressants would score lower on the BAI, additional analyses were performed. These results revealed the opposite. The third mean BAI score of those participants not taking antidepressants was 7.1 while that of the participants taking antidepressants was 13.6 representing a significant difference ($p = .014$). (see Table 5).

It was thought that another contributing factor causing the anxiety scores of the participants to decrease instead of increase could be lack of adherence to the goals of the smoking cessation program. When asked by the investigator during the second follow up contact, 15 subjects (30%) responded that they were not smoking cigarettes and 35 (70%) indicated that they were still smoking cigarettes. Thirteen subjects (26%) reported that

Table 4

Treatment Group BAI Scores Across Time (N = 25)

Source of Variation	Type III Sum of Squares	<i>df</i>	Mean Square	<i>F</i>	<i>Sig</i>
Time *					
Treatment Group	222.907	2	111.453	5.685	.006
Error (time)	941.093	48	19.606		

Table 5

BAI Measures Across Sample at Third Measure (N = 50)

Source of Variation	Mean	N	sd	df	F	Sig
Taking Antidepressants	13.6	25	10.7			
Not Taking Antidepressants	7.1	25	7.1			
Between Groups (Combined)		50		1	6.554	.014
Smoking Same Amount	16.4	13	10.2			
Smoking Less	10.1	22	10.0			
Not Smoking	5.5	15	4.8			
Between Groups (Combined)		50		2	5.291	.008

they were smoking the same amount as prior to participating in the smoking cessation program and 22 (44%) reported that they had reduced the amount of cigarettes smoked prior to participating in the program. Of the participants who indicated a reduction in smoking, some reported that they had significantly decreased the amount of cigarettes they were smoking daily. It was felt that the fact that 70% of the participants were not smoke-free at the time of the second follow-up might explain why the anxiety measures did not increase between the first and second measures as expected. However, this does not offer an explanation for the further decrease in anxiety levels of the treatment group between the second and third measures. It is possible that the provision of the leisure education intervention produced an interaction effect which caused the anxiety levels to continue to decrease in the treatment group. However, further investigation is needed to validate this assumption.

Further analysis was performed and it was found that participants reporting that they were no longer smoking displayed significantly lower anxiety scores than the participants who were smoking the same amount and those who reported they had decreased the amount of cigarettes they previously smoked. The mean BAI score at the second follow-up measure of those reporting that they no longer smoked was 5.5 while the mean BAI score of those smoking the same amount was 16.4 and the score of those who had reduced the amount of smoking was 10.1. These results indicate a significant difference between groups ($p = .008$). (see Table 5).

Limitations

Population.

Participation in this study was limited to individuals eligible for treatment by the VHA. Therefore, the results of this study may not be considered to represent the general population. Many of the participants had various pre-existing physical and mental health diagnoses which would complicate their ability to control their nicotine addiction and/or anxiety without prescribed medication.

Group Assignment.

The participants were assigned to the treatment and control groups using an adapted randomization method instead of a true randomization method. The mean baseline BAI measure of the treatment group was 14.3 while that of the control group was 11.8. While this difference is not statistically significant it does represent a difference of 2.5 in the mean scores of the two groups. This difference could be attributed to the group assignment method used. Further data collection should be modified to utilize a true randomization method instead of alternating group assignment to give each participant equal chance of being assigned to each group.

Sample Size.

The power analysis performed prior to beginning the study indicated that a sample size of 50 would be adequate to identify the interaction effect of the leisure education intervention on anxiety levels. However, means used in the power analysis model (Rexilius, et al., 2002) varied from means obtained in this study which resulted in a statistical power which is low (.29). Additional data collection would be needed to

improve statistical power of the interaction effect of the leisure education intervention on anxiety levels.

Appropriateness of Anxiety Measurement Instrument.

The anxiety measurement instrument used for this study was the Beck Anxiety Inventory (BAI). The BAI consists of 21 items which yield possible scores of 0 – 3 each. The possible range of an overall BAI measure is 0 – 63. The mean BAI measures for the two groups during the three measures ranged from 10.1 – 14.3 and the standard deviations ranged from 8.2 – 11.5. The relatively low anxiety scores and large standard deviations indicate that the BAI measurement instrument may not be sensitive enough for a study of this type. This instrument was developed to distinguish symptoms of anxiety disorders from symptoms of clinical depression in adult psychiatric patients. The use of the BAI to detect anxiety levels in a population other than adult psychiatric patients may not be appropriate. Therefore, another instrument which is more precise in measuring anxiety levels in the general population should be used for further studies of this type.

Use of Prescription Antidepressants by Participants

During the interview by the investigator to obtain the second follow-up measure the participants were asked if they were taking any prescription antidepressants. 15 (60%) of the participants in the treatment group and 10 (40%) in the control group reported that they were taking antidepressants. As discussed earlier these medications proved to have an effect on anxiety levels of the participants.

Overall Summary of Conclusions and Recommendations

It is recommended that this study be continued to include additional participants. This will increase the likelihood that the difference in the baseline BAI mean scores of

the two groups as well as the standard deviations will decrease which will allow for a determination of whether or not the intervention did, in fact, cause a statistically significant effect.

However, based on review of the methods used for this study, it is further recommended that the study be redesigned to yield results which will more adequately measure the true effect of the intervention on anxiety levels of the participants. The redesign should include a true randomization method for group assignment for the participants rather than an adapted randomization method. It should also include the use of a more appropriate anxiety measurement instrument. These modifications to the design would greatly improve the ability to obtain statistical results which would more precisely measure the interaction effect of the intervention on anxiety levels of the participants.

Due to the statistically significant findings regarding the differences in anxiety measures between the participants taking and not taking prescription antidepressants at the time of the second follow-up measure, further study should also monitor more closely the participants' use of antidepressants throughout the study. It is possible that those participants who had been deemed medically appropriate by their physician for prescription antidepressants could possess inherently higher symptoms of trait anxiety.

It is also important to note that those participants who reported that they had quit smoking at the time of the second follow-up measure scored significantly lower as a group on the BAI than those participants who reported smoking the same amount or those who had decreased the amount of cigarettes they were smoking at the time of this measure. This could also indicate that those individuals who were successful in smoking

cessation could possess lower trait anxiety than those who were unsuccessful with cessation.

To further improve the study it is also recommended that the one-time leisure education intervention be increased to a program which would include 3-4 leisure education sessions. This would allow participants to benefit from additional leisure education interventions and further their knowledge regarding the importance of incorporating leisure activities into their smoking cessation plan.

Further recommendations include that this redesigned study be expanded to include patients at multiple VA Medical Centers which provide smoking cessation programs. A larger study which incorporates multiple VA healthcare facilities would provide additional participants from across the country and assure that the sample would be truly representative of all veterans receiving healthcare from the VHA.

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Appendix A

Middle Tennessee State University IRB Approval

April 23, 2007

Mary Ann Aquandro & Dr. Peter Cunningham
Department of Health and Human Performance
maaquandro@mtsu.com, peters@mtsu.edu

Re: Protocol Title: "The Effect of a Leisure Education Program on Anxiety Levels of..."
Protocol Number: 07-099

Dear Investigator(s),

This letter is to confirm receipt of the revised Informed Consent Document as well as the approval letter from the VA Research and Development Committee.

Although the above protocol was originally approved as falling under expedited review, upon further review, I found your study to be exempt from Institutional Review Board (IRB) continued review. The exemption is pursuant to 45 CFR 46.101(b)(2) which involves the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, there are no identifiers involved; and, any disclosure of the human subjects' responses could not reasonably place the subjects at risk.

You will need to submit an end-of-project report to the Office of Compliance upon completion of your research. Complete research means that you have finished collecting and analyzing data. Should you not finish your research within the one (1) year period, you must submit a Progress Report and request a continuation prior to the expiration date. Please allow time for review and requested revisions. Please note, your study expires December 4, 2007. Please contact my office to determine what type of report you need to file, i.e. end-of-project or progress.

According to MTSU Policy, a researcher is defined as anyone who works with data or has contact with participants. Anyone meeting this definition needs to be listed on the protocol and needs to provide a certificate of training to the Office of Compliance. If you add researchers to an approved project, please forward an updated list of researchers and their certificates of training to the Office of Compliance before they begin to work on the project. Any changes to the protocol must be submitted to the IRB before implementing this change.

Please note that any unanticipated harms to participants or adverse events must be reported to the Office of Compliance at (615) 494-8918. Also, all research materials must be retained by the PI or faculty advisor (if the PI is a student), for at least three (3) years after study completion. Should you have any questions or need additional information, please do not hesitate to contact me.

Sincerely,

Tara M. Prairie
Compliance Officer

Appendix B

VATVHS Informed Consent Form

 Department of Veterans Affairs		VA RESEARCH CONSENT FORM Version Date: 2/7/07	
Title of Study: The Effect of a Leisure Education Program on Anxiety Levels of Participants in a Smoking Cessation Program			
Principal Investigator:	Mary Ann Aquadro	VAMC:	Tennessee Valley Healthcare System
Participant Name:		Date:	

PURPOSE OF THE STUDY

You are being asked to take part in a research study at the Tennessee Valley Healthcare System Murfreesboro Campus because you are a cigarette smoker and have voluntarily agreed to participate in the Smoking Cessation Program provided by the Preventive Medicine Clinic. This study will examine the effect of a brief verbal Leisure Education Program on anxiety during the smoking cessation process.

DESCRIPTION OF THE PROCEDURES AND APPROXIMATE DURATION OF THE STUDY

If you agree to participate in this research study you will be asked to complete a Beck Anxiety Inventory three times. The Beck Anxiety Inventory consists of 21 brief statements and should take approximately 5 minutes to complete each time. You will be asked to complete the Beck Anxiety Inventory at the time you consent to participate in this research study or during the initial study visit and then approximately one week and three-four weeks following your initial study visit. The second and third completions of the Beck Anxiety Inventory will be accomplished by telephone, email or postal mail depending on your preference. You will not have to return to the medical center to complete it.

Participants in the study will be randomly assigned to a Treatment Group or a Control Group. Your chances of being assigned to either group are 50/50. A coin will be flipped prior to the beginning of the study to determine the group assignment for the first participant. The remaining participants will be assigned on an alternating basis to one of the two groups.

DESCRIPTION OF THE DISCOMFORTS, INCONVENIENCES, AND/OR RISKS

There are no costs, discomforts or risks associated with participation in this study. The only inconveniences will be approximately 5-20 minutes of your time to complete the initial Beck Anxiety Inventory and the Leisure Education session depending upon your group assignment and approximately 5 minutes of your time to complete the follow up inventories.

For study participants who are veterans:

As a veteran subject you will not be required to pay for any treatment received as a research subject which is being done solely for the purpose of this research study. However, your insurance carrier will be billed for all routine care and clinical procedures, if applicable. If you are in a "priority group # 7 veteran category" you are subject to making a co-payment as indicated by a means test. Your doctor should be able to provide you with this information or refer you to the appropriate individual for any questions you may have. As a veteran, you will receive medical care and treatment for injuries suffered as a result of participating in a VA research program in accordance with Federal Law. You will incur no additional charges for additional medical care that may result from injury or complications that are a direct result of your participation in this study.

Date of Approval: <u>10/10/06</u> VA FORM 10-1088 JAN 1995	Expiration Date: <u>10/10/07</u> (SEE INSTRUCTIONS)	SUBJECT'S INITIALS: _____
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 Department of Veterans Affairs		VA RESEARCH CONSENT FORM Version Date: 2/7/07	
Title of Study: The Effect of a Lifestyle Education Program on Anxiety Levels of Participants in a Smoking Cessation Program			
Principal Investigator: Mary Ann Aquadro		VAMC: Tennessee Valley Healthcare System	
Participant Name:		Date:	

ANTICIPATED BENEFITS RESULTING FROM STUDY PARTICIPATION

Taking part in this study may or may not personally help you, but your participation may lead to knowledge that will help others. You are not required to take part in this research study. Your participation is entirely voluntary. You can refuse to participate now or you can withdraw from this study at any time after giving your consent without affecting your healthcare/services or other rights. This will not interfere with your regular medical treatment, if you are a patient.

ALTERNATIVE PROCEDURES/OTHER TREATMENT AVAILABLE:

None at this time other than the traditional Smoking Cessation Program without this added educational intervention.

CONFIDENTIALITY AND PRIVACY

Your rights of privacy will be maintained in the following manner. Your medical records will be maintained according to this medical center's requirements and in accordance with the Privacy Act of 1974 and all other applicable privacy and confidentiality regulations. All information obtained about you during the research study will be kept as confidential as legally possible and will be accessible only to the investigator and any appropriate government agency. Research records, like any other hospital records, may be inspected by federal regulatory authorities, including the Department of Veterans Affairs, Food and Drug Administration (FDA), state regulatory authorities, and legally authorized parties. You will be asked to sign a separate consent form explaining your rights under the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

RESEARCH RESULTS

In the event new information becomes available that may affect the risks and/or benefits associated with this study or your willingness to participate in it, you and your physician will be notified so you can make a decision whether or not to continue your participation in this study.

All study data or information collected during this study will be maintained in a locked file cabinet in the Preventive Medicine Clinic or in my office depending on the document. Those documents related to the Smoking Cessation Program traditionally maintained on Smoking Cessation Program participants by the Preventive Medicine Clinic will be maintained in the Clinic. The additional documents generated by this study will be maintained in my office. For purposes of recording the results of this study your personal information will be coded to protect your privacy and confidentiality. After the information is no longer needed it will be destroyed after 6 years. Access to this coded information will only be granted to the Principal Investigator (Mary Ann Aquadro) and, if needed, the three members of her Dissertation Committee who are faculty members of Middle Tennessee State University (Peter Cunningham, Ph.D. Cheryl Ellis, Ph.D and Minsoo Kang, Ph.D). Access to uncoded data will be limited to Mary Ann Aquadro.

Effective Date: 10/10/06	Expiration Date: 10/10/12	SUBJECT'S INITIALS:
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VA FORM 10-1086

10-1086

Page 2 of 4

 Department of Veterans Affairs		VA RESEARCH CONSENT FORM Version Date: 2/1/07	
Title of Study:	The Effect of a Leisure Education Program on Anxiety Levels of Participants in a Smoking Cessation Program		
Principal Investigator:	Mary Ann Aquadro	VAMC:	Tennessee Valley Healthcare System
Participant Name:		Date:	

If results of this study are reported in medical journals or at meetings, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent.

CONTACT INFORMATION

If you have questions about this study or need to report a research-related injury, you can contact:

Mary Ann Aquadro at this phone number 615-867-6000 x3365.

If you have general questions about giving consent or your rights as a participant in this study you can call the VA Tennessee Valley Healthcare System Institutional Review Board at (615) 340-2866 or the Research and Development Service Office at (615) 340-5346 or the Middle Tennessee State University Institutional Review Board Office at (615) 494-8918.

STATEMENT OF PERSON AGREEING TO PARTICIPATE IN THIS RESEARCH STUDY

I have read () this consent form or have had it read to me ().

_____ has explained the study to me and all of my questions have been answered. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me.

If I do not take part in this study, my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled.

I have been told my rights as a research subject, and I voluntarily consent to participate in this study. I have been told what the study is about and how and why it is being done. All my questions have been answered.

I will receive a copy of this consent form and a copy will be placed in my medical chart and a copy filed in the VA Tennessee Valley Healthcare System Research and Development Service Office, Nashville Campus.

Subject's Signature

Date

IRB Approval Date: _____	Expiration Date: _____	SUBJECT'S INITIALS: _____
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 Department of Veterans Affairs		VA RESEARCH CONSENT FORM Version Date: 2/7/07	
Title of Study: The Effect of a Leisure Education Program on Anxiety Levels of Participants in a Smoking Cessation Program			
Principal Investigator: Mary Ann Aquadro		VAMC: Tennessee Valley Healthcare System	
Participant Name:		Date:	

Signature of Witness **
 (** NOT an individual associated with the research study)

Witness (print)

Signature of Person Obtaining Consent

Date

Date Approved: <u>SEP 14 2007</u>	Expiration Date: <u>MAY 2 2008</u>	SUBJECT'S INITIALS: <u>[Signature]</u>
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Appendix C

VATVHS Authorization to Use/Disclose Protected Health Information Form

 Department of Veterans Affairs		VA RESEARCH CONSENT FORM Version Date: 2-7-07	
Title of Study:	The Effect of a Leisure Education Program on Anxiety Levels of Individuals Participating In a Smoking Cessation Program		
Principal Investigator:	Mary Ann Aquadro	VAMC:	Tennessee Valley Healthcare System
Participant Name:		Date:	

Authorization for Release of Protected Health Information for Research Purposes

Protected Health Information (PHI) is individually identifiable health information that has been collected or maintained by VA Tennessee Valley Healthcare System (VATVHS), including information that is collected for research purposes only, and can be linked back to the individual participant. Once this has occurred, use or disclosure of such information must follow federal privacy guidelines. A decision to participate in this research means that you agree to let the research team use and share your PHI as described below.

In accordance with 38 U.S.C. § 7332, the information that will be released includes information regarding the following conditions:

- Drug Abuse
- Alcoholism or Abuse of Alcohol
- Testing for or Infection with Human Immunodeficiency Virus (HIV)
- Sickle cell anemia
- None of the above

As part of the study, Mary Ann Aquadro may report the results of your study and/or non-study related information to those groups named below. If your research record is reviewed by any of these groups, they may also need to review your entire VATVHS medical record. Your records may also be reviewed in order to meet federal or state regulations. Reviewers may include representatives from the Food and Drug Administration, Office of Human Research Protections, the VATVHS Research and Development Committee, the Institutional Review Board and representatives of the Department of Veterans Affairs.

The study results will be retained in your research record for at least six years after the study is completed. At that time the research information not already in your medical record will be destroyed. Any research information in your medical record will be kept indefinitely.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Director of Health Information Management (VATVHS, 1310 24th Avenue South, Nashville, TN 37212-2637) at this facility or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Director of Health Information Management receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your right as a VHA patient to treatment or benefits outside the study.

If you revoke this authorization, Mary Ann Aquadro can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

IRB Approver Initials: <i>MAA</i>	IRB Expiration Date: <i>12/31/07</i>	IRB Number: <i>07-001</i>
VA Form 10-1086		Page 1 of 2

 Department of Veterans Affairs		VA RESEARCH CONSENT FORM Version Date: 2-7-07	
Title of Study: The Effect of a Leisure Education Program on Anxiety Levels of Individuals Participating in a Smoking Cessation Program			
Principal Investigator: Mary Ann Aquadro		VAMC:	Tennessee Valley Healthcare System
Participant Name:		Date:	

The VHA complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 and its privacy regulations and all other applicable laws that protect your privacy. We will protect your information according to these laws. Despite these protections, there is a possibility that your information could be used or disclosed in a way that it will no longer be protected. Our Notice of Privacy Practices (a separate document) provides more information on how we protect your information. If you do not have a copy of the Notice, the research team will provide one to you.

I have read this authorization form and have been given the opportunity to ask questions. If I have questions later, I understand I can contact Mary Ann Aquadro at (615) 367-3300 x3358. I will be given a signed copy of this authorization form for my records. I authorize the use of my identifiable information as described in this form and I certify that my signature is provided freely, voluntarily and without coercion.

Signature of Participant: _____

Date: _____

IRB Approval Date: 10/2/2007	IRB Termination Date:
------------------------------	-----------------------

Appendix D

VATVHS Research and Development Committee Approval Letter

Department of
Veterans Affairs

Memorandum

Date: October 26, 2006
 From: Chair, Research and Development Committee (151)
 Subject: IRB # 060954, "The Effect of a Leisure Education Program on Anxiety Level of Participants in a Smoking Cessation Program" (No Funding)
 To: Mary Ann Aquadro, M.S./Occupational Therapy (TVHS)

1. At the meeting on October 26, 2006, the Research and Development (R&D) Committee reviewed the following documentation: (a) VU IRB Application for Human Research dated October 6, 2006; (b) VU IRB approval letter dated October 10, 2006; (c) VA TVHS Request to Conduct Research; (d) VA TVHS Clinical Impact Sheet; (e) Research Staff Request; (f) VFA 10-1436; (g) training documentation for the principal investigator; (h) VAI 13-0398 (safety survey); and (i) VAF 10-1086, version date September 6, 2006.

2. Please note that the original copies of the signed consent forms must be maintained by the investigator. Signed copies of the consent form are to be given to the study participants and copies sent to the Research and Development Service for scanning into the participants' electronic medical records. Secondary documentation of the consent process must also be maintained in the Computerized Patient Record System (CPRS) and/or other record system (i.e. office/clinic file, medical record, case report form, etc.).

3. Please be reminded any serious and unexpected adverse events involving study participants enrolled at the VATVHS are to be promptly reported to the IRB and Research Office. If the adverse event is alarming, you are required to report the event immediately.

4. Please note that this approval is for a 12-month period only, based upon the IRB approval date. Any further changes to the protocol and/or consent form must be presented to the IRB and the R&D Committee for approval before implementation of the changes.

5. The Veterans Health Administration requires the contributions of the Department of Veterans Affairs to research are appropriately acknowledged. Please find attached a copy of the *VA Handbook 1306.19, Presentation of Research Results*, for your reference.

R&D Committee Approval: October 26, 2006
 Approval extended to VAFs 10-1086, version date September 6, 2006

for Roy Zan, M.D., Ph.D.

CC: VU IRB

Attachments: (3)

Appendix E

VATVHS Department of Preventive Medicine Smoking Cessation Intake Evaluation

Department of Preventive Medicine and Health

Alvin C. York VA Medical Center

Smoking Cessation Initial Evaluation:

Date _____

Patient Name _____

Medical Information:

Allergies: _____ BP: _____

Medical History:

Medications:

History of: MI _____ Angina _____ Seizures _____ Anorexia _____

MAO Inhibitors _____ (such as furazolidone/Furoxone, isocarboxazid/Marplan, nialamide, pargyline, phenelzine/Nardil, procarbazine/Marplan, Selegiline/Eldaprl or Deprenyl, tranlycypromine/Parnate, moclobemide/Aurorix, brofaromine/Consonar)

Hypersensitivity or allergy to: wellbutrin or zyban _____

Nicotine patch _____

Name of Interviewer

Department of Preventive Medicine and Health

Alvin C. York VA Medical Center

Smoking Cessation Intake Evaluation

Date of Interview ___/___/___ Interviewer Initials _____

1. Name (last) _____ (first) _____ (middle initial) _____

2. Social Security Number _____ - _____ - _____

3. Address (Street or P O Box) _____

City _____

State _____ (Zip Code) _____

4. Phone Numbers (day or work phone) _____

(evening or home) _____

5. Gender male _____ female _____ 6. Date of Birth ___/___/___ 7. Age _____

8. Which of the following best describes your occupation? If you are retired, please check your former occupation, Mark only one.

- Homemaker Clerical or Office Student Sales
 Service worker, laborer Factory Worker, Machine Operator Managerial Military
 Craftsperson or supervisor Professional or Technical Other _____

9. Are you presently retired? (circle one) Yes No

10. Are you now? Married Single/Never Married Widowed Divorced

11. Which of these best describes your race or ethnic group?

- White Black American Indian/Eskimo Asian/Pacific Islander Hispanic Other

12. Please indicate the highest level of education you have completed. Mark only one.

- Some high school or less High school graduate Technical, vocational school
 Some college College graduate Post college Graduate degree

13. Please indicate average annual household income.

- less than \$10,000 per year \$30,000 – 40,000 per year
 \$10,000 – 20,000 per year \$40,000 – 50,000 per year
 \$20,000 – 30,000 per year greater than \$50,000 per year

14. Number of adults (18 years or older) living in household _____

15. Number of children (less than 18 years old) living in household _____

Tobacco History

16. At what age did you begin to smoke (use tobacco) ? _____ years

17. What brand(s) of cigarettes (or tobacco) do you usually smoke now?

18. What type is your current brand? Mark one in each column.

- | Size? | Filter? | Menthol? |
|--|-------------------------------------|--------------------------------------|
| <input type="checkbox"/> Regular | <input type="checkbox"/> Filter | <input type="checkbox"/> Menthol |
| <input type="checkbox"/> King Size | <input type="checkbox"/> Non-filter | <input type="checkbox"/> Non-menthol |
| <input type="checkbox"/> Long/100s | | |
| <input type="checkbox"/> Extra longs/120s | | |
| <input type="checkbox"/> Super slims | | |
| <input type="checkbox"/> Deluxe, Wides, Specials | | |

19. Are any of these words on your cigarette pack?

- Lights/Low Tar/Milds
 Ultra/Ultra Lights/Ultra Low Tar
 Extra Milds/Extra Lights
 None of above words are on my pack

20. How many cigarettes do you currently smoke per day? _____

21. How many cigarettes did you smoke per day at your heaviest rate? _____

22. How many times have you seriously tried to stop smoking?

- Never (skip to question #25)
 Once

27. Do your household members, friends, co-workers smoke? Mark one in each row.

	<u>No</u>	<u>Yes, a few</u>	<u>Yes, many</u>
Household members	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Friends	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Co-workers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

28. How sure are you that you are ready to stop smoking at this time?

- Not sure at all
- Not too sure
- Fairly sure
- Quite sure
- Extremely sure

MARK THE MOST APPROPRIATE ANSWER FOR THE FOLLOWING QUESTIONS

29. How soon after you wake up do you smoke your first cigarette?

After 30 minutes

Within 30 minutes

30. Do you find it difficult to refrain from smoking in places where it is forbidden, such as the library, theater, doctor's office?

No Yes

31. Which of all the cigarettes you smoke in a day is the most satisfying?

The first one in the morning

Any other one than the first one in the morning

32. How many cigarettes a day do you smoke?

1 – 15

16 – 25

26 or more

33. Do you smoke more during the morning than the rest of the day?

No Yes

34. Do you smoke when you are so ill that you are in bed most of the day?

No Yes

Appendix F

Beck Anxiety Inventory



NAME _____ DATE _____

Below is a list of common symptoms of anxiety. Please carefully read each item in the list. Indicate how much you have been bothered by each symptom during the PAST WEEK, INCLUDING TODAY, by placing an X in the corresponding space in the column next to each symptom.

	NOT AT ALL	MILDLY <small>(1 out of 4)</small>	MODERATELY <small>(2 out of 4)</small>	SEVERELY <small>(3 out of 4)</small>
1. Numbness or tingling.				
2. Feeling hot.				
3. Wobbliness in legs.				
4. Unable to relax.				
5. Fear of the worst happening.				
6. Dizzy or lightheaded.				
7. Heart pounding or racing.				
8. Unsteady.				
9. Terrified.				
10. Nervous.				
11. Feelings of choking.				
12. Hands trembling.				
13. Shaky.				
14. Fear of losing control.				
15. Difficulty breathing.				
16. Fear of dying.				
17. Scared.				
18. Indigestion or discomfort in abdomen.				
19. Faint.				
20. Face flushed.				
21. Sweating (not due to heat).				

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 Tel. (312) 343-7000

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Appendix G

Leisure Education Session

Leisure Education Session

The following verbal and written educational information was provided to each participant in the treatment group by the researcher during their initial visit to the Preventive Medicine Clinic to enter the smoking cessation program. The participants were encouraged by the researcher to take the written information home and review it many times during the next few weeks as they participated in the smoking cessation process.

- 1.) The participants were introduced to the benefits of leisure pursuits and the potential benefits of leisure activity participation to reduce the symptoms, especially anxiety, of nicotine withdrawal. This was accomplished by discussing six categories of leisure activities and the importance of having a balanced leisure lifestyle which includes a variety of activities. Handouts with information regarding the six categories of leisure activities and an extensive list of possible activities were given to the participant. The participants were encouraged to explore their leisure interests during the upcoming weeks and choose some activities which would be enjoyable for them and feasible for their participation. Participants were informed that it would be very important to have leisure activities which require physical activity and/or mental concentration which will refocus their feelings of nicotine cravings into physical and/or mental activity. Participants who have attempted to quit smoking in the past were encouraged to explore the effects of idle time on their success in remaining smoke-free during those past attempts.
- 2.) Potential barriers to participation were discussed as well as possible methods of overcoming the barriers. A handout listing potential barriers was given to the participant. Alternative activities were also discussed. Participants were encouraged to think about their nicotine cravings during idle time and which leisure activities they may pursue to refocus the feelings of the nicotine cravings into alternative thoughts and actions.
- 3.) Participants were asked to consciously think about their feelings during nicotine cravings in the upcoming weeks and how they deal with these feelings. Will they succumb to the feelings by smoking, merely tolerate the unpleasant feelings and associated symptoms (i.e. depression, anxiety, perceived stress, etc.), or will they become actively involved in a leisure activity? If they became involved in an activity, was that effective in meeting their needs to overcome the feelings of nicotine cravings? A handout which lists potential personal leisure needs and benefits was distributed to the participants to aid in exploring their feelings during the smoking cessation process during the next few weeks.

4.) Participants were given a handout to encourage them to plan potential leisure activity participation as they engage in the smoking cessation process.

Appendix H

Written Leisure Education Information

Six Categories of Leisure Activities

For an improved balanced leisure lifestyle, it is necessary to participate in a variety of leisure activities. It is important to have at least one which you enjoy and participate in regularly in each of the following categories.

Physical Activities – Activities such as walking regularly, a personal exercise program, jogging, sports which require physical exertion, aerobics, etc.

Social Activities – Any activity which involves others in a social atmosphere. This includes family gatherings, visiting friends, group or club participation, church gatherings or any other activity which involves participating with others.

Solitary Relaxation Activities – Activities which allow you to be alone and relax, yet are constructive and enjoyable. Examples would be reading for enjoyment, watching television for knowledge or entertainment, houseplants, listening to music, computer games, etc.

Creative Expression Activities – Activities such as writing music or poetry, ceramics, woodworking, photography, leather crafts, painting, or any other activity which allows you to express feelings and creativity.

Intellectual Stimulation Activities – Activities which require using some thought to improve knowledge or increase personal growth. These activities include crossword puzzles, educational television shows, reading for knowledge, continuing education, educational computer activities, etc.

Spectator Appreciation Activities – Activities which allow you to be passive, but allow enjoyment through appreciation or interest. Such activities would be attending movies or watching them at home, attending concerts, plays, attending sporting events or watching them on television, people watching, etc.

Activity Inventory

Antiques	Euchre
Beach combing	Exercising
Backgammon	Exotic cooking
Backpacking	Fairs
Badminton	Aquariums
Baking	Archery
Chess	Art Object/Appreciation
Circuses	Collections of any items
Clay	Attending Yard/Garage Sales
Composing music/songs	Auto mechanics
Computer games/activities	Baseball
Crafts	Basketball
Cribbage	Boating – Canoe/Motor/Sail
Cross country skiing	Books
Dancing	Bowling
Darts	Boxing
Deck tennis	Bridge
Decorating	Camping
Dieting/Nutrition	C.B. operating
Doing nothing in particular	Candle making
Dolls	Canning/Preserving
Dominoes	Cards
Drama	Car racing
Drawing	Ceramics
Dreaming	Charades
Eating	Checkers
Embroidery	Home Improvement Projects
Filmmaking	Football
Fishing	Four square
Flying	Frisbee

Gardening/Yard Work	Model Railroads
Golf	Motorcycling
Sunbathing	Nature Collecting/Study/Walks
Shopping	Painting
Guitar playing	Pets
Gun collecting	Photography
Gymnastics	Physical Fitness/Exercise
Handball	Picnics
Hang gliding	Pinball
Hiking	Pitching horseshoes
Hockey – Ice/Field	Pottery
Horseback riding	Printing
Horse racing	Quilting
Houseplants	Racing Sports
Hunting	Racquetball
Ice Fishing	Reading
Instrument playing	Restoring antiques/autos
Jewelry making	Riflery
Jogging/Running	Sightseeing
Knitting/Crocheting	Sculpturing
Kite flying	Singing
Leaf collecting	Scuba/Skin Diving
Leatherwork	Snorkeling
Listening to Music	Swimming
Martial Arts	Table Tennis
Member of Church/Club/School/ Social Group	Tennis
Member of a Community Organization/Political Group	Theater Movies/Plays
Metal Work	Watching Television
Miniature Golf	Volleyball
Model Building	Volunteer work
	Water polo
	Water skiing

Watching sports in person or on TV

Weaving

Weight lifting

Wood refinishing/working

Word games

Working on your car/truck

Wrestling

Writing poetry/stories

Yoga/Meditation

Other _____

Barriers to Leisure Participation

Directions: According to your own experience, what are the major barriers preventing you from enjoying leisure? Please use the scale provided and rate each of the following barriers as they apply to your life.

1 = This is rarely a barrier for me

2 = This is sometimes a barrier for me

3 = This is often a barrier to me

Rating Scale

_____ Often I don't feel like doing anything

_____ I have too many family obligations

_____ Work is the main priority now

_____ I don't think leisure is important

_____ I don't know what is meaningful to me in my free time

_____ I have a great deal of daily stress

_____ I have a bad habit of making too many commitments

_____ I don't have enough money to do what I want to do

_____ I am unemployed and I don't think leisure is possible under those circumstances

_____ I don't have the physical skills

_____ I don't have the artistic or creative skills

_____ I don't have enough free time

_____ I don't know what's going on or what is available

_____ I never feel well enough

_____ There is no one to participate with

_____ Social situations are awkward for me

_____ Recreation programs and facilities are not available

_____ Making decisions about doing something is difficult for me

_____ Following through on my intentions is difficult

What Prevents You from Participating?

Please check any of the following which have prevented you from participating in leisure activities in the recent past.

_____ Depression

_____ Took too much energy

_____ Low motivation

_____ Physical discomfort

_____ Fear or Anxiety

____ Lack of leisure skills / Don't know how

____ Afraid to ask someone

____ No one to participate with

____ Don't know what to do

____ Not having enough money

____ Not having enough time

____ Couldn't get transportation

Personal Leisure Needs and Benefits

- Doing something meaningful
- Being physically active
- Being committed to something
- Keeping busy
- Doing lots of different things
- Relaxing and taking it easy
- Doing something different from work or school
- Being able to do what I want
- Being spontaneous
- Making and carrying out plans
- Trying my own method of doing things
- Competing with others
- Competing with myself to do better
- Laughing and enjoying others and activities
- Making use of my skills
- Improving my skills
- Developing my skills
- Having something to show for my efforts
- Getting approval for what I do
- Being successful at what I do
- Having a feeling of personal worth
- Learning more about myself
- Developing personal relationships
- Being a part of a group/team
- Meeting new people
- Developing friendships
- Helping others
- Being in attractive surroundings

Adapted from LEAP Workbook by Pat O'Dea-Evans (1990)

Leisure Planning Guide

List some activities you plan to participate in for:

Physical Activity _____

Social Activity _____

Solitary Relaxation Activity _____

Creative Expression Activity _____

Intellectual Stimulation Activity _____

Spectator Appreciation Activity _____

Activities which will be appropriate for participation during the evenings after work:

Activities which will be appropriate for participation on days which you do not work:

Appendix I

Beck Depression Inventory

Beck Depression Inventory

Please read each group of sentences. Then pick out the statement in each group which best describes the way you have been feeling the past week, including today. You may choose more than one statement in the group if each applies equally well. Be sure to consider all the statements in each group before making your choice. Write the statement number (0-3) in the blank beside each group.

_____ 1. 0 I do not feel sad.

1 I feel sad.

2 I am sad all the time and can't snap out of it.

3 I am so sad or unhappy that I can't stand it.

_____ 2. 0 I am not particularly discouraged about the future.

1 I feel discouraged about the future.

2 I feel I have nothing to look forward to.

3 I feel that the future is hopeless and that things cannot improve.

_____ 3. 0 I do not feel like a failure.

1 I feel I have failed more than the average person.

2 As I look back on my life all I can see is a lot of failures.

3 I feel I am a complete failure as a person.

_____ 4. 0 I get as much satisfaction out of things as I used to.

1 I don't enjoy things the way I used to.

2 I don't get real satisfaction out of anything anymore.

3 I am dissatisfied or bored with everything.

- ___5. 0 I don't feel particularly guilty.
1 I feel guilty a good part of the time.
2 I feel quite guilty most of the time.
3 I feel guilty all of the time.
- ___6. 0 I don't feel I am being punished.
1 I feel I may be punished.
2 I expect to be punished.
3 I feel I am being punished.
- ___7. 0 I don't feel disappointed in myself.
1 I am disappointed in myself.
2 I am disgusted with myself.
3 I hate myself.
- ___8. 0 I don't feel I am any worse than anybody else.
1 I am critical of myself for my weaknesses or mistakes.
2 I blame myself all the time for my faults.
3 I blame myself for everything bad that happens.
- ___9. 0 I don't have any thoughts of killing myself.
1 I have thoughts of killing myself but I would not carry them out.
2 I would like to kill myself.
3 I would kill myself if I had the chance.
- ___10. 0 I don't cry any more than usual.
1 I cry more now than I used to.
2 I cry all the time now.
3 I used to be able to cry, but now I can't cry even though I want to.
- ___11. 0 I am no more irritated now than I ever am.
1 I get annoyed or irritated more easily than I used to.
2 I feel irritated all the time now.
3 I don't get irritated at all by the things that used to irritate me.

- ___12. 0 I have not lost interest in other people.
1 I am less interested in other people than I used to be.
2 I have lost most of my interest in other people.
3 I have lost all of my interest in other people.
- ___13. 0 I make decisions as well as I ever could.
1 I put off making decisions more than I used to.
2 I have greater difficulty in making decisions than before.
3 I can't make decisions at all anymore.
- ___14. 0 I don't feel I look any worse than I used to
1 I am worried that I am looking old or unattractive.
2 I feel that there are permanent changes in my appearance that make me look unattractive.
3 I believe that I look ugly.
- ___15. 0 I can work as well as before.
1 It takes an extra effort to get started at doing something.
2 I have to push myself very hard to do something.
3 I can't do any work at all.
- ___16. 0 I can sleep as well as usual.
1 I don't sleep as well as I used to.
2 I wake up 1-2 hours earlier than usual and find it hard to get back to sleep.
3 I wake up several hours earlier than I used to and cannot get back to sleep.
- ___17. 0 I don't get more tired than usual.
1 I get tired more easily than I used to.
2 I get tired from doing almost nothing.
3 I am too tired to do anything.

- ___18. 0 My appetite is worse than usual.
1 My appetite is not as good as it used to be.
2 My appetite is much worse now.
3 I have no appetite at all anymore.
- ___19. 0 I haven't lost much weight, if any, lately.
1 I have lost more than 5 pounds.
2 I have lost more than 10 pounds
3 I have lost more than 15 pounds.
I am purposely trying to lose weight by eating less. ___ Yes ___ No
- ___20. 0 I am no more worried about my health than usual.
1 I am worried about physical problems such as aches and pains; or upset stomach; or constipation.
2 I am very worried about physical problems and it's hard to think of much else.
3 I am so worried about my physical problems that I cannot think about anything else.
- ___21. 0 I have not noticed any recent change in my interest in sex.
1 I am less interested in sex than I used to be.
2 I am much less interested in sex now.
3 I have lost interest in sex completely.

_____ TOTAL SCORE