EXPLORING THE RELATIONSHIP BETWEEN SPIRITUAL WELL-BEING
AND SMOKING CESSATION TREATMENT

Kia Kerrin, DSW

A DISSERTATION

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Degree of Doctor of Social Work

Signature __________________________
Ram Cnaan, Ph.D.
Associate Dean, Social Work
University of Pennsylvania
Graduate Group Chairperson

Signature_____________________________
Richard J. Gelles, Ph.D.
Dean, School of Social Policy and Practice

Dissertation Committee
Robert Schnoll, Ph.D.
Associate Professor
Department of Psychiatry, University of Pennsylvania

E. Paul Wileyto, Ph.D.
Senior Research Investigator, Department of Biostatistics & Epidemiology
Director of Biostatistics, Tobacco Use Research Center
School of Medicine, University of Pennsylvania
DEDICATION

I would like to dedicate this dissertation to my family who has been my support system since day one. I would have not been able to get through this program without my mother (Ethel Wilson), father (Samuel Wilson), brothers and sister-in-laws (Camara & Sharon Wilson and Sekou Wilson & Cecily McCarty). Their guidance, support and encouragement were the forces that kept me motivated and focused towards completion. I would like to dedicate this dissertation to my son (Stephen M. Kerrin Jr.) who continued to bring me joy no matter what level of stress I may be under. My nieces, (Layla, Camielle, and Naomi Wilson), and my nephews (Cameron Wiggins, Caleb Wiggins, Skylor Wilson and Savion Wilson), their love was a driving force in my life.

I would also like to dedicate this dissertation to every woman and man who risked their lives (including my parents and elders in my family) and many who lost their lives so that a young African-American woman, like me, would have the opportunity to receive a doctorate degree from an Ivy League institution. May my work be a testament that educational opportunities should not be limited based on race or gender. May your struggles and stories never be forgotten. I know this step in my life is largely due to others who have paved the way of excellence.

And of course, to my Lord and Savior Jesus Christ. From henceforth let no man trouble me: for I bear in my body the marks of the Lord Jesus (Gal: 6-17). We have different gifts, according to the grace given to each of us. If your gift is prophesying, then prophesy in accordance with your faith; if it is serving, then serve; if it is teaching, then teach; if it is to
encourage, then give encouragement; if it is giving, then give generously; if it is to lead, do it diligently; if it is to show mercy, do it cheerfully (Romans 12:6-8).

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I would also like to acknowledge the Center for Interdisciplinary Research on Nicotine Addiction in which my research data was collected, the research staff that worked on the project in particular, Patricia Goelz. I would also like to acknowledge the School of Social Policy and Practice at the University of Pennsylvania for starting the Doctorate in Clinical Social Work Program. Lastly, I would like to acknowledge all my friends, colleagues and classmates who supported me in this process.
ABSTRACT

UNDERSTANDING THE ROLE OF SPIRITUAL WELL-BEING
IN A SMOKING CESSATION PROGRAM

Kia Kerrin, MSW
Ram Cnaan, Ph.D.

Tobacco use, particularly cigarette smoking, is the single most preventable cause of death in the United States of America. The negative health effects of cigarette smoking are a major public health concern that can be reduced through quitting. Preliminary data has shown that spirituality can aid in the success of addiction treatment programs and smoking cessation programs. However, the current data are limited in their support of the relationship between spirituality and smoking cessation. This research study further explored the relationship between spiritual well-being and smoking cessation. A sample of 178 cigarette smokers was included in the research study to assess the relationship between levels of spiritual well-being and abstinence after an 8 week nicotine patch smoking cessation treatment program. The study was conducted through the University of Pennsylvania and Northwestern University. The proposed study was completed in conjunction with an ongoing NIH-funded clinical trial (R01 DA025078; An Effectiveness Trial of Maintenance Therapy for Nicotine Dependence). The proposed study involved the inclusion of a spiritual well-being scale at the baseline session. Subjects received the 21mg transdermal nicotine patch for 8 weeks, along with smoking cessation counseling. The Spiritual Well Being scale was utilized to determine if spiritual well-being was a predictor of abstinence at the 8 week mark. This research study was intended to be a catalyst to determine
whether spirituality should play a part in smoking cessation programs. Concerning the relationship between the spiritual well-being scale and quitting smoking and the spiritual well-being scale and dropping out of the smoking cessation program, there were no significant findings. Although, these main relationships were not found there were other significant relationships that may suggest these areas should be explored in more depth. Relationships were found between religious well-being and compliance with patch usage. The initial findings also suggest there is a relationship between scores of religious well-being and race.

**Keywords:** spiritual well-being, smoking cessation
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Chapter 1: Spirituality

Spirituality is a complex and difficult concept to capture. It is one of those concepts that almost everyone knows exists and yet, when people discuss it and attempt to define it, they find the concept elusive. Often people claim that they gain strength and moral guidance from their spirituality yet they cannot put a finger on what spirituality “is”. As this dissertation focuses on the power of spirituality in smoking cessation, it is important to define it and review the state of knowledge regarding its’ meaning and power.

Definition of Spirituality

Spirituality has been defined in several ways. Some state that spirituality and religion are synonymous, while others feel spirituality does not have to correlate with a particular religion or God. The Merriam-Webster dictionary defines spirituality as 1: something that in ecclesiastical law belongs to the church or to a cleric as such; 2: clergy; 3: sensitivity or attachment to religious values; and 4: the quality or state of being spiritual. This definition emphasizes religion as it pertains to spirituality.

The National Interfaith Coalition on Aging (1975) described spiritual well being as “the affirmation of life in a relationship with God, self, community and environment that nurtures and celebrates wholeness.” This definition states the relationship with God, as well as, other important entities in one’s life such as self and community. This is a slightly more holistic
approach to understanding spirituality. The connection between self and the environment or self and the community can be a spiritual understanding.

Hawks et al. (1995) defined spirituality as a sense of relatedness or connectedness to others, a provision for meaning and purpose in life, the fostering of well-being (through a stress buffering effect), and having a belief in and a relationship with a power higher than oneself. This definition begins to explore the two dynamics of spirituality: the connectedness to others and meaning and purpose in life, as well as, a religious connection, i.e., a relationship with a higher power. This concept stresses the understanding of purpose in life as a spiritual journey. The understanding of meaning and purpose in life may not include the belief in a higher being but often does for those practicing religion.

Spirituality can be understood as a dynamic principle that guides a person’s view of the world and relationship with a higher life force, as well as providing a sense of hope, moral conviction, faith, love, and trust (Hicks, 1999). Again, the definition separates two key dimensions: 1) a view of the world, and 2) a belief in a higher life force. This definition takes the concept even further by stating that spirituality provides hope, moral, conviction, faith, love and trust, all elements which may be helpful in a therapeutic intervention.

The existence of a higher being or an essence other than oneself has been debated for generations. Even though the existence is debatable, the fact that many Americans identify with a religion and/or spirituality cannot be denied. If religion and spirituality is a tool used in one’s life why should it be excluded from therapy? With the push of evidence-based practice it is necessary to study whether religion or spirituality can play a role in the success of a therapeutic program. For this reason the proposed study, Understanding the Role of Spiritual Well-Being in
a Smoking Cessation Program, will explore spirituality through the use of a quantitative measure, the Spiritual Well Being Scale. The Spiritual Well-Being Scale constructed by Paloutzian & Ellison (1982, 1991) is the most widely used instrument for both research and clinical evaluations of spirituality.

Relevance of Spirituality

Spirituality is often left out of the therapist/client dialogue because of beliefs that they are not necessarily related to the direct therapy. Spirituality is often seen as not being a tangible tool for therapists to use in a session and for that reason not valued. Strategies such as cognitive-behavioral therapy are more easily manualized and defined and therefore justified for a counseling session. The relevance of spirituality and religion are further being studied and findings are promising.

Koenig (2007), described the relationship between religion, spirituality and health outcomes. Koenig, stated the following:

“What exactly is “religious coping”? Religious coping is the use of religious beliefs or practices to reduce the emotional distress caused by loss or change. Patients may “turn over” their problems to God, trusting God to handle them so that they don’t have to ruminate or worry about them. They may believe that God has a purpose in allowing them to experience pain or suffering, which gives suffering meaning and makes it more bearable. A host of religious cognitions like these are mobilized to
reduce anxiety, increase hope, or increase a sense of control. With regard to religious practices that facilitate coping, patients may pray, meditate, read religious scriptures, attend religious services, perform religious rituals (receive the sacraments or be anointed with oil for example) or rely on support from clergy or members of their church, synagogue, mosque or temple. Religious beliefs and practices, then, are used to regulate emotion during times of illness, change and circumstances that are out of patients’ personal control (pp 20).”

In recent years, the scientific study of religion related to age and its’ importance for coping with the stresses of life has become more accepted and acknowledged (Levin & Koenig, 2004). Murdock (date) randomly sampled nearly 300 gerontology social workers and found that social workers tend to think favorably about religion and spirituality, as part of a holistic response to the needs of their diverse clientele. Yet, a substantial proportion (70%) admitted they had only minimal preparation for dealing with religion or spirituality. The therapists appear ready to explore these strategies with their client base but the field is not properly preparing the social workers. With more supportive research, the field could take religion and spirituality more seriously.

Organized social work in the 20th century tried to distance itself from its origins which were in the form of religious charity in favor of becoming a scientific and professional enterprise (Moody, 2005). It is only recently that social work has come to a more favorable view of religion (Cnaan et al., 1999). This change in viewpoint could be
due to recent increase in research on religion and spirituality. However, this field has more room to grow.

Interest in the impact of spirituality has been shown in other fields besides social work such as the medical field. The need for training to integrate spirituality into patient care has been increasingly recognized within medical education. In 1992, only three medical schools offered courses on religion, spirituality and medicine. By 2006, over one hundred of the 141 medical schools in the U.S. and Canada had some courses in spirituality and medicine (70 percent of which are required; Puchalski, 2006). The next step is from courses, to research, and to applied evidence-based practice.

By the year 2000, the number of studies examining the relationship between some aspect of religion, spirituality and health or health-care had grown to nearly 1,200, about 70 percent of which were on mental health and 30 percent on physical health (Koenig, McCullough, & Larson 2001). Koenig et al. further (2001) stated, the following:

“It appears that psychological and social factors influence the physiological systems of the body that are directly responsible for good health and the ability to fight disease. Therefore, if religious/spiritual involvement can be shown to enhance psychological health and social interactions; it is reasonable to hypothesize that religious factors may improve physical health as well doing so by reducing psychological stress, increasing social support and encouraging positive health behaviors (p.53).

Koenig et al. (2001), Moody (2005), Cnaan et al. (1999), and Puchalski (2006) support the relevance of spirituality in the field of public health, including for smoking cessation. This
paper will focus mainly on spirituality as it relates to substance abuse and smoking cessation. The following section will explore research in spirituality and substance abuse.

**Spirituality and Substance Abuse**

The use of spirituality has been studied in several forms of addiction treatment. Participants have shown interest in using spirituality as part of their treatment and spirituality may also aid in their quit attempt. Understanding spirituality in other forms of addiction can support exploring the use of spirituality in smoking cessation counseling. Investigators have found that aspects of spirituality may be related to recovery from addiction (Kelly et al., 2011).

As we consider other drug addiction treatments, it is notable that the success of Alcoholics Anonymous is generally attributed to its strong spiritual focus (Alcohol Anonymous, 1952). Kelly et al. (2011) examined the relationship among Alcoholic Anonymous, spirituality/religiousness, and alcohol use, and tested whether the observed relation between AA and better alcohol outcomes can be explained by spiritual changes. Controlling for a variety of confounding variables, attending Alcoholic Anonymous was associated with increases in spiritual practices, especially for those initially low on this measure at the time of intake. Results also showed that AA was consistently associated with better subsequent alcohol outcomes, which was partially mediated by increases in spirituality. This meditational effect was demonstrated in both outpatients and aftercare samples and both alcohol outcomes (proportion of abstinent days; drinks per drinking days). Kelly and colleagues’ study supports the association between spirituality and success in recovery but also the increase in spirituality lead to success. This supports the fact that therapists should discuss this in sessions in an attempt to increase client spirituality which can possibly increase success rates.
Spirituality and substance use are strongly related in twelve step programs, such as, Alcoholic Anonymous. In 1939, Bill W. (one of the co-founders of Alcoholic Anonymous) stated that men and women with substance abuse problems “have been not only mentally and physically ill, they have been spiritually sick: (AA World Services, 2001, pp.64).

Alcoholics Anonymous® is a fellowship of men and women who share their experience, strength and hope with each other that they may solve their common problem and help others to recover from alcoholism. The only requirement for membership is a desire to stop drinking. There are no dues or fees for AA membership; we are self-supporting through our own contributions. AA is not allied with any sect, denomination, politics, organization or institution; does not wish to engage in any controversy, neither endorses nor opposes any causes. Our primary purpose is to stay sober and help other alcoholics to achieve sobriety (Alcoholic Anonymous, 2011)

There are particular elements of the AA meetings that have spiritual elements such as saying the serenity prayer and the following:

- admitting that one cannot control one's addiction or compulsion;
- recognizing a higher power that can give strength;
- examining past errors with the help of a sponsor (experienced member);
- making amends for these errors;
- learning to live a new life with a new code of behavior; and
- helping others who suffer from the same addictions or compulsions.
The use of spirituality or religion is not new as it has been prevalent in the twelve step program which has a Protestant foundation (Miller, 1998). This limits the ability to generalize results to other religions and beliefs. However, there are clearly lined out elements (such as prayer or a belief of a higher power) of spirituality in AA that could be explored in a counseling session or used as a foundation to manualize how to approach spiritual in a session if a client is interested.

The use of spirituality in treating addiction is not only used in AA but also in other research studies and treatments for addiction. Heinz, Disney, Epstein, Glezen, and Clark (2010) used focus groups in 2005-2006 with 25 urban methadone-maintained outpatients to examine beliefs about the role of spirituality in addiction and its appropriateness in formal treatment. They found that spirituality and religious practices suffered during active addiction but went “hand-in-hand” with recovery. Participants agreed that integration of a voluntary spiritual discussion group into formal treatment would be preferable to currently available alternatives (Heinz et al., 2010).

The relationship of spirituality, religiosity and self-efficacy with drug and/or alcohol cravings was researched by Mason, Deane, Kelly, and Crowe (2009). In their study, 77 male participants at an Australian Salvation Army ages 19 to 74 years old completed a cross-sectional survey. Of the clients, 75% reported that spirituality and religious faith were useful components of the treatment program; however, spirituality and self-efficacy had significant relationships with cravings. Self-efficacy mediated the relationship between spirituality and drug and/or alcohol cravings. This research expresses the importance of spirituality and religion which supports the need for clinicians to research and address this area.
Galanter, Dermatis, Bunt, Williams, and Trujilo (2007) used a 6-item Spirituality Self-Rating Scale to reflect a global measure of spiritual orientation to life. The scale and the measures related to recovery from addiction and treatment response were applied in three diverse treatment settings: 1) a general hospital inpatient psychiatry service, 2) a residential therapeutic community, and 3) a methadone maintenance program. Findings on these patient groups were compared to responses given by undergraduate college students, medical students, addiction faculty, and chaplaincy trainees. The results showed that for certain patients spiritual orientation is an important aspect of their recovery (Galanter et al., 2007). Once again the elements of spiritual well-being have been seen as helpful in fighting addictions. Spirituality as a tool in recovery for alcohol and drug abuse has been studied and research has shown correlation between increase in spirituality and success rates. Spirituality and smoking cessation has been relatively under-studied but there are some studies that have supported the use of spirituality for smoking cessation.

**Spirituality and Smoking Cessation**

Gonzales and colleagues (2007) noted that patient spiritual resources are increasingly included in the treatment of medical conditions such as cancers and alcohol and drug dependence, but use of spiritual resources is usually excluded from tobacco dependence treatment. Gonzales and colleagues’ study concluded that smokers, especially heavy smokers, may be receptive to using spiritual resources in a quit attempt and that spirituality in tobacco dependence treatment warrants additional investigation and program development. This supports the need for more research in the area of smoking cessation and spirituality which is the focus of the proposed study.
Koenig et al. (2001) reviewed a growing body of literature suggesting that aspects of spirituality are related to healthy lifestyles; including being a non-smoker, coping with stress, and recovery from addiction. Smoking cessation has major and immediate health benefits that aide in decreasing the risk of heart attacks, strokes, chronic lung disease and various cancers including lung cancer (NCI, 2010).

Hawks et al. (1995) stated that health educators are in a position to develop, implement, and evaluate spiritual health interventions within the context of comprehensive programs. Imagery, mediation, and group support activities may address various components of spiritual health such as meaning and purpose in life, self-awareness, and connectedness with self and others. In researching the effects of a quit attempt, results can show the relevance and the personal need for including spiritual health in smoking cessation counseling.

Some populations may benefit more from a spiritual or religious element to smoking cessation than others. In Kaholokula’s (2008) study former and current Native American smokers were studied for the purpose of developing a culturally informed smoking cessation program. The study consisted of ten focus groups with a total of 52 Native Hawaiian men and women from a rural community in Hawaii. The transcriptions resulted in 11 strategies, 23 supports, and 13 barriers to smoking cessation. Native Hawaiians reported having used more behavioral and religious/spiritual strategies to quit smoking compared with other smokers. Religion and spirituality is important in the Native Hawaiian culture and for this reason it was a vital part in their smoking cessation success (Kaholokula, 2008).

The influence of religious and spiritual beliefs as it relates to choices about health can began as early as childhood. Another study used data from a nationally representative sample of
US adolescents in grades 7 through 12 to explore the effects of public and private religiosity on initiation, escalation, and cessation of smoking (Nonnemaker, McNeely, & Blum, 2006). The study found that adolescents' decisions to experiment with smoking are influenced by both their individual practice of their faith and by participation in a larger faith community. Private religiosity was protective against initiation of regular smoking and initiation of experimental smoking among nonsmokers but only when the young person frequently attended religious services or a religious youth group. In contrast, public religiosity did predict reduction and cessation of cigarette use among regular smokers. The above mentioned study brings up the complexity of the term religiosity and whether the participants were active in their place of worship but it does show some value in religion in smoking habits or religious leaders. Also, these findings may not be applicable to an adult population.

These findings of the relationship between spirituality and smoking can be detected in the Koenig (1998) study as well. The Koenig (1998) study of 3968 persons age 65 and older showed that religiously active persons are less likely to smoke cigarettes, and if they do smoke, they smoke fewer cigarettes than who?. Given the association between smoking and disease, and the widespread prevalence of both smoking and religious activity, this finding has implications for public health, namely, positive associations between religious practices and health behaviors.

McFadden et al. (2011) assessed the potential impact of spiritual beliefs on lifestyle choices such as tobacco use. A patient survey was conducted and among 501 patients who participated, 370 were nonsmokers and 131 were smokers. Compared with smokers, nonsmokers more often participated in religious activities such as regular weekly church attendance daily prayer and Bible study (48% vs. 24%). Current smoking was negatively
correlated with religious activities. From this study we can deduce that nonsmokers are more likely to engage in religious activities such as prayer, Bible study and regular church attendance. Could there be a fall in religious beliefs or activities that make clients more likely to fail in their quit attempt? Revisiting their religious or spiritual strengths and reconnecting them to these factors could play a vital role in recovery.

Smoking cessation has many health benefits; for this reason many smoking cessation programs and medications have been developed to aid smokers in the quitting process. The previous studies discussed the interest of spirituality and religion being incorporated in smoking cessation programs.

**Non-Christian Spirituality and Smoking Cessation**

In the United States, spirituality is often discussed in respect to a Judeo-Christian doctrine; however, spirituality can take many forms in different religions. The following section looks into Buddhist and Muslim spirituality in order to better understand the complexity of the concept. In the Yong et al. (2009) study a prospective examination of the perceived relevance and role of religion and religious authorities in influencing smoking behavior among Muslims in Malaysia and Buddhists in Thailand were conducted. Survey instruments were given and data were collected from 1482 Muslim Malaysians and 1971 Buddhist respondents. Results revealed that over 90% of both religious groups reported that their religion guides their day-to-day behavior at least sometimes, but Malaysian Muslims were more likely to report that this was always the case. Currently, religion and spirituality is still playing a large role in people’s lives yet we are still leaving this major aspect of one’s life out of our sessions.
In the Beitel et al. (2007) study a spirituality-focused manual was created for the treatment of addiction and HIV-risk behavior. The theoretical base was pulled from cognitive psychology and Buddhist philosophy which could make it suitable for individuals of diverse faiths. The therapy development process began with focus groups. The therapy was then codified in manual format, and a controlled clinical trial was conducted. The participant’s experiences were recorded and coded. The results show that participants supported and valued an integration of spiritual-focused interventions in addiction treatment (Beitel et al., 2007). Developing manuals to teach spirituality to therapist would be invaluable especially if more research is proven to show their correlation.

Spirituality has shown to have an impact on one’s health outcomes and for this reason should be explored more in research. In the future, spirituality could be looked at as a tool for recovery just as cognitive-behavioral therapy is used as a method of recovery. It is important to have effective smoking cessation programs as cigarette smoking can be detrimental to the health of the cigarette smoker and even those exposed to secondhand smoke.

**Chapter 2: Smoking**

According to the National Institute of Drug Abuse, tobacco use, particularly cigarette smoking, is the single most preventable cause of death in the United States (NIDA, 2009). Smoking cigarettes can be detrimental to the health of a cigarette smoker as well as to those who are exposed to the smoke. However, due to various addictive properties of the nicotine components within the cigarettes, reducing usage or quitting entirely can be very challenging for cigarette smokers who want to quit. Through the use of tobacco, nicotine is one of the most
heavily used addictive drugs and the leading preventable cause of disease, disability, and death (NIDA, 2009).

Health Effects of Cigarette Smoking

In the United States of America, cigarette smoking accounts for 90% of lung cancer cases and approximately 38,000 deaths per year as a result of secondhand smoke (NIDA, 2009). The tar in cigarettes increases a smoker’s risk of lung cancer, emphysema, and bronchial disorders. The carbon monoxide in smoke increases the chance of cardiovascular diseases (NIDA, 2009).

Cigarette smoking is responsible for approximately 443,000 deaths—one in every five deaths—each year in the United States. The chronic diseases caused by tobacco use lead the causes of death and disability in the United States and unnecessarily strain our health care system. The economic burden of cigarette use includes more than $193 billion annually in health care costs and loss of productivity (CDC, 2011).

The adverse health effects for cigarette smoking accounts for nearly 1 of every 5 deaths, each year in the United States (CDC). The negative effects from the use of cigarettes, plagues many Americans, as well as their family members. According to the Center for Disease Control and Prevention, smoking harms nearly every organ of the body, causing many diseases and reducing the health of smokers in general (see figure 1).

Figure 1: The health consequences causally linked to smoking and exposure to secondhand smoke
Cigarette smoking not only harms the smoker, but it can also harm others who inhale the second hand smoke. According to the United States Department of Health and Human Services (1988), there are no risk-free levels of exposure to secondhand smoke. Nonsmokers exposed to secondhand smoke at home or work increase their risk of developing heart disease by 25 to 30 percent and lung cancer by 20 to 30 percent. The finding is of major public health concern due to the fact that nearly half of all nonsmoking Americans are still regularly exposed to secondhand smoke. Secondhand smoke contains more than 50 cancer-causing chemicals, and is itself a known human carcinogen. Table 2, from the U.S. Department of Health and Human Services (2004, 2006), lists causal relationships between smoking and diseases.

### Table 1: Causal conclusions on smoking and diseases of the respiratory tract other than lung cancer: the 2004 and 2006 reports of the Surgeon General

<table>
<thead>
<tr>
<th>Smoking Cancers</th>
<th>Chronic Diseases</th>
<th>Secondhand Smoke Exposure</th>
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<tbody>
<tr>
<td>Oropharynx, Larynx, Esophagus</td>
<td>Stroke, Blindness, cataracts</td>
<td>Middle ear disease, Respiratory symptoms, impaired lung function</td>
</tr>
<tr>
<td>Trachea, bronchus, and lung</td>
<td>Periodontitis, Aortic aneurysm, Coronary heart disease, Pneumonia</td>
<td>Lower respiratory illness, Sudden infant death syndrome</td>
</tr>
<tr>
<td>Acute myeloid leukemia</td>
<td>Atherosclerotic peripheral vascular disease, Chronic obstructive pulmonary disease, asthma, and other respiratory effects</td>
<td>Nasal irritation, Lung cancer</td>
</tr>
<tr>
<td>Stomach, Pancreas</td>
<td>Comprehensive effects in women (including reduced fertility)</td>
<td>Coronary heart disease</td>
</tr>
<tr>
<td>Kidney and ureter, Cervix, Bladder</td>
<td></td>
<td>Reproductive effects in women: low birth weight</td>
</tr>
</tbody>
</table>

**Active Smoking**

The evidence is sufficient to infer a **causal conclusion** between smoking and

- Acute respiratory illnesses, including pneumonia, in persons without underlying chronic respiratory disease.
Involuntary Exposure to Tobacco Smoke

The evidence is sufficient to infer a causal conclusion between secondhand smoke exposure from parental smoking and:

- Lower respiratory illnesses in infants and children
- Middle ear disease in children, including acute and recurrent otitis media and chronic middle ear effusion
- Cough, phlegm, wheeze, and breathlessness among children of school age
- Ever having asthma among children of school age
- Onset of wheeze illnesses in early childhood

From maternal smoking during pregnancy and:

- Persistent adverse effects on lung function across childhood
- Lower level of lung function during childhood
- Odor annoyance
- Nasal irritation

Smoking and lung cancer

Tobacco’s role in increasing the chance of lung cancer is one of the most widely known facts of tobacco’s harmful effects on human health. Smokers carry an additional risk of 10- to 20-fold of developing lung cancer compared to non-smokers (23 times for men and 13 times for women smokers). Doll and Hill’s (1950) paper demonstrated the association between smoking and lung cancer which has become a public health standard. Tobacco use has been reported to be the main cause of 90% of male and 79% of female lung cancers. Ninety percent of deaths from lung cancer are estimated to be due to smoking.

The risk of lung cancer development is 20-40 times higher in lifelong smokers compared to non-smokers (Toraks, 2005). The complexity of tobacco smoke leads to some confusion about the mechanisms by which it causes lung cancer. Among the multiple components of tobacco smoke, 20 carcinogens convincingly cause lung tumors in laboratory animals or humans and are, therefore, likely to be involved in lung cancer induction (Hecht, 1999). Lung cancer is the leading cause of cancer death in the United States for both men and women (see table 3). Lung cancer is the most preventable form of cancer death in our society (CDC, 2011). Smoking can also lead to other health problems, such as, cardiovascular disease.

Table 3 Lung cancer estimates for 2011 (CDC, 2011): www.cancer.org, American Cancer Society

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<thead>
<tr>
<th></th>
<th>Male</th>
<th>Female</th>
<th>Total</th>
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<tr>
<td>New Cases of Lung Cancer</td>
<td>115,060</td>
<td>106,070</td>
<td>221,130</td>
</tr>
<tr>
<td>Deaths from Lung Cancer</td>
<td>85,600</td>
<td>71,340</td>
<td>156,940</td>
</tr>
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</table>
Smoking and Cardiovascular Disease

The most important behavioral risk factors of heart disease and stroke are unhealthy diet, physical inactivity and tobacco use. Behavioral risk factors are responsible for about 80% of coronary heart disease and cerebrovascular disease. Smoking causes coronary heart disease, the leading cause of death in the United States (USDHEW, 1967). Cigarette smoking causes reduced circulation by narrowing the blood vessels (arteries) and puts smokers at risk of developing peripheral vascular disease (i.e., obstruction of the large arteries in the arms and legs that can cause a range of problems from pain to tissue loss or gangrene) (USDHEW, 1967). Smoking causes abdominal aortic aneurysm (i.e., a swelling or weakening of the main artery of the body—the aorta—where it runs through the abdomen) (USDHEW, 1967).

Smoking and the Respiratory Tract and Reproduction

Other health effects of smoking are lung diseases (e.g., emphysema, bronchitis, chronic airway obstruction) by damaging the airways and alveoli (i.e., small air sacs) of the lungs (CDC, 2011). Smoking has many adverse reproductive and early childhood effects, including increased risk for—infertility, preterm delivery, stillbirth, low birth weight, and sudden infant death syndrome (SIDS) (CDC, 2011). One of the ways to decrease the chances of suffering from one of these health problems is through quitting smoking.
Addictive Properties and Carcinogens

Quitting smoking cigarettes can be very difficult and one of the main reason why is because of it’s addictive properties, nicotine. In the 1988 report, The Health Consequences of Smoking: Nicotine Addiction: A Report of the Surgeon General (U.S. Department of Health and Human Services, 1988) the pharmacologic basis of tobacco addiction is described as follows:

1. Cigarettes and other forms of tobacco are addicting.
2. Nicotine is the drug in tobacco that causes addiction.
3. The pharmacologic and behavioral processes that determine tobacco addiction are similar to those that determine addiction to drugs such as heroin and cocaine.

Nicotine addiction is an important element to understand the complexity of quitting. Of those individuals who have ever tried smoking, about one-third become daily smokers (USDHHS, 1994). Of those smokers who try to quit, less than 5 percent are successful at any one time (USDHHS, 2004). Any efforts to reduce tobacco-related disease must take into account the addiction potential of a tobacco product.

Cigarette smoking is a large health concern in the United States of America. The 2004 Surgeon General’s report, The Health Consequences of Smoking: A Report of the Surgeon General (USDHHS, 2004), concluded that the evidence is sufficient to infer a causal relationship between smoking and cancers of the lung, larynx, oral cavity, pharynx, esophagus, pancreas, bladder, kidney, cervix, and stomach, and acute myeloid leukemia. In addition, the report found that evidence suggests a causal relationship between smoking and colorectal and liver cancers. Each puff of each cigarette contains a mixture of thousands of compounds, including more than 60 well-established carcinogens.
Measurements of carcinogens or their metabolites in urine, blood, and breath can provide convenient and reliable quantitative information on human exposure to carcinogens. The information provided by these measurements allows for an objective evaluation of carcinogen doses in smokers. These measurements are called biomarkers. Urinary biomarkers are the most widely applied biomarkers of carcinogen exposure in smokers (Hecht, 2002). Urine samples are easy to collect in large quantities and isn’t as intrusive or painful as a blood draw. Carcinogens in cigarette smoke and/or their metabolites are frequently present in large quantities of urine. Reducing exposure to carcinogens can have positive effects on one’s health. Cigarette smokers can receive assistance in quitting through smoking cessation programs like cognitive behavioral therapy.

The Benefits of Smoking Cessation

The negative health effects of cigarette smoking is a major public health concern which can be reduced through quitting. Quitting smoking has both immediate and long-term positive effects on a person’s health. According to the Surgeon General, ex-smokers live longer than people who continue to smoke; quitting smoking also lowers the risk of lung cancer, other forms of cancer, heart attack, stroke and chronic lung disease. Considering these health effects it is important to study how smoking cessation treatments help cigarette smokers decrease or quit smoking (American Cancer Society, 2009). Smoking cessation has major and immediate health benefits that aid in decreasing the risk of heart attacks, strokes, chronic lung disease and various cancers including lung cancer (NIH, 2009). The chart summarizes these benefits.
Table 4: Benefits that can be reaped from quitting smoking are summarized in the timeline below:

Adapted from Smoking Cessation Guidelines for Australian General Practice 2004.

The risk of harm can be decreased or prevented by quitting or decreasing the amount of cigarettes a person smokes. For this reason many smoking cessation programs and medications
have been developed to aid smokers in the quitting process. One of the major therapies used in smoking cessation is cognitive-behavioral therapy (CBT).

Cognitive-behavioral Therapy

Cognitive-behavioral therapy is a form of treatment that focuses on a person’s cognitive, behavioral and/or emotional processes that may undermine effectively dealing with a particular problem. The basis of the treatment is recognizing and identifying these maladaptive processes and problem solving ways to rethink and act on these thoughts, behaviors and/or emotions in a more positive way. Cognitive-behavioral therapy has been implemented in treatments for anxiety, eating disorders, depression, abuse, anger, and smoking, among others. Cognitive behavioral therapy has been well researched which makes it a useful tool for evidence-based practice (Butler, Chapman, Forman, & Beck, 2006).

The history of cognitive-behavioral therapy can be traced to rational emotive therapy, rational emotive behavior therapy and cognitive therapy. Rational Emotive Therapy was developed by Ellis who later changed the name of the treatment to Rational Emotive Behavioral Therapy as not to negate the importance of behavior in the change process. Ellis believed there were numerous aspects that affected problem systems including cognitive, emotional, behavioral and environmental determinants (Ellis, 1993).

With this basis Ellis developed the ABC model which is A= the acting event, B= the person’s rational or irrational beliefs and C= the emotional, behavioral, and cognitive consequences. The basis of this therapy is that our beliefs have direct effects on how we feel (Ellis, 1993). Cognitive Therapy was developed by Beck et al. (1979) for the treatment of
depression. In cognitive therapy the maladaptive thought process is assumed to be the driving force towards the disorder or problem.

The foundation of the smoking cessation program in this study is cognitive behavioral therapy. Participants are taught skills to apply to their day to day activities. Skill sets are taught instead of just using will power. The counseling program provides a strong supplement to using the transdermal nicotine patch (reviewed below).

**Summary of Counseling Protocol**

As mentioned, the theoretical framework for the smoking cessation program is based on cognitive-behavioral therapy. The smoking cessation program consists of 13 sessions that are primarily over the phone. The counseling sessions vary from 15 minutes to 60 minutes depending on the session. The timing of the sessions is held to a strict schedule as the smoking cessation program is part of a research study.

**Pre-Quit Session**

The Pre-Quit Session is a 60 minute group session. The session begins with a welcome to the participants to congratulate them for joining the program and attempting to quit smoking. The counselor introduces him or herself by briefly sharing their education and work related experience. After the congratulations and the counselor’s introduction, the participant’s responsibility is reviewed (i.e., completing questionnaires and taking medications correctly). A study overview is discussed so participants are aware of what takes place at each session. The nicotine patch is discussed in terms of storage, proper use and possible side effects.

After the study procedures are fully discussed, participants are given an opportunity to discuss their own experiences in more detail. Each group member gives a brief introduction
about who they are and what led them to the program. They also respond to questions about their smoking experience.

Questions such as the following are asked:

1. How did you come to the decision to quit?
2. How long have you been smoking?
3. How much do you currently smoke?
4. Have you ever tried to quit?
5. What was your longest smoke-free period?
6. What strategies helped you remain smoke-free during that period?
7. What strategies did not seem to help?
8. How did you end up smoking again (where, when, who was there)?
9. Did you try to quit again immediately after that?
10. Are there any obstacles for you in quitting, such as concerns about weight gain or coping without cigarettes?
11. How much do you want to quit?
12. How confident are you that you could quit for good?

After the participant introductions the counselor begins to discuss what led the participant to wanting to quit. Participants are asked to list reasons why they want to quit. The counselor then asks the participants to share their responses and each response is grouped into physical benefits, social benefits and psychological benefits. Participants are given a visual of the many positive aspects of quitting, including the physical benefits such as a reduction to many illnesses, social benefits such as not having to sit in smoking sections, and psychological benefits such as
not having to worry about purchasing cigarettes or feeling guilty or self-conscious because you smoke.

The counselor then begins to explain the cycle of addiction. The physical component as well as the behavioral component is discussed. The physical component discusses nicotine and the addiction. The behavioral component discusses the habit of cigarette smoking. The discussion of habits leads to participants starting to think about and list triggers. Participants are then given wrap sheets. They are called wrap sheets because you can fold it around your cigarette box. The rap sheet includes a section to write down the time you lit your cigarette, what you were doing at the time you had your cigarette and how you were feeling (happy, sad, depressed).

Next the participants are given skills on how to manage their triggers. The technique is called avoid, alter or substitute. For instance, if the participant’s trigger is coffee then the participant could avoid by not drinking coffee, alter by drinking coffee to go instead of in the kitchen (which is an altering of location), or substitute by drinking tea instead of coffee. These strategies along with medication are revisited at each follow-up session.

Strengths of CBT Components in Counseling Protocol

The smoking cessation program has many basic components of cognitive-behavioral therapy. The overall structure of the counseling explores dynamics of smoking including the physical addiction, the habit or behavior, and what led the person to light a cigarette. The study makes an assumption that the participant is able to distinguish the feelings, emotions, thoughts and behaviors that are attached to their trigger. The thought process is the first step in coming up with a plan to stop smoking. This is a basic principle of cognitive-behavioral therapy.
Another element of CBT that is evident in the protocol is educating participants about their triggers. Understanding triggers makes the participant aware of their thought process and behaviors attached to cigarette smoking. This concept is made more concrete with the use of wrap sheets. The wrap sheets make the participant look at their habit of smoking more careful (Ellis, 1993).

Participants are asked to complete the form every time they light up a cigarette. The wrap sheets allow the participants to discover or unveil their own particular behavior of smoking. For example, asking the participant what they were doing when they lit their cigarette and what time it was when they began smoking, is an exploration of their thought process and emotions. By having the participants circle how they feel allows the participant to think about the emotions that may be attached to their smoking and what they were thinking about before they started smoking. Another CBT component is in the introduction; the participants are asked to explain a little bit about their smoking history and their past quit attempts.

Cognitive-behavioral therapy is conducive for research settings because it’s brief and highly structured. Researchers have to make sure all the participants are given the same amount of information in the same amount of time. CBT makes it easier for the counselor to stay on track because of the tangible assignments. Many sessions are over the phone instead of in-person because this study is an effectiveness trial and therefore the protocol was designed to be as close to real-life as possible versus a more carefully controlled trial (i.e. efficacy trial). This study incorporates a CBT model for a smoking cessation program; however, CBT alone is not as effective treatment as CBT when coupled with a medication. Several studies have shown the effectiveness of CBT along with a medication is enhanced.
Cognitive-behavioral Therapy in Conjunction with Medications

Only about 4 to 7% of people are able to quit smoking on any given attempt without medicines or other help incentives (average across attempts). Quitting smoking can be challenging but there are many programs available to assist smokers. Some of these programs are telephone and in-person counseling, psychoeducational and cognitive behavioral therapy. Also pharmacological treatment has been found to be an effective source of assistance.

Several research studies have looked into the use of CBT for smoking cessation. Cigarette smokers often have other mental health disorders such as depression. For this reason CBT can be very helpful because it is commonly used for those suffering from depression and for cigarette smokers. In the Hall et al. (1996) study the counselors used a CBT model for smoking cessation treatment with cigarette smokers who have a history of major depressive disorder (MDD). Participants were also given the nicotine gum. Mood management was completed in 10 group sessions over 8 weeks and standard treatment was given in 5 group sessions. The cognitive-behavioral intervention increased the amount of participants with Major Depressive Disorder who were abstinent. Those with past MDD had the greatest abstinence rates.

In Evins (2001) study, bupropion was used in conjunction with cognitive-behavioral therapy (CBT) to treat the smoking behavior and for stabilizing psychiatric symptoms in patients with schizophrenia. The study consisted of a 3-month, double blinded, placebo-controlled trial. Those in the active drug group had an improvement in negative symptoms and greater stability of psychotic and depressive symptoms. Those in the active group also had significant weight
loss. The study suggests that bupropion combined with cognitive-behavioral therapy may facilitate smoking reduction in cigarette smokers with schizophrenia.

Other studies have looked at the correlation between major depressive disorder and smoking cessation. Notriptyline is another drug that appears promising when coupled with CBT to help those wanting to quit who also suffer from MDD (Hall et al., 1998). In the Hall and colleagues (1998) study they replicated that MDD history-positive participants are helped by the 10-session cognitive-behavioral treatment. Also there was a correlation between serum levels and abstinence which suggests the medication was helpful. These studies show the success of CBT which is often coupled with a medication. For this study CBT was used in conjunction with transdermal nicotine patch. In this review of CBT for smoking cessation the selected studies often had psychiatric patients, the research is limited for the general population and for this reason the most related studies were selected.

**Nicotine Patch**

Nicotine replacement therapy (NRT) increases smoking cessation rates significantly vs. placebo or counseling alone (Fiore et al., 2008; Schnoll & Lerman, 2006). Nicotine gum is often used improperly and is not effective across all settings (Cepeda-Benita et al., 1993). Nicotine nasal spray and inhaler can be aversive, lowering compliance rates vs. other NRTs (Kaufmann et al., 2004; West et al., 2001). While there are data to support the use of the nicotine lozenge, the 2008 PHS treatment guideline concluded that the scientific support for this NRT is limited (Fiore et al., 2008). Relative to these NRTs, transdermal nicotine (nicotine patch) has the fewest side effects and yields the highest compliance rates. As a consequence, the transdermal nicotine patch is the most widely used form of tobacco dependence treatment in the US (Jonk et al., 2005;
Pierce & Gilpin, 2002) and Europe (Tilson, Bennett, & Barry, 2004; West et al., 2005). The transdermal nicotine patch is also available over-the-counter (OTC), allowing for new recommendations concerning its use to be easily disseminated and adopted.

A meta-analysis of 40 placebo-controlled clinical trials of transdermal nicotine (Stead et al., 2008) and the recent PHS guideline (Fiore et al., 2008) concluded that transdermal nicotine increases the odds of cessation vs. placebo by ~70%. However, only ~20% of smokers are able to maintain abstinence for 6 months following patch treatment (Fiore et al., 2008; Stead et al., 2008) even when patches are accessed OTC (Pierce & Gilpin, 2002). At 12-months, only ~9% of individuals who use transdermal nicotine are abstinent (Russell et al., 1993; Imperial Cancer Research Fund General Practice Group, 1993). At 6-months, the efficacy of standard therapy with transdermal nicotine is comparable to bupropion (Hughes, Stead, & Lancaster, 2007), but lower than the new nicotinic receptor partial agonist medication, varenicline, which produces 6-month quit rates of ~35% (Cahill, Stead, & Lancaster, 2007; Gonzalez et al., 2006; Jorenby et al., 2006). Bupropion and varenicline, however, can yield side effects and have numerous medical contraindications that limit who can use these treatments (Schnoll & Lerman, 2006). For instance, the Federal Aviation Administration and the Federal Motor Carrier Safety Administration have recently added varenicline to their list of drugs that should not be used by pilots or truck drivers.

**Age and Gender**

Research has shown that the success of smoking cessation treatment can be greatly affected and produce differing outcomes based on associated factors, such as, age and gender. In the McWhorter, Boyd, and Mattson (1990) study, independent predictors of quitting were: (1)
older age; (2) White race; (3) fewer cigarettes smoked/day; (4) higher household income; and (5) hospitalization in the follow-up period. Predictors of relapse were: (1) younger age; (2) urban residence; and (3) female gender.

According to Dietz, Sly, Arheart, and McClure (2010) young adults (18-24 years) have the highest smoking rate of any age group. They studied 4401 young adults using telephone interviews as part of the evaluation for the Tobacco Free Florida Campaign. The study researched which factors influenced young adult cigarette smokers with a focus on lifestyle, tobacco use tolerance, and attitude/beliefs. The study found that 20.3% of the young adults smoked cigarettes, males were more likely to be smokers at a prevalence rate of 25.1% than females with a smoking prevalence of was 15.6%. Non-Hispanic Whites were more likely to be smokers than other racial/ethnic groups at a prevalence rate of 23.8%. The findings suggested that as young adults reject negative labels attached to smokers, they are more likely to smoke.

Similar studies in other countries have looked socio-demographic descriptors as they relate to smoking and smoking cessation. Kaleta, Korytkowski, MAkowiec-D Browska, Usidame, B K-Romaniszyn, and Fronczak (2012) collected data on a representative sample of 7,840 individuals including 1,206 individuals who met the criteria of long-term smoking cessation and 2,233 current smokers. The data was collected through the Global Adult Tobacco Survey (GATS). Smoking cessation rate was calculated as calculated as the number of former smokers divided by the number of ever smokers. The study found that the quit rate for women was 30.4% and for men was 37.9%. Older age, high education attainment, awareness of smoking health consequences was associated with long-term quitting among genders (Kaleta et.al., 2012).
In the Osler and Prescott (1998) study, quitting smoking was positively associated with male sex and cigar smoking and negatively associated with the amount of tobacco smoked, inhalation, and alcohol consumption. Furthermore, in women, smoking cessation was positively associated with level of education and body mass index (BMI). These studies suggest that age and gender can be a predictor of quitting. Due to the effects of age and gender or cigarette smokers these two elements will be control variables in the proposed research study.

**Summary and Research Question**

Studies have shown that cognitive-behavioral therapy and the nicotine patch have been effective resources for quitting smoking. Preliminary data has shown that spirituality can aid in the success of addiction treatment programs and positively affect a quit attempt in a smoking cessation program. Interest in including spirituality in a smoking cessation program has also been assessed. These studies led to the proposed research question. Specifically, among cigarette smokers participating in a nicotine patch smoking cessation program, to what extent does the level of spiritual well-being explain success (defined as abstinence at the 8 week point) of a smoking cessation program when controlling for age and gender?

The proposed research study can be a catalyst for determining whether spirituality should play a part in smoking cessation programs. The research findings can build on the concept of adding a spiritual piece to future programming. Participants in the smoking cessation program will complete the Spiritual Well-Being Scale (Paloutzian & Ellison, 1982) at the initial baseline session before treatment. Data will be analyzed to see if levels of spiritual well-being in any way relate to cigarette smokers probability of quitting smoking. The analysis from the proposed study will help guide further addiction research and smoking cessation programs by providing an
additional method for participants to explore during the quitting process. If spiritual well-being is related to quitting, smoking cessation programs can be structured to give counselors diverse skills to equip potential quitters with the knowledge they need to avoid or decrease the chance of harmful effects from smoking. The study hypotheses are:

1. Cigarette smokers with higher levels of spiritual well-being who participate in a smoking cessation program are more likely to quit smoking when controlling for age and gender.

2. Cigarette smokers with higher levels of spiritual well-being will be less likely to drop out of the treatment program when controlling for age and gender.
Chapter 3: Research Design and Methods

Study Population

A sample of 178 cigarette smokers was included in the proposed study, Understanding the Role of Spiritual Well-Being in a Smoking Cessation Program, to assess the relationship between levels of spiritual well-being and abstinence after an 8-week behavioral counseling and nicotine patch smoking cessation treatment program. The study was conducted through two large city university sites (the University of Pennsylvania and Northwestern University) with extensive experience conducting smoking cessation studies. As was done for previous smoking cessation studies at this center, recruitment consisted of media ads (newspaper, radio) as the main form for recruitment, as well as, flyers.

The proposed study was completed in conjunction with an existing study, Dr. Robert Schnoll’s, An Effectiveness Trial of Maintenance Therapy for Nicotine Dependence, study. The proposed study involved the inclusion of a spirituality measure at the baseline session. The research design and methods section will focus on just the portions of Dr. Schnoll’s study that is needed for the purpose of this study, Understanding the Role of Spiritual Well-Being in a Smoking Cessation Program. Dr. Schnoll’s study involves randomization to either 8-weeks, 24-weeks, or 52-weeks of behavioral and nicotine patch treatment. To eliminate the potential effect of treatment duration, my assessment of whether a participant is quit or not occurred at the 8-week mark when all participants were still using the patch.

Research Design

This was a longitudinal study and the baseline Spiritual Well Being scale was used to determine if spiritual well-being was a predictor of abstinence at the 8 week mark amongst 178
community smokers from Philadelphia (UPENN) and Chicago (Northwestern University) participating in a combined CBT and transdermal nicotine patch treatment study. Subjects received the 21mg transdermal nicotine patch for 8 weeks along with CBT-based smoking cessation counseling.

Individuals contacting the recruitment line were initially screened for eligibility by phone. Those eligible were scheduled for an intake session, where eligibility was confirmed. Those eligible at the intake session and interested in the trial completed informed consent forms, the HIPAA documents, and the baseline measures, which included the Spiritual Well-Being Scale (Week -2). At week -1, participants received their patches, a single in-person counseling session (a pre-quit session), and set a target quit date (TQD) for one week later (Week 0). At Week 0, all participants received a second counseling session by phone and began the 21mg transdermal nicotine patch treatment. During the subsequent weeks, participants received two additional counseling sessions by phone (10-15 minutes each), and completed study measures. Participants who self-reported abstinence during the 7 days prior to the outcome measure time-point were asked to attend the site to provide a breath sample for biochemical verification. The primary outcome was the 7-day point prevalence abstinence at week 8 (self-reported abstinence for 7 days prior to the assessment and carbon monoxide [CO] of ≤ 10ppm). Those who did not complete this assessment were considered to be smokers, based on the intent-to-treat model.

Study Procedures

Intake Session (Week -2)

Participants were scheduled to meet the Study Coordinator for an intake session at the respective site. At this intake session, the participant’s eligibility was confirmed with a medical
history and a physical exam (including a pregnancy test for women). If eligible and willing to proceed, the participant completed informed consent and HIPAA documents and were officially registered on the study. Hard copies of eligibility screening data and consent/HIPAA forms were stored in a subject’s study binder. Eligibility data were entered into the web-based Data Management System used successfully in our previous multi-site smoking cessation clinical trials (Schnoll et al., 2010).

During the Intake Session, the Study Coordinator completed a baseline assessment. This assessment collected data on smoking history, demographics, depression, baseline smoking rate/behavior (including CO) and spiritual well-being. All baseline data were collected on Case Report Forms (CRFs) devised for this study and was stored in the participant’s study binder. Once the baseline data collection was complete, the participant initiated treatment.

**Behavioral Counseling Sessions (Week -2 to Week 8)**

All subjects received a manual-based intervention from a trained smoking cessation counselor from Week -2 to Week 8. Behavioral counseling was included given its’ demonstrated efficacy at helping smokers quit (Fiore et al., 2008) and to increase compliance with procedures and retention. Phone counseling was selected for all sessions (except the initial session) since it has demonstrated clinical and cost-effectiveness and can increase compliance and external validity (Fiore et al., 2008; Hollis et al., 2007; Stead et al., 2007). Since all study participants can access telephone counseling through the Pennsylvania and Illinois quit-lines, use of telephone counseling in this trial is consistent with community-based practice and an effectiveness trial. The counseling program began with a 1-hour in-person individual counseling session to prepare for the target quit day (Week -2); at the next session, participants will receive a 30-minute “quit-
day” session by phone to prepare for quitting (Week 0). Lastly, participants received 15-minute booster sessions by phone at Weeks 4 and 8. The counseling program was designed to enhance awareness of the harmful effects of smoking, assist the person in developing skills to quit and avoid relapse, and instruct the smoker on NRT use. Compliance with patch use recommendations was emphasized. A random 25% of sessions were audio-taped and assessed for protocol adherence. An experienced and trained counselor at each site conducted all sessions and will not conduct any assessments.

Pre-Quit Session (Week -2; 1-hour)

At the pre-quit visit, subjects received introductory materials (e.g., program overview and logistics) and materials to help them prepare for their quit date. A quit day for Week 0 was selected. Support and encouragement was provided by the counseling staff. The counselor reviewed the personal risks of continuing to smoke (e.g., cancer) and provided a quit plan. Specific strategies were described: 1) gradual reduction before quit day (i.e., scheduled smoking); 2) self-talk of reasons for quitting; 3) enlisting support of friends and family; 4) awareness of tempting situations and the need to avoid them or create a plan for using alternatives (e.g., distraction); and 5) removing smoking cues. A tip sheet of strategies was given.

Quit Day Session (Week 0; 30 Minutes)

This session focused on nicotine patch use and strategies to manage withdrawal and avoid relapse. Subjects were urged to maintain awareness of tempting situations (e.g., being around smokers) and to develop a repertoire of alternatives to cope with dangerous situations. Other skills for avoiding relapse that were discussed and encouraged: developing an exercise
regimen, relying on the support of friends and family, reminding oneself of the reasons for quitting, and use of self-distraction and reinforcement. These techniques helped avoid relapse (Anderson & Wetter, 1997; Fiore, Jorenby, & Baker, 1997). The counselor reviewed NRT use and clarified concerns that subjects may have.

Relapse Prevention Sessions (Weeks 4 and 8)

These “booster” sessions focused on relapse prevention. Previous session material was reviewed and successes or failures were assessed. The Session 1 quit plan was either revised or reinforced depending on the degree of progress. Problem-solving was a central component to these sessions; the counselor had participants identify tempting situations (i.e., when slips occurred or cravings high). New concerns about sustained abstinence were probed (e.g., fear of stress reactions or weight gain) and strategies for managing these issues were discussed.

Transdermal Nicotine Treatment

During the Pre-Quit counseling session, the counselor reviewed the purpose of using the nicotine patch (e.g., to help manage withdrawal symptoms; not a substitute for behavioral quitting strategies), provided directions on how to use the patch (e.g., abstinence from smoking, patch location, time, activity, and potential skin reactions), and answered any questions. The supply of transdermal patches for the study was distributed at this point. Participants were instructed to promptly discontinue the patch and contact the respective study coordinator if they experienced severe or persistent local skin reactions (e.g., severe redness, itching, or swelling) at the site of patch application or a generalized skin reaction (e.g., raised patches, hives, or generalized rash). Any serious adverse reactions or significant side effects of transdermal nicotine were evaluated by a physician at the respective site. Patch use by such individuals was
monitored and adjusted as needed. Based on previous and ongoing experience with nicotine patch studies at the UPENN site (e.g., Lerman et al., 2004; Schnoll et al., 2008), few serious adverse events were expected. Data from any subject experiencing adverse effects (even if requiring discontinuation of medication) was analyzed based on an intent-to-treat model. Consistent with the lack of evidence for a difference in effect with tapering (e.g. 4 weeks 21mg, 2 weeks 14mg, 2 weeks 7mg) versus no tapering, all participants received the 21mg dose throughout the treatment phase.

*Mid-treatment Assessments*

After the baseline assessment at Week -2, assessments were conducted during the clinical trial at Weeks 0, 4, and 8. These assessments were conducted by a trained and experienced Research Assistant (not the counselor) and were completed over the telephone following the counseling session. These assessments required only about 15 minutes to complete. Assessments included measures of treatment side-effects, adherence to patch use and smoking behavior.

*Outcome Assessments*

The primary outcome variable was 7-day point prevalence abstinence at Week 8, biochemically-confirmed with CO. All data were collected by telephone by a trained and experienced Research Assistant. Participants reporting abstinence for the 7-days prior to Week 8 were asked to attend the respective clinic to provide a CO sample. Costs for transportation and financial incentives were provided to increase compliance with this requested visit.
Table 5 Measures/Events

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Setting

University of Pennsylvania Tobacco Use Research Center (TURC)

The PENN Tobacco Use Research Center (TURC), which began in 1999, is an NCI/NIDA-funded center devoted to the evaluation of treatments for nicotine dependence (PI: Dr. Caryn Lerman). The TURC is part of the Department of Psychiatry at the PENN School of Medicine but it is located off-campus, in a community office building within the downtown city of Philadelphia. The TURC has been the treatment facility used to support several large clinical trials, small pilot projects, post-doctoral fellows, and core trial facilities (e.g., Lerman et al., 2004, 2006; Schnoll et al., 2008). The UPENN TURC provides the necessary infrastructure for this trial. The TURC encompasses 6,500 square feet, including space for faculty and staff offices, conference rooms, clinic rooms for treatment and assessment, several small laboratory rooms for biological assessments and storage, and data storage facilities (paper and computer). The efficacy trial of extended transdermal nicotine treatment was conducted through the UPENN TURC.

Northwestern University Behavioral Medicine Program

The Northwestern University Department of Preventative Medicine is part of the university’s School of Medicine and is comprised of faculty and staff devoted to teaching and research. In addition to preparing students to address disease prevention and control, improve access to and quality of health care, and better organize and finance health care services, the Department of Preventative Medicine supports leading-edge research into numerous medical conditions, including behavioral science and addictions research. The Department of Preventive Medicine is home to several nationally and internationally renowned landmark collaborative studies, including the Women's Health Initiative (WHI). Within this Department, the Behavioral
Medicine Program is a clinical and research unit that uses a multidisciplinary approach to understanding, preventing, and treating disease. Researchers with backgrounds in clinical psychology, kinesiology, nutrition, public health, nursing and medicine conduct grant-funded projects to understand the influences of psychological, socio-cultural, and biological factors on health. Behavioral Medicine faculty specialize in the development and implementation of behavioral interventions to promote health, including the evaluation of treatments for nicotine dependence. The Behavioral Medicine Program is located in downtown Chicago with convenient access to city residents. The Behavioral Medicine Program is comprised of 25,243 sq. feet of office space, including suites for faculty and administrative personnel, consulting rooms and meeting rooms for participant assessment and data collection, laboratory suites for the collection and storage of biological data, and data management and storage facilities.

Sample Size and Recruitment Procedures

Based on previous studies researching spirituality, the proposed study sample consisted of 178 adult (>18 years of age), female and male cigarette smokers who were interested in entering into a smoking cessation program. With a sample of 178 and alpha of .05, power of .80 requires an odds ratio of 1.559 or greater. The study utilized a sample of cigarette smokers who were voluntarily interested in a smoking cessation program. From previous studies at the center we expected that about 12 participants would complete the measure each month and with this understanding we expected the study to take 15 active recruitment months.

As was done for previous smoking cessation studies at this center (Schnoll et al., in 2008; Spring et al., 2007), we utilized media ads (newspaper, radio) as the main form of recruitment. We utilized media sources with large African American and Hispanic-American readership or
listenership as well as media sources with young adult audiences. This method of recruitment, though expensive, has allowed this research group to ascertain large (i.e., >500) and diverse (i.e., >30% racial/ethnic minority) study samples in their clinical trials. As a secondary form of recruitment, we distributed posters and flyers advertising the study to medical clinics across the UPENN and Northwestern-affiliated hospitals. The ads and flyers included instructions for enrollment and a toll-free phone number for participants to call to enroll in the study. A Research Assistant at the sites screened incoming calls from prospective participants for basic eligibility (e.g., number of cigarettes/day) and study interest.

**Study Inclusion Criteria**

1) Males and females over age 18 who smoke at least 10 cigarettes/day.

2) Able to communicate in English.

3) Able to use the transdermal nicotine patch safely (e.g., no allergy to latex).

4) Able to provide written informed consent for study procedures.

**Study Exclusion Criteria**

1) Are unable to communicate in English.

2) Have a current medical condition that would make using transdermal nicotine patch unsafe (e.g., allergy to latex);

3) Pregnant or planning to become pregnant or lactating.

4) Participants with asthma, diabetes, hypertension, or heart disease (e.g., coronary artery disease, abnormal heart rhythm, an arrhythmia) will be permitted to enroll in the study with medical clearance from the participant’s physician.

**Retention**
Both sites have extensive experience with retaining study participants in clinical trials and maintaining compliance with study protocols. First, in terms of retention of study participants, in our efficacy trial of extended transdermal nicotine, less than 10% of participants withdrew from the study (Schnoll et al., 2010). Further, our rates of assessment completion at week 8 were 74%. For the Northwestern University fluoxetine trial, 31% of participants withdrew from the trial (Spring et al. ?); this rate is higher than we expect in the proposed study, since this trial included intensive in-person group therapy and 10% of withdrawals were due to drug side-effects. The assessment completion rate approached 67%, which compares favorably to large smoking cessation randomized trials (e.g., Jorenby et al., 1999; Gonzales et al., 2006).

To ensure a high level of retention and compliance in this trial we: 1) educated subjects about the benefits of complying with the protocol; 2) used phone counseling and assessments and require only abstinent subjects at week 8 to attend clinic; 3) scheduled in-person sessions at times convenient for the subject, including evening and weekends; 3) maintained close contact to meet subjects’ needs; and 4) as is standard practice in smoking cessation trials (Hall et al., 2004; Niaura et al., 2005), provided financial incentives for completion of sessions. As is advised in smoking cessation clinical trials (Hughes et al., 2003), we utilized intent-to-treat (completed orientation, baseline and pre-quit visit) for primary analyses, which assumes that missing outcome data are coded as smokers.

Subject Payments, Tracking Procedures

Participants were provided compensation but it was not substantial enough to provide undue inducement to participate in the research. Rather, the compensation was meant to show appreciation for the completion of study measures and/or travel to the treatment site for study-
related responsibilities. There were 3 time-points for which we provided reimbursements. We provided $20.00 for each time-point for which assessments were complete (weeks 0, 4, 8).

**Data on Refusers and Drop-outs**

Any data collected on drop-outs was analyzed. Drop-outs were included as smokers in the study. Attendance was tracked by Research Assistants who recorded study participation in the research database.

**Measures**

*Demographics and Smoking History Assessment*

Standard surveys collected: demographics (e.g., age, gender, and ethnicity) and smoking history (e.g., age at initiation, prior abstinence periods, past use of nicotine treatments, current rate).

*Abstinence (primary outcome)*

Smoking status was assessed and biochemically verified (saliva sample). A standard timeline follow-back method (Brown, Burgess, Sales, & Whiteley, 1998) was used, as was done previous studies at the Transdisciplinary Tobacco Use Research Center (Lerman, Kaufmann et al., 2004). Participants who reported complete abstinence (not even a puff of a cigarette) for at least the 7 days prior to the assessment at week 8 were asked to complete an in-person visit for biochemical verification of abstinence. The primary outcome was biochemically verified 7-day point prevalence at 8 weeks. As per convention, participants assumed to be smoking if they self-report to be smoking, could not be reached to provide data, failed to provide a CO sample or provide a CO sample at week 8 that is > 10ppm (SRNT Subcommittee on Biochemical Verification, 2002).
Biochemical Verification

Self-reports of smoking cessation during treatment and at the end of the treatment phase were verified using carbon monoxide (CO) with a cutoff of 10ppm. Subjects reporting abstinence, but exhibiting CO levels above threshold, were treated as smokers in the analysis (for the sessions in which CO was taken) (SRNT, 2002).

Spiritual Well-Being

Spirituality or spiritual well-being was defined as a sense of relatedness or connectedness to others, a provision for meaning and purpose in life, the fostering of well-being (through a stress buffering effect), and having a belief in and a relationship with a power higher than self (Hawks et. al., 1995). Spiritual Well-Being was measured with the administration of the Spiritual Well-Being Scale (SWBS).

The Spiritual Well-Being (SWB) Scale is a 20-item self-report assessment instrument which is intended to measure people’s overall SWB as it is perceived by them in both a religious well-being sense and an existential well-being sense. The measure is constructed of these two subscales, one that represents religious well-being (RWB) and one that represents existential well-being (EWB). Each subscale contains 10 items. All of the RWB items contain the word “God.” The EWB items contain no specifically religious language, instead asking about such things as life purpose, satisfaction, and relations with the people and situations around us. Each item is rated on a 6-point Likert Scale with answer options ranging from “strongly agree” to “strongly disagree,” with no midpoint. The items are scored from 1 to 6, with a higher number representing more well-being. These scores are summed in order to yield three scale
scores; one score for RWB, one score for EWB, and one score for total SWB. RWB and EWB scores can range from 10 to 60. SWB total scores can range from 20 to 120.

Reliability

Test and re-test reliability coefficients for four different samples with 1, 4, 6, and 10 weeks between testings ranged from .88 to .99 for RWB, .73 to .98 for EWB, and .82 to .99 for SWB. The internal consistency reliability coefficients, based on data from over 900 subjects across seven studies, ranged from .82 to .94 for RWB, .78 to .86 for EWB, and .89 to .94 for SWB. These data indicate high internal consistency and reliability (Paloutizian & Ellison, 1982).

Validity

The SWB scale appears to measure what is intended. Face validity is evident by examination of the content of the items. Also, the authors report a factor analysis of the items, whose results yield factors that correspond to the two subscales (Paloutizian & Ellison, 1982). The RWB items cluster strongly together on one factor. The EWB items tend to cluster together on two subfactors that connote life direction and satisfaction. These results are generally consistent with the conceptual structure guiding the development of the scale. Some subsequent research may suggest a more complex factor structure (Ledbetter et al., 1991).

Validity is also indicated by correlations between the SWB scale and other measures with which it ought to be associated on theoretical grounds. For example, people who scored high on SWB scored lower on loneliness, higher on self-confidence, and higher on intrinsic religious orientation. The SWB, RWB, and EWB scores were all positively correlated with a sense of purpose in life (Paloutizian & Ellison, 1982).
Populations (from other studies)

The original sample consisted of 206 students from Biola College, Westmont College, Pepperdine University, and the University of Idaho. Various initial studies employed over 500 subjects, including men and women (married and single), college and high school students, senior citizens, religious and non-religious people, and people from large cities, small towns, and rural areas. Subsequent research has included a wide variety of sample including people with AIDS, terminal cancer patients, nurses, sociopathic convicts, medical outpatients, outpatient counselees, people with eating disorders, sexually abused outpatients, and people in several Christian denominations (Hill & Hood, 1999).

Training of data collectors

I reviewed the Spiritual Well-Being Scale with Dr. Robert Schnoll, the Principal Investigator of the overarching study along with the Project Manager. Kia Kerrin met with Robert Schnoll’s staff to explain why the measures were added and the proper way to complete the forms. The Project Manager followed-up with the research assistants on the proper way to complete the form.

Data Analysis

The hypothesis was that “cigarette smokers who participate in a smoking cessation program with higher levels of spiritual well-being are more likely to be quit at the 8 week mark and more likely to still be attending the program.” Levels of spiritual well-being were measured by the scores from the SWB scale. The statistical analyses were based on binary abstinence (vs. smoking) at the 8-week point of the study. Abstinence was defined as biochemically-confirmed 7-day point prevalence. A logistic regression model was estimated to identify predictors of
abstinence. Other variables were included as covariates such as demographics (race, gender, age, amount of cigarettes smoked per day). Categories that had single observations (i.e. race) were collapsed into one group for analysis.

**Administrative Arrangements**

Dr. Robert Schnoll, the Principal Investigator, of the smoking cessation study had agreed to include the Spiritual Well-Being Scale into his current baseline study measures packet. The Spiritual Well-Being Scale was approved by the IRB to be included in the study. The measures were entered in an Access database.

**Human Subjects**

The measures for the study, *Understanding the Role of Spiritual Well-Being in a Smoking Cessation Program*, were supplements to the currently enrolling smoking cessation study, *An Effectiveness Trial of Maintenance Therapy for Nicotine Dependence*. The University of Pennsylvania Institutional Review Board approved all procedures for the smoking cessation study, *An Effectiveness Trial of Maintenance Therapy for Nicotine Dependence* (protocol number: 809140). A copy of the measures was submitted with a cover letter stating the time point in which the measures were administered. The Spiritual Well-being Scale was an addendum to the existing measures packets at the Baseline Session. Study measures were included in the packets upon approval of the University of Pennsylvania’s Institutional Review Board. Participants also completed a HIPPA privacy rights form.

Several steps were taken to keep all data confidential. All participants were assigned an identification number. Data were reviewed and analyzed using this numeric system. No personal
information was sent via email. Hard copy measures were saved in a chart and locked in a file
cabinet. Data entered was saved in a secured computer password assessed database.

No data were collected without the participant’s written informed consent. Each
participant had the study objectives and the type of data to be collected in this trial clearly
explained to them before the study initiation. Separate consent was obtained for the audio-taping
and video-taping. Participants could decline to provide consent for video and audio taping and
still enroll in this trial (they will not be video or audio-taped). Data may only be disclosed to
entities that required disclosure of information to (e.g., PENN and Northwestern IRB, NIH). All
data were stored in locked file cabinets and password protected electronic databases. A database
manager at UPENN was responsible for database security.

Paper-based records were kept in a secure location and only were accessible to personnel
involved in the study. Computer-based files were only made available to personnel involved in
the study through the use of access privileges and passwords. Whenever feasible, identifiers
were removed from study-related information. Precautions were in place to ensure the data were
secure by using passwords and encryption, because the research involves web-based surveys.
Audio and/or video recordings were transcribed and then destroyed to eliminate audible
identification of subjects.
Chapter 4: Results

General Analysis

The sample for this analysis included 178 participants of which 91 were male and 87 were female. The mean age was 46 years old with the youngest participant being 20 years old and the oldest being 70 years old with a standard deviation of 11.93. The racial breakdown of the participants was 3 Asian, 82 Black or African-American, 90 White, 1 more than one race, 2 unknown or not reported. The educational breakdown of the participants were 1 completed grade
school, 10 completed some high school, 35 completed high school or GED, 83 completed some college or technical school and 49 completed college or beyond. Participant’s marital status were 76 never married, 31 married, 52 divorced or separated, 3 widowed and 16 marriage-like relationship. See table 6 for all characteristics of participants.

Participants smoking data were as follows: cigarettes smoked per day (cpd) ranged from 6 to 70 with the mean being around 17. Participants’ Fagerstrom Test for Nicotine Dependence (FTND) score ranged from 0 to 10 with the mean being around 5. The overall Spiritual Well-being scoring ranged from 20 to 104 with the mean being 47. When the scale was broken down into the subset scales the scores for religious well-being (RWB) ranged from 10 to 60 with a mean of 25; the existential well-being (EWB) scores ranged from 10 to 46 with a mean of 21.

Table 6: Characteristics of Participants (N = 178)

<table>
<thead>
<tr>
<th>Variable</th>
<th>N or Mean</th>
<th>% or SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>91</td>
<td>51.12</td>
</tr>
<tr>
<td>Female</td>
<td>87</td>
<td>48.88</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td>82</td>
<td>46.07</td>
</tr>
<tr>
<td>White</td>
<td>90</td>
<td>50.56</td>
</tr>
<tr>
<td>Asian</td>
<td>3</td>
<td>1.69</td>
</tr>
<tr>
<td>More than one race</td>
<td>1</td>
<td>.56</td>
</tr>
<tr>
<td>Unknown or Not Reported</td>
<td>2</td>
<td>1.12</td>
</tr>
</tbody>
</table>
Marital Status
Never Married 76 42.70
Married 31 17.42
Divorced or Separated 52 29.21
Marriage – Like Relationship 16 8.99
Widowed 3 1.69

Education
Grade School 1 0.56
Some High school 10 5.62
High School Graduate or GED 35 19.66
Some College or Technical School 83 46.63
College Graduate or Beyond 49 27.53

Age 45.7 11.929

Variable N or Mean % or SD
Cigarettes per day 17.48 8.05
SWB 47.37 18.80
RWB 25.65 13.54
EWB 21.72 8.86

Preliminary Data Analysis
A one way ANOVA test the relationship between SWB and EWB and potential covariates (e.g., age, gender) as well as the relationship between 8-week abstinence and potential covariates. Categories that had single observations (i.e. race) were collapsed into one group for analysis. The ANOVA tests whether the means of a population are the same (your null hypothesis) or if they differ between populations (your research hypothesis) by looking at the
variances. A one-way analysis of variance (ANOVA) is used if there is a categorical independent variable (with two or more categories) and a normally distributed dependent variable and you wish to test for differences in the means of the dependent variable broken down by the levels of the independent variable. Bartlett's test is used to test whether samples are from populations with equal variances. The analysis of variance assumes that variances are equal across groups or samples. The Bartlett test can be used to verify that assumption. When these tests were run there were only statistical differences in religious well-being and race (see highlighted table for significant findings and tables in appendix for non-significant findings).

Tables 7: One-way ANOVA – religious well-being and race

<table>
<thead>
<tr>
<th>Race</th>
<th>Mean</th>
<th>Std Dev.</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>White</td>
<td>30.56</td>
<td>14.54</td>
<td>90</td>
</tr>
<tr>
<td>Other</td>
<td>27.40</td>
<td>9.66</td>
<td>88</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Source</th>
<th>SS</th>
<th>Df</th>
<th>MS</th>
<th>F</th>
<th>Prob. &gt; F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Between Groups</td>
<td>4576.02</td>
<td>3</td>
<td>1525.34</td>
<td>9.52</td>
<td>0.0001</td>
</tr>
<tr>
<td>Within Groups</td>
<td>27874.68</td>
<td>174</td>
<td>160.2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>32450.70</td>
<td>177</td>
<td>183.34</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Regression models were conducted, religious well-being as it relates to age, existential well-being as it relates to age, spiritual well-being as it relates to age, religious well-being as it relates to FTND, existential well being as it relates to FTND score, spiritual well-being as it relates to FTND, religious well-being as it relates to cpd, existential well-being as it relates to cpd, spiritual well-being as it relates to cpd. The regression model were conducted to test the linear relationship between the dependent and independent variables. The ANOVA examined the
covariates were categorical (race, etc.) and regression was used for when covariates were continuous (e.g., age). The only area that was found to be significant was religious well-being as it relates to age (see highlighted table below for significant findings and the tables in the appendix for non-significant findings).

### Tables 8: Regression model religion to age

<table>
<thead>
<tr>
<th>Religious Well-being</th>
<th>Coef.</th>
<th>[95% Conf. Interval]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>-.21</td>
<td>-.38 -.05</td>
</tr>
<tr>
<td>Cons</td>
<td>35.39</td>
<td>27.55 43.22</td>
</tr>
</tbody>
</table>

Pearson’s Chi Square Test was used for 8 week abstinence as it relates to sex, 8 week abstinence as it relates to race, 8 week abstinence as it relates to education, 8 week abstinence as it relates to marital status, 8 week abstinence as it relates to age. A chi square test is used to analyze the relationship between two categorical variables. There were no significant findings (see tables in appendix).

### Research Hypotheses

There were two main research hypotheses that guided this study which are discussed below. An additional hypothesis was tested in a post hoc analyses.

**Research Hypothesis 1**

1. Cigarette smokers who participate in a smoking cessation program with higher levels of spiritual well-being are more likely to quit smoking.
This hypothesis was tested by using logistic regression models. The models were run to test 8 week abstinence as the outcome and religious well-being, age and race as predictors. Logistic regression is used for predicting the outcome of a categorical variable based on one or more predictor variables. Simple logistic regression assumes that the outcome variable is binary (i.e., coded as 0 and 1). None of the tests results were found to be significant (see tables in appendix).

Research Hypothesis 2

2. Cigarette smokers with higher levels of spiritual well-being will be less likely to drop out of the smoking cessation program.

This hypothesis was tested by using the two-sample t-test. The tests were run to determine if there was a relationship between existential well-being and eligible (actively in study) vs. withdrew (dropped out of study), religious well-being and eligible vs. withdrew and spiritual well-being and eligible vs. withdrew. An independent sample t-test is used to compare the means of a normally distributed interval dependent variable for two independent groups. None of the test results were found to be significant (see tables in appendix).

Post Hoc Analyses

The explanatory research question that was explored was, does spiritual well-being impact adherence to treatment (see table 9)? Random effects logistic regression models were used to examine post hoc questions. The post hoc analyses tested the relationship between weekly patch usage and religious well-being, existential well-being, spiritual well-being, sex, race and education. The sample size was 168 instead of 178 because 10 of the participants were missing patch data. There was a significant relationship between patch usage and religious well-being. Patch use is defined as daily use used to calculate weekly use. Daily use was coded 0, 1, 2
depending on how long, which was a binary coding. Then, weekly use (binary) was either 5 or 6 days of weekly use.

Tables 9: Religious Well-being, Sex, Race, Education & Weekly Patch Usage

<table>
<thead>
<tr>
<th>Variables</th>
<th>OR</th>
<th>[95% Conf. Interval]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Religious Well-being</td>
<td>1.08</td>
<td>1.01     1.15</td>
</tr>
<tr>
<td>Sex</td>
<td>2.45</td>
<td>.53     11.36</td>
</tr>
<tr>
<td>Race 3</td>
<td>27.93</td>
<td>.13     6219.59</td>
</tr>
<tr>
<td>Race 5</td>
<td>12.26</td>
<td>.06    2713.14</td>
</tr>
<tr>
<td>Race 7</td>
<td>2.95</td>
<td>.001   6547.57</td>
</tr>
<tr>
<td>Edu 3</td>
<td>.02</td>
<td>.001     .79</td>
</tr>
<tr>
<td>Edu 4</td>
<td>.17</td>
<td>.01      4.12</td>
</tr>
<tr>
<td>Edu 5</td>
<td>.28</td>
<td>.01     8.07</td>
</tr>
<tr>
<td>Week 2</td>
<td>.49</td>
<td>.18     1.29</td>
</tr>
<tr>
<td>Week 3</td>
<td>.36</td>
<td>.14     .93</td>
</tr>
<tr>
<td>Week 4</td>
<td>.49</td>
<td>.18     1.29</td>
</tr>
<tr>
<td>Week 5</td>
<td>.54</td>
<td>.20     1.44</td>
</tr>
<tr>
<td>Week 6</td>
<td>.36</td>
<td>.14     .93</td>
</tr>
<tr>
<td>Week 7</td>
<td>.19</td>
<td>.07     .48</td>
</tr>
<tr>
<td>Week 8</td>
<td>.10</td>
<td>.04     .27</td>
</tr>
<tr>
<td>_cons</td>
<td>1.29</td>
<td>.001   1045.06</td>
</tr>
</tbody>
</table>

Chapter 5: Discussion, Implications and Conclusions

Findings

There were no significant findings for the main hypotheses concerning the relationship between the spiritual well-being scale and quitting smoking and spiritual well-being scale and dropping out of the smoking cessation program. The hypotheses suggested that there would be a
relationship between spiritual well-being and quit rates and drop-out rates. Although, these main relationships were not found, there were other significant relationships that may suggest that these areas should be explored in more depth. Relationships were found between religious well-being and patch usage. The findings also suggest there is a relationship between religious well-being and race. Lastly, there’s a relationship between religious well-being and age; the older the participant the higher the religious well-being.

The research study was intended to be a catalyst to determine whether spirituality should play a part in smoking cessation programs. Concerning the relationship between the spiritual well-being scale and quitting smoking and the spiritual well-being scale and dropping out of the smoking cessation program, there were no significant findings. Although, these main relationships were not found there were other significant relationships that may suggest these areas should be explored in more depth. Relationships maybe found at later points, possibly at the 52 week point.

It should also be taken into account that the overall mean spirituality scores for this study were low in comparison to previous studies completed with members from religious groups. For example, the mean spirituality score for a group of 285 Conservative Baptist was 105, while the mean spirituality score for this current study was 47.37. This could be the reason why spirituality didn’t have an effect; possibly religious people seek their own networks for quitting smoking and those who come to the program from this current study are less spiritual (Paloutzian & Ellison, 1991).

Findings & Literature Review, Discussion and Future Research
Heinz, et al. (2010), found that spirituality and religious practices suffered during active addiction but went “hand-in-hand” with recovery. Based on this literature and others like it, this research hoped to find a significant relationship between quitting and spiritual well-being scores but no relationship was found.

Some populations may benefit more from a spiritual or religious element to smoking cessation than others. In Kaholokula’s (2008) study former and current Native American smokers were studied for the purpose of developing a culturally informed smoking cessation program. The study consisted of ten focus groups with a total of 52 Native Hawaiian men and women from a rural community in Hawaii. The transcriptions resulted in 11 strategies, 23 supports and 13 barriers to smoking cessation. Native Hawaiians reported having used more behavioral and religious/spiritual strategies to quit smoking compared with other smokers. Religion and spirituality is important in the Native Hawaiian culture and for this reason it was a vital part in their smoking cessation success (Kaholokula, 2008). This literature suggests that strength of spiritual well-being is highly related to the group being studied. Future research could look in to study particular populations. The sample were also highly motivated to quit since they were treatment seekers. This may have reduced variance.

Religious well-being and age and race seemed to have a relationship and because of this may need to be explored in a smoking cessation program. In particular, this relationship may be important in counseling sessions and counseling protocols. The relationship between religious well-being and patch usage also may suggest how the discussion of religion may help with medication compliance.
The sample size of this study was a slight limitation, however, the larger study is still ongoing and after more data are collected the data set can be revisited to see if there are any significant changes with a larger sample size. The scale was also only administered once which could have been a limitation.

Gonzales and colleagues (2007) noted that patient spiritual resources are increasingly included in the treatment of medical conditions such as cancers and alcohol and drug dependence, but use of spiritual resources is usually excluded from tobacco dependence treatment. Future research could test whether quit rates improve when including a spiritual or religious component to treatment as compared to treatment as usual.

**Conclusion**

Gonzales and colleagues’ study concluded that smokers, especially heavy smokers, may be receptive to using spiritual resources in a quit attempt and that spirituality in tobacco dependence treatment warrants additional investigation and program development. This current research data could be reviewed again to look at the relationship between spirituality and quitting based on amount of cigarettes smoked per day. However, as mentioned, more studies are needed in the area of spirituality and religion. For this reason future research should continue with so many unchartered areas of study.

Organized social work in the 20th century tried to distance itself from its origins which were in the form of religious charity in favor of becoming a scientific and professional enterprise (Moody, 2005). It is only recently that social work has come to a more favorable view of religion (Cnaan et al., 1999). This change in viewpoint could be due to recent increase in research on religion and spirituality. However, this field has more room to grow. The only way
to better understand these relationships is to continue to study the possible relationships and strengths of spirituality and religiosity in addiction


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mechanism of behavior change. *Alcoholism: Clinical and Experimental Research* 35, 454-463


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<table>
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<th>Name</th>
<th>Page</th>
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<tbody>
<tr>
<td>Figure 1</td>
<td>The health consequences causally linked to smoking and exposure to secondhand smoke</td>
<td></td>
</tr>
<tr>
<td>Table 2</td>
<td>Causal conclusions on smoking and diseases of the respiratory tract other than lung cancer: the 2004 and 2006 reports of the Surgeon General</td>
<td></td>
</tr>
<tr>
<td>Table 3</td>
<td>Lung cancer estimates for 2011 (CDC, 2011); <a href="http://www.cancer.org">www.cancer.org</a>, American Cancer Society</td>
<td></td>
</tr>
<tr>
<td>Table 4</td>
<td>Benefits that can be reaped from quitting smoking</td>
<td></td>
</tr>
<tr>
<td>Table 5</td>
<td>Measures/Events</td>
<td></td>
</tr>
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<td>Table 6</td>
<td>Demographics - Gender</td>
<td></td>
</tr>
<tr>
<td>Table 7</td>
<td>Demographics – Age</td>
<td></td>
</tr>
<tr>
<td>Table 8</td>
<td>Demographics – Race</td>
<td></td>
</tr>
</tbody>
</table>
### SWB Scale

For each of the following statements circle the choice that best indicates the extent of your agreement or disagreement as it describes your personal experience:

<table>
<thead>
<tr>
<th>Statement</th>
<th>SA</th>
<th>MA</th>
<th>A</th>
<th>D</th>
<th>MD</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I don't find much satisfaction in private prayer with God.</td>
<td>SA</td>
<td>MA</td>
<td>A</td>
<td>D</td>
<td>MD</td>
<td>SD</td>
</tr>
<tr>
<td>2. I don't know who I am, where I came from, or where I'm going.</td>
<td>SA</td>
<td>MA</td>
<td>A</td>
<td>D</td>
<td>MD</td>
<td>SD</td>
</tr>
<tr>
<td>3. I believe that God loves me and cares about me.</td>
<td>SA</td>
<td>MA</td>
<td>A</td>
<td>D</td>
<td>MD</td>
<td>SD</td>
</tr>
<tr>
<td>4. I feel that life is a positive experience.</td>
<td>SA</td>
<td>MA</td>
<td>A</td>
<td>D</td>
<td>MD</td>
<td>SD</td>
</tr>
<tr>
<td>5. I believe that God is impersonal and not interested in my daily situations.</td>
<td>SA</td>
<td>MA</td>
<td>A</td>
<td>D</td>
<td>MD</td>
<td>SD</td>
</tr>
<tr>
<td>6. I feel unsettled about my future.</td>
<td>SA</td>
<td>MA</td>
<td>A</td>
<td>D</td>
<td>MD</td>
<td>SD</td>
</tr>
<tr>
<td>7. I have a personally meaningful relationship with God.</td>
<td>SA</td>
<td>MA</td>
<td>A</td>
<td>D</td>
<td>MD</td>
<td>SD</td>
</tr>
<tr>
<td>8. I feel very fulfilled and satisfied with life.</td>
<td>SA</td>
<td>MA</td>
<td>A</td>
<td>D</td>
<td>MD</td>
<td>SD</td>
</tr>
<tr>
<td>9. I don't get much personal strength and support from my God.</td>
<td>SA</td>
<td>MA</td>
<td>A</td>
<td>D</td>
<td>MD</td>
<td>SD</td>
</tr>
<tr>
<td>10. I feel a sense of well-being about the direction my life is headed in.</td>
<td>SA</td>
<td>MA</td>
<td>A</td>
<td>D</td>
<td>MD</td>
<td>SD</td>
</tr>
<tr>
<td>11. I believe that God is concerned about my problems.</td>
<td>SA</td>
<td>MA</td>
<td>A</td>
<td>D</td>
<td>MD</td>
<td>SD</td>
</tr>
</tbody>
</table>
12. I don't enjoy much about life. SA MA A D MD SD
13. I don't have a personally satisfying relationship with God. SA MA A D MD SD
14. I feel good about my future. SA MA A D MD SD
15. My relationship with God helps me not to feel lonely. SA MA A D MD SD
16. I feel that life is full of conflict and unhappiness. SA MA A D MD SD
17. I feel most fulfilled when I'm in close communion with God. SA MA A D MD SD
18. Life doesn't have much meaning. SA MA A D MD SD
19. My relation with God contributes to my sense of well-being. SA MA A D MD SD
20. I believe there is some real purpose for my life. SA MA A D MD SD

Scoring

Items are scored from 1 to 6, with the higher number representing more well-being.

Negatively worded items (#1, 2, 5, 6, 9, 12, 13, 16, 18) are reversed scored. Odd number items assess religious well-being: even numbered items assess existential well-being (Paloutizian & Ellison, 1982). These scores are summed in order to yield three scale scores; one score for RWB, one score for EWB, and one score for total SWB. RWB and EWB scores can range from 10 to 60. SWB total scores can range from 20 to 120.
The Fagerstrom Test for Nicotine Dependence: a revision of the Fagerstrom Tolerance Questionnaire

TODD F. HEATHERTON, LYNN T. KOZLOWSKI, RICHARD C. FRECKER & KARL-OLOV FAGERSTROM
Table 3. Items and scoring for Fagerström Test for Nicotine Dependence (FTND)

<table>
<thead>
<tr>
<th>Questions</th>
<th>Answers</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. How soon after you wake up do you smoke your first cigarette</td>
<td>Within 5 minutes</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>6–30 minutes</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>31–60 minutes</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>After 60 minutes</td>
<td>0</td>
</tr>
<tr>
<td>2. Do you find it difficult to refrain from smoking in places where it is forbidden e.g. in church, at the library, in cinema, etc.?</td>
<td>Yes</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>0</td>
</tr>
<tr>
<td>3. Which cigarette would you hate most to give up?</td>
<td>The first one in the morning</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>All others</td>
<td>0</td>
</tr>
<tr>
<td>4. How many cigarettes/day do you smoke?</td>
<td>10 or less</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>11–20</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>21–30</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>31 or more</td>
<td>3</td>
</tr>
<tr>
<td>5. Do you smoke more frequently during the first hours after waking than during the rest of the day?</td>
<td>Yes</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>0</td>
</tr>
<tr>
<td>6. Do you smoke if you are so ill that you are in bed most of the day?</td>
<td>Yes</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>0</td>
</tr>
</tbody>
</table>

© Permission to use this scale for other than research purposes should be obtained from K. O. Fagerström

Maintenance Therapy: PHONE SCREEN (10.22.10)

<table>
<thead>
<tr>
<th>OVERALL STUDY STATUS:</th>
<th>Eligible</th>
<th>Ineligible</th>
<th>Refused</th>
</tr>
</thead>
<tbody>
<tr>
<td>PHONE SCREEN DF:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eligible</td>
<td>Ineligible</td>
<td>Today's Date:</td>
<td>RA Initials:</td>
</tr>
<tr>
<td>RA Initials:</td>
<td>________</td>
<td></td>
<td>_________</td>
</tr>
<tr>
<td>Question</td>
<td>YES</td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>-----</td>
<td>----</td>
<td></td>
</tr>
<tr>
<td>NAME:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AGE: (If &lt;18, ineligible)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DOB:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Referral Source: (i.e. Radio, Newspaper)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADDRESS:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CITY:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>STATE:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ZIP:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date of Source:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Description: (i.e. Metro, WXPN, UPenn)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HOME #:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WORK#:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Best time to call:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SEX:</td>
<td>M</td>
<td>F</td>
<td></td>
</tr>
<tr>
<td>HT:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WT:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>May we contact you about other studies at Penn for which you may be eligible?</td>
<td>YES</td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td>Do you consider yourself to be Hispanic or Latino</td>
<td>YES</td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td>What race do you consider yourself (list options)? White Black or African Amer. Amer. Indian or Alaska Native Native Hawaiian or other Pacific Islander More than one race: Please list Asian Unknown</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Do you smoke menthol or regular cigarettes?</td>
<td>REG</td>
<td>MEN</td>
<td></td>
</tr>
<tr>
<td>2. Are you able to communicate in English? (If NO, ineligible)</td>
<td>YES</td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td>3. During the past 7 days, how many cigarettes did you smoke on a typical day? (if &lt;10, ineligible)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Do you plan to live in the area for at least the next 12 months? (If NO, ineligible)</td>
<td>YES</td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td>5. Are you pregnant, breast-feeding, or planning on becoming pregnant in the next 12 months? (If YES, ineligible)</td>
<td>YES</td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td>6. Are you menopausal or unable to have children (i.e. tubal ligation, hysterectomy, etc.) (If YES, proceed to 7); if NO, proceed; if male, n/a.)</td>
<td>YES</td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td>a. Have you used birth-control methods to avoid pregnancy for at least the past month (i.e. condoms, the Pill, etc.)? (If YES, proceed; if NO, ineligible)?</td>
<td>YES</td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td>b. What type of birth control do/will you use? Specify type:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. On a typical week (7 days), about how many glasses of beer, wine, &amp; hard liquor do you drink?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Beer (12 oz.) ____ Wine (6-8 oz.) ____ Liquor (1.5 oz.) ____</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Have you ever had a diagnosis of psychosis or schizophrenia (If YES, ineligible)?</td>
<td>YES</td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td>9. Have you ever had a diagnosis of bipolar disorder (If YES, ineligible)?</td>
<td>YES</td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td>10. Do you currently have heart disease (i.e., current diagnosis or coronary artery disease, an abnormal heart rhythm or an arrhythmia, heart failure, heart valve disease, congenital heart disease, heart muscle disease or cardio-myopathy, pericardial disease, aorta disease, or vascular disease)? (If YES, eligible only with physician approval. This can be Frank or PCP.)</td>
<td>YES</td>
<td>NO</td>
<td></td>
</tr>
</tbody>
</table>
11. Have you had a heart attack in the last 6 months (If YES, ineligible)?

YES  NO

12. Do you have asthma (If YES, eligible only with physician approval)?

YES  NO

13. Do you have diabetes (If YES, eligible only with physician approval)?

YES  NO

14. Do you have an ulcer (If YES, eligible only with physician approval)?

YES  NO

15. Do you have high blood pressure (>160 over 100)? If YES, proceed to question a; If NO, proceed to 16.

YES  NO

a. Are you on medication to control your high blood pressure? (If YES, eligible with physician approval; if NO, ineligible)

YES  NO

16. Are you allergic to latex or adhesive tape (If YES, ineligible)?

YES  NO

17. Are you currently taking or recently discontinued (within past 14 days) any of the following (if YES, ineligible)

YES  NO

a. Antipsychotics (e.g., Haldol/haloperidol, Loxitane, Thorazine/chlorpromazine)?

YES  NO

b. Atypical antipsychotics (e.g., Abilify, Clozaril/clozapine, Risperdal, Seroquel, Zyprexa, Geodon)?

YES  NO
c. Mood stabilizers (e.g., Lithium, Lamictal/lamotrigine, Neurontin/gabapentin, Topamax/topiramate)?

YES  NO
d. Anti-depressants (e.g., tricyclics: Norpramin/desipramine, Elavil/amitriptyline; SSRIs:Lexapro, Prozac, Zoloft; MAOIs: Nardil, Parnate; Effexor/Effexor XR, Remeron/mirtazepine, Serzone/nefazodone)? (If YES, proceed to question d2. If NO, proceed to 20)

YES  NO
d2. For what reason and/or diagnosis (If psychosis, schizophrenia or bipolar disorder, INELIGIBLE. If depression or anxiety, etc. ELIGIBLE)?

18. What medications do you currently take (list all and check for eligibility):

________________________________________________________________________

19. IF ELIGIBLE for study: After hearing the program description, are you interested in coming in for the initial pre-quit study appointment?

YES  NO

If NO, why?

Time  Not interested  Privacy  Distance  Patch Concerns  Doesn’t want to be randomized Other ________

If YES, eligibility appt. date and time: Date: _____/_____/_____

Time: _____:____ AM  PM

If YES, counseling appt. date and time: Date: _____/_____/_____

Time: _____:____ AM  PM
Why am I being asked to volunteer?

You are being invited to participate in a research study. Your participation is voluntary which means you can choose whether or not you want to participate. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The research team is going to talk to you about the research study, and they will give you this consent form to read. You may also decide to discuss it with your family, friends, or family doctor. You may find some of the medical language difficult to understand. Please ask the study doctor and/or the research team about this form. If you decide to participate, you will be asked to sign this form. You are being asked to volunteer for this study of treatments for smoking because you are a smoker.

What is the purpose of this research study?

You are being asked to participate in a research study because you are a smoker, meet the inclusion criteria of the study and have expressed an interest in quitting. The purpose of this research study is to: (a) compare the effectiveness of 8 weeks (standard treatment) of nicotine patch treatment versus 24 weeks (extended treatment) of nicotine patch treatment versus 52 weeks (maintenance treatment) of 21mg nicotine patch treatment (14mg or 7mg nicotine patches will also be available for those participants who may need a lower dose of nicotine); and (b) examine the role that specific factors may have in whether people quit or not.

How long will I be in the study? How many other people will be in the study?
You will be asked to be in this study for about 54 weeks. We expect to recruit about 600 people for this trial.

**What am I being asked to do?**

At the initial eligibility and pre-quit visits, you will: provide written informed consent and HIPAA authorization, have a brief medical examination to determine your eligibility for the study; and complete questionnaires about your smoking habits, behaviors, and mood (2 hours) and have your first, small-group smoking cessation counseling session (60 minutes; total visit time is 3-hours). We may ask you if some of these activities can be recorded or videotaped for quality assurance purposes. This will only occur with your verbal approval.

During your physical, you will complete an electrocardiogram (ECG) to check your heart function. An ECG is used to track the electrical activity of your heart over time. To test your heart function, a research study personnel will place several electrodes (small plastic patches) to your upper chest. You should not feel any pain. The information gathered from the ECG will allow us to check that your heart is healthy. You will also be asked to provide two saliva samples (5 ml saliva each, or about one tablespoon each) to check the nicotine levels in your blood and to allow us to explore differences in genes between people that may relate to response to treatment. Because we do not yet understand the role of nicotine metabolism and genetic differences fully in smoking cessation, you will not receive the results or feedback from this analysis. If after the medical examination you are eligible, you will begin the 52-week (12-month) smoking cessation program.

The cessation program that is part of this study includes nicotine patch treatment and behavioral counseling. You will be randomly assigned to receive either the standard treatment (8 weeks of active patch treatment), the extended treatment (24 weeks of the active patch treatment), or the maintenance treatment (52 weeks of active patch treatment). You will have an equal chance of being allocated to the groups (this is similar to making a choice by the toss of a coin). It is very important to use only the nicotine patches given to you as part of this program and to tell the research staff if you use any medications (including other smoking cessation treatments) while you are taking part in this program.

The smoking cessation counseling includes one 60 minute in-person small group counseling session (at tonight’s visit), one 30-minute individual session over the phone that will occur in 2 weeks on your target quit date (study week 0) and then ten, 15 minute individual phone sessions over the course of the year (Weeks 4, 8, 12, 16, 20, 24, 30, 36, 42, 48). In these sessions you will learn skills to help you quit smoking and remain smoke free. Each session will begin with a review of any treatment side effects, an assessment of your smoking practices and completion of questionnaires that should take about 20 minutes. In total then, you can expect the monthly study sessions to take about 40 minutes. A study coordinator may listen in to these study sessions or these sessions may be recorded to ensure the treatment is consistent for all participants. However, this will only happen with your verbal consent at the start of the call.
At week 8, week 24, week 36, and week 52 you will be asked to revisit the Center to have your vitals checked as well as to complete another ECG. If you are a woman of child-bearing potential, you will also repeat a urine pregnancy test. You will also complete a carbon monoxide (CO) breath test if you have quit smoking. The purpose of this CO breath test is to verify that you are smoke-free.

As part of your participation in this study, studies will be conducted with the saliva samples you provide. These studies will examine biological factors (such as family genetic make-up) related to smoking and other behaviors. This research will be conducted on an experimental basis only, and you will not be provided with any additional information about these test results. Because we want to protect your confidentiality, we will identify your saliva samples with an identification number only (not your name). Only authorized study personnel will be able to link your identification number with your name. Your samples will be stored in our private gene bank, which can be accessed only by authorized study personnel. We will keep your samples for a maximum of 10 years after study completion. At that time, your saliva samples will be destroyed and we will break the link identifying your name with your saliva samples. However, you can request that your samples be destroyed at any time after the study is completed.

Please circle “yes” or “no” and sign your initials on the line to give us permission to store your saliva samples in a private gene bank for a maximum of 10 years.

**YES**, I give permission to have my saliva stored for up to 10 years

**NO**, I do not give permission to have my saliva stored for up to 10 years.

______ (Initials)

**What are the possible risks or discomforts?**

The potential risks to participants, and their likelihood and seriousness, are described below. You can choose, as an alternative, to not enroll in this study. Overall, there is minimal risk for serious adverse reactions as a consequence of enrolling in this study.

**Assessment:** You may experience emotional distress during assessments from discussing feelings and attitudes about smoking or from learning about the risks from smoking. These events happen very rarely and in almost all cases are short-lived and of low intensity, lasting for 1-2 weeks. Study personnel will be alerted to expect this from a small number of subjects and will be trained to make referrals for mental health services as needed. Personnel will be trained to query for adverse emotional reactions during assessments and will be trained to deal with such reactions and to provide additional referrals if needed. In addition, if
assessments indicate psychiatric concerns, referrals to appropriate psychological services will be provided.

**Nicotine Replacement Therapy (NRT):** Nausea, vomiting, weakness, diarrhea, dizziness, and rapid heart beat occur rarely and are most often caused by continuing to smoke while using the patch. Another possible side effect of regular smoking while wearing the patch is elevated blood pressure. If these reactions occur, you can call the Emergency Contact listed on page 1 of this form and/or your doctor. If these reactions occur as a consequence of concurrent patch and tobacco use, you may be asked to stop using the patch, reestablish the quit day, and restart cessation attempts. We will not require that you remove the patch if you return to smoking, unless you are experiencing side effects that concern you. Instead, we will advise that you continue to wear the patch and work with your counselor to try and quit smoking again. The risk of adverse response to the patch will be minimized by admitting you to the study only if you do not have preexisting conditions that increase the risk for these reactions (i.e., serious heart disease). Some individuals who use the patch experience minor skin irritation, such as redness, rash, or minor swelling, and insomnia and dream abnormalities. Insomnia and dream abnormalities can be resolved by removing the patch during the night while sleeping. All of these reactions cease once the patch is removed. You should not stop using the patch without discussing your symptoms with the study physician.

**Reproductive Risks:** Because NRT safety for an unborn baby is unknown, participants will be told that they should not become pregnant while on this study. If you are currently pregnant, it is important that you inform the investigator because you will not be able participate in the study. If you are able to become pregnant, you will be given a pregnancy test before entry into the study as well as repeat pregnancy tests at weeks 8, 24, 38 and 52. You are asked to use a medically accepted method of birth control while you participate in the study. You should not become pregnant while you are using the nicotine patches. If you do become pregnant, you must tell the investigator and consult an obstetrician or maternal-fetal specialist immediately. If you become pregnant during the study, you will discontinue the study medication and will be asked to remain on study completing only the counseling and study questionnaires. We will follow your pregnancy to collect information regarding adverse events and complications, as well as, information about the outcome of your pregnancy. If your pregnancy results in a live birth, we will collect general health outcome information pertaining to your child for a period of up to two weeks.

**Withdrawal Syndrome:** Many people who quit smoking exhibit a pattern of symptoms related to withdrawal from tobacco use. These symptoms include: sadness and anxiety, irritability, anger, difficulty concentrating, appetite change and weight gain, insomnia, and decreased heart rate. Eliminating the risk for these would not be possible, although in most cases these events are short-lived and have low intensity, lasting for 2-4 weeks. The study personnel will be trained to recognize these symptoms and educate you about them (e.g., their duration, methods for reducing them). Use of the patch will minimize the severity of withdrawal.

**Threats to Privacy/Confidentiality:** Since self-report and biological data will be collected and stored as part of this study, it is possible that your privacy or confidentiality can be threatened.
Study sites have sophisticated computer systems to prevent the unauthorized access to study data and sites have long-established protocols to guard against improper use of hard copies of data (e.g., locked files, numeric coding procedures). The present research team has not experienced the unauthorized use of study data. A web-based data collection procedure will minimize the possibility of loss of privacy or confidentiality.

**What if new information becomes available about the study?**

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

**What are the possible benefits of the study?**

The direct benefit you may receive from participating in this study is that you may quit smoking completely or decrease the amount of your smoking.

**What other choices do I have if I do not participate?**

If you do not participate in this smoking cessation study, you can investigate additional quit-smoking options that may be available through other organizations like the National Cancer Institute. You may quit without any assistance or you may continue to smoke.

**Will I be paid for being in this study?**

As a token of our appreciation for participating in the study, you may be paid up to $180 for participating in counseling sessions and completion of measures. You will also be asked to attend the site to provide additional measures (as described under the section, “what am I being asked to do” above); you will receive an additional $15/visit for completing these in-person assessments as well as a $15 stipend for travel costs. Payments for completing the phone based sessions ($15 per session) will be cumulated, and you will be paid in cash following your completion of the in-person visits after Weeks 8, 24, 36, and 52. For example, if you complete the study sessions on weeks 0, 4, and 8, at the end of the Week 8 in-person visit, you will receive $45 plus the $30 for completing the in-person visit. The most you will receive at one time is $90 cash.
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Will I have to pay for anything?

There will be no charge to you for participating in this research study. You will receive the quit smoking counseling and nicotine patch at no cost to you. You also may be reimbursed for parking and public transportation expenses related to your participation in the study.

What happens if I am injured or hurt during the study?

If you have a medical emergency during the study you should go to the nearest emergency room. You may contact the Principal Investigator or Emergency contact listed on page one of this form. You may also contact your own doctor, or seek treatment outside of the University of Pennsylvania. Be sure to tell the doctor or his/her staff that you are in a research study being conducted at the University of Pennsylvania. Ask them to call the telephone numbers on the first page of this consent form for further instructions or information about your care. In the event that you are hurt or injured as a result of participation in this research study, please contact the investigator listed on page one of this form.

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.
There are no plans for the University of Pennsylvania to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

If you think you have been injured as a result of taking part in this research study, tell the person in charge of the research study as soon as possible. The researchers’ name and phone number are listed in the consent form.

**When is the Study over? Can I leave the Study before it ends?**

This study is expected to end after all participants have completed all visits, and all information has been collected. This is expected to take more than 5 years. This study may also be stopped at any time by your physician, the study Sponsor, or the Food and Drug Administration (FDA) without your consent because:

- The Primary Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The Sponsor, the study Principal Investigator, or the Food and Drug Administration (FDA) has decided to stop the study.

If you decide to participate, you are free to leave the study at anytime. Withdrawal will not interfere with your future care.

**Who can see or use my information? How will my personal information be protected?**

We will do our best to make sure that the personal information in your medical record and the study record will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. If this study is being overseen by the Food and Drug Administration (FDA), they may review your research records. Please refer to the HIPAA portion of this document that explains more specifically how your personal information will be protected.

**Electronic Medical Records and Research Results: What is an Electronic Medical Record?**

An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system.

An EMR is simply a computerized version of a paper medical record.
If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study, results of research-related procedures (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS.

Once placed in your EMR, these results are accessible to appropriate UPHS workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by UPHS to be appropriate to have access to your EMR (e.g. health insurance company, disability provider, etc).

**Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?**

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any question, concerns or complaints at the University of Pennsylvania by calling (215) 898-2614.

**Financial Disclosure**

Dr. Schnoll, the principal investigator leading this medical research study, serves as a consultant to Glaxo Smith Kline, one of several companies that manufactures the nicotine patch.
However, Glaxo Smith Kline is not involved with this study. If you would like more information, please ask the researchers or the study coordinator.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal health information to outside organizations or people involved with the operations of this study.

What personal health information is collected and used in this study and might also be shared (disclosed)?

The following personal health information will be collected, used for research, and may be disclosed or released during your involvement with this research study:

- Name
- Address
- Telephone number
- Your medical history
- Allergies
- Current and past medications
- Information from a physical examination that generally also includes blood pressure reading, heart rate, breathing rate and temperature
- Smoking behavior and history and alcohol use
- Pregnancy status
- Attitudes and beliefs about smoking
- Psychological well-being, withdrawal effects

Why is your personal health information being used?

Your personal contact information is important for the University of Pennsylvania Health System and School of Medicine research team to contact you during the study. Your health information and results of tests and procedures are being collected as part of this research study and for the advancement of medicine and clinical care. The Principal Investigator may also use the results of these tests and procedures to treat you.

Which of our personnel may use or disclose your personal health information?

The following individuals and organizations may use or disclose your personal health information for this research project:

- The Principal Investigator and the Investigator’s study team (other University staff associated with the study)
- The University of Pennsylvania Institutional Review Boards (the committees charged with overseeing research on human subjects) and University of Pennsylvania Office of Regulatory Affairs
- The University of Pennsylvania Office of Human Research (the office which monitors research studies)
Authorized members of the University of Pennsylvania and the University of Pennsylvania Health System and School of Medicine workforce who may need to access your information in the performance of their duties (for example: to provide treatment, to ensure integrity of the research, accounting or billing matters, etc.).

**Who, outside of the University of Pennsylvania Health System and the School of Medicine, might receive your personal health information?**

As part of the study, the Principal Investigator, study team, and others listed above, may disclose your personal health information, including the results of the research study tests and procedures to the following:

- Government agency and/or their representative: The National Institutes of Health (study sponsor) will receive regular reports about this study which may include your personal health information since they need to confirm the accuracy of the results and the proper use of funds that support this study.
- Food and Drug Administration (FDA)

The Principal Investigator or study staff will inform you if there are any changes to the list above during your active participation in the trial. Once information is disclosed to others outside the University of Pennsylvania Health System or School of Medicine the information may no longer be covered by the federal privacy protection regulations.

In all disclosures outside of the University of Pennsylvania Health System and School of Medicine, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier unless disclosure of the direct identifier is required by law.

In records and information disclosed outside of the University of Pennsylvania Health System and School of Medicine, you will be assigned a unique code number. The Principal Investigator will ensure that the key to the code will be kept in a locked file. The key to the code will be destroyed at the end of the research study.

**How long will the University of Pennsylvania Health System, the School of Medicine and the study Sponsor be able to use or disclose your personal health information?**

Your authorization for use of your personal health information for this specific study does not expire. This information may be maintained in a research repository (database). However, the University of Pennsylvania Health System and School of Medicine may not re-use or re-disclose your personal health information collected in this study for another purpose other than the research described in this document unless you have given written permission for the Principal Investigator to do so. However, the University of Pennsylvania Institutional Review Board may grant permission to the Principal Investigator or others to use your information for another purpose after ensuring that appropriate privacy safeguards are in place. The Institutional Review Board is a committee whose job it is to protect the safety and privacy of research
subjects. Results of all tests and procedures done solely for this research study and not as part of your regular care will not be included in your medical record.

Will you be able to access your records?
You will be able to request access to your medical record when the study is completed. During your participation in this study, you will not be able to access your medical records. This will be done to prevent the knowledge of study results from affecting the reliability of the study. Your information will be available should an emergency arise that would require your treating physician to know this information to best treat you. You will have access to your medical record and any study information that is part of that record when the study is over or earlier, if possible. The investigator is not required to release to you research information that is not part of your medical record.

Can you change your mind?
You may withdraw your permission for the use and disclosure of any of your personal information for research, but you must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use your personal information that was collected prior to your written request if that information is necessary to the study. If you withdraw your permission to use your personal health information that means you will also be withdrawn from the research study.

You will be given a copy of this Research Subject Authorization Form describing your confidentiality and privacy rights for this study. You will also be given the University of Pennsylvania Health System and School of Medicine’s Notice of Privacy Practices that contains more information about the privacy of your health information.

By signing this document you are permitting the University of Pennsylvania Health System and School of Medicine to use and disclose personal health information collected about you for research purposes as described above.

A copy of this consent and HIPAA authorization form will be given to you.
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