Comparison of effective smoking cessation methods in underserved population

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Thesis

COMPARISON OF EFFECTIVE SMOKING CESSATION METHODS
IN UNDERSERVED POPULATIONS

by

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I would like to thank my family for their unconditional support and encouragement.
Comparaison de méthodes efficaces de cessation du tabagisme dans les populations sous-servies

Vivek Desai

Abstract

Background and objectives

In the U.S., smoking accounts for significant morbidity and mortality. While U.S. smoking rates have declined since the 1960s, they remain high, especially within the homeless population. However, effective smoking cessation programs have not been developed for this population. The primary goal of this project proposal is to facilitate smoking cessation among homeless populations. The secondary goal is to reduce the number of cigarettes smoked per day in this population. To achieve these goals, this project couples pharmacotherapy with nicotine patch and behavioral group therapy to reduce tobacco smoking among homeless adults.

The greatest challenge to quitting smoking is nicotine addiction. Nicotine, a highly addictive substance, is the primary molecule in tobacco. Nicotine, when consumed, usually by smoking cigarettes or via chewing tobacco, produces the effects of reward and pleasure, which then become associated with smoking or chewing tobacco.

The homeless have a unique challenge regarding smoking cessation for two reasons. The first is that this population has a higher rate of smoking compared to the general population. Secondly, the homeless have a higher rate of mental illness than the general population and those with mental illness have higher rates of smoking. This raises
unique challenges for the homeless population and their healthcare providers whose goal is to help them quit smoking and maintain their health.

Nicotine replacement therapy (NRT), with nicotine patch, has been shown to be an effective smoking cessation tool for the general population. These therapies, available over the counter, are relatively easy to access, affordable and easy to store, making NRT a useful tool for smoking cessation in the homeless population. In addition, cognitive behavioral therapy (CBT) has been shown to be effective in both smoking cessation and as therapy for mental illness. Therefore, NRT coupled with CBT could be a useful tool for smoking cessation programs for the homeless.

Proposal

A group of 50–60 participants will be recruited from Boston Health Care for the Homeless Program where they will receive 24 weeks of NRT in the form of a 21-mg/day nicotine patch coupled with 3 months of weekly CBT.

Conclusion

The primary goal for this study is to increase smoking cessation amongst the homeless population in Boston. The secondary goal is to decrease the number of cigarettes smoked daily for the program participants. If these goals are met, this study can be implemented as a standard smoking cessation program for the homeless.
# TABLE OF CONTENTS

- TITLE ............................................................................................................. i
- COPYRIGHT PAGE ....................................................................................... ii
- READER APPROVAL PAGE ......................................................................... iii
- ACKNOWLEDGMENTS .................................................................................... iv
- TABLE OF CONTENTS ................................................................................... vii
- LIST OF TABLES ............................................................................................... ix
- LIST OF ABBREVIATIONS ............................................................................... x
- INTRODUCTION ............................................................................................... 1
  - Background ..................................................................................................... 1
  - Statement of the Problem ............................................................................. 2
  - Hypothesis ..................................................................................................... 3
  - Objectives and specific aims ........................................................................ 3
- REVIEW OF THE LITERATURE ................................................................. 5
  - Existing research .......................................................................................... 13
- METHODS ......................................................................................................... 24
  - Study design .................................................................................................. 24
  - Study population and sampling ................................................................... 24
  - Treatment (or intervention) ......................................................................... 25
## LIST OF TABLES

<table>
<thead>
<tr>
<th>Table</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Study Variables and Measure</td>
<td>26</td>
</tr>
<tr>
<td>2</td>
<td>Timeline for Project</td>
<td>28</td>
</tr>
</tbody>
</table>
LIST OF ABBREVIATIONS

BHCHP .........................................................Boston Healthcare for the Homeless Program
CBT.................................................................Cognitive Behavioral Therapy
CDC.................................................................Centers for Disease Control
CO.................................................................Carbon Monoxide
HEARTH .......... Homeless Emergency Assistance and Rapid Transition to Housing Act
HUD..............................U.S. Department of Housing and Urban Development
MI.................................................................Motivational Interviewing
NHCHC.........................National Healthcare for the Homeless Council
NRT...............................................................Nicotine Replacement Therapy
PTSD.............................................................Post-Traumatic Stress Disorder
RCT...............................................................Randomized Controlled Trial
SRNT..........................Society for Research on Nicotine and Tobacco
VA.................................................................U.S. Department of Veterans Affairs
INTRODUCTION

Background

In the United States, smoking accounts for 32% of coronary heart disease deaths, 79% of hospitalizations due to COPD and 87% of deaths caused by lung cancer.\(^1\) According to the Centers for Disease Control (CDC), between 2005 and 2013, cigarette smoking declined from 20.9% to 17.8% of U.S. adults over age 18. Among daily smokers, the average number of cigarettes smoked per day declined from 16.7 in 2005 to 14.2 in 2013.\(^1\) Although smoking has declined over the last 50 years, 42.1 million Americans age 18+ continue to smoke cigarettes daily.\(^1\) Approximately 480,000 deaths and $290 billion annually are attributed to smoking, of which approximately $130 billion are direct medical costs.\(^1\)

Historically interventions such as encouraging and assisting tobacco users to quit have been the most efficient and effective approach to reducing tobacco-related disease, death, and healthcare costs.\(^2\) Quitting smoking has immediate and long-term health benefits, which include reduced risk for heart disease within 1 to 2 years of quitting.\(^3\) Offering cessation assistance to people who attempt to quit in response to these interventions maximizes the impact of these interventions on cessation.\(^2\)

Population-wide cessation efforts, specifically policies, systems, or environmental changes, are most efficient and effective at reaching many smokers.\(^2\) Implementation of effective public health interventions can reduce smoking-related disparities and accelerate progress toward meeting the Healthy People 2020 target to reduce the proportion of U.S. adults who smoke cigarettes to ≤12.0%.\(^1\) Despite these efforts, public
health interventions have not been effective in all populations, including the homeless, which continues to have alarming smoking rates estimated between 60-80%.4

Statement of the Problem

Homeless people have higher rates of smoking (60 to 80%) compared to the general adult population, 17.8%.5–7 In major efforts to aid smoking cessation, public health projects have increased unit tobacco prices and have implemented comprehensive smoke-free policies.2 Additionally, hard-hitting media campaigns, specifically those targeting the harmful effects of smoking and second-hand smoke have also been effective.8 Despite these efforts the homeless population continues to have high smoking rates.4,5,9,10 This has been attributed to several factors: psychosocial problems regarding homelessness, co-morbid psychiatric illness, and the daily stressors of finding food and water, safe shelter, and home.5,9 Homeless people often do not receive smoking cessation counseling and treatment because of their low access to primary medical care, and the many other competing conditions that need attention when they do receive medical care.11,12

Smoking cigarettes is a physiological and psychological addiction that makes quitting particularly challenging. Poor or infrequent counseling regarding the effects of smoking and cessation options also add to the challenges of cessation for the homeless. Often, few resources, such as counseling, medications and outreach programs are available to the homeless to aid in smoking cessation largely due to their lack of primary health care.8,9 Additionally, proper counseling regarding nicotine withdrawal symptoms such as anxiety, weight gain and severe cravings is often difficult for the homeless to access. Quitting becomes even more challenging when those attempting to quit are unaware of
nicotine withdrawal symptoms. As a result the homeless have higher rates of relapse when they attempt to quit. Because of a myriad of co-morbid psychiatric conditions and environmental triggers such as constantly being with other homeless individuals who smoke, also present challenges when quitting is considered.

Smoking can also be very expensive. A result of increasing tobacco prices (due to public health efforts to aid smoking cessation), in 2016, a pack of cigarettes in Massachusetts costs between $9 and $10, including $0.53 in state and federal sales tax. Smoking a pack of cigarettes per day costs approximately $3,300 per year in Massachusetts.

Currently, the general population can access many smoking cessation programs, but the homeless population has very few options.

**Hypothesis**

Pharmacotherapy coupled with group behavioral therapy will reduce tobacco smoking among homeless adults by 25%.

**Objectives and specific aims**

The primary goal of this project is to facilitate an increase in smoking cessation among the homeless population. The secondary goal for this project is to reduce the number of cigarettes smoked per day in this population.

- to provide health education to a targeted adult segment of the Boston homeless population on tobacco use
- to provide assistance to this targeted Boston homeless population on resources for tobacco cessation pharmacotherapy
• to offer behavioral therapy to this targeted Boston homeless population on tobacco cessation programs and strategies
Overview

Tobacco smoking has been a significant part of American society since 1621 when the first tobacco farms were documented in Virginia. Smoking was considered a national pastime until 1964 when the U.S. Surgeon General released a report warning of the health hazards of smoking. This was the first government report linking smoking and ill health, including cancer and heart disease. At the time, the percentage of adult smokers was approximately 43%. This report reviewed more than 7,000 research articles that found causal effects between smoking and disease processes, such as cardiovascular disease, lung cancer, laryngeal cancer and bronchitis. Despite the widespread exposure of these health warnings, smoking rates did not actually decline for about 15 years, as public attitudes and social acceptance of this behavior were among the greatest barriers to smoking cessation.

Approximately 50 years following the release of the historic Surgeon General’s report in 1964, the United States has more former smokers than current smokers. Approximately 42 million Americans over the age of 18 continue to be daily smokers. However, despite this decrease in smokers, smoking remains a significant contributor to morbidity and mortality.

Mass-media anti-smoking advertisements and public service announcements, along with increased prices of tobacco, and cultural changes have contributed to the overall decrease in smoking rates. Smoking bans in indoor places also have helped decrease cigarette smoking rates. However, cigarette smoking remains the leading cause of preventable disease and death in the United States, accounting for more than 20% of
One of the challenges of addressing this public health problem is the difficulty that smokers face in breaking nicotine addiction. Public health officials must recognize this when addressing this nationwide health problem that afflicts the homeless to a greater degree than the general population and is poorly served.

**Nicotine**

Nicotine is a central nervous system stimulant that is highly addictive. It acts on the brain’s neuronal receptors called nicotinic acetylcholine receptors. Acetylcholine is an organic compound, a neurotransmitter, naturally produced in the body and is similar to nicotine in structure. Acetylcholine is responsible for and assists in muscle contraction and cognitive functions such as learning, memory, and attention. Nicotine, not produced by the body but ingested, binds to acetylcholine receptors and is considered an acetylcholine agonist because it acts on the same receptors in the brain. This makes nicotine highly addictive because it commandeers brain receptors that serve vital functions.

In essence, once in the blood, nicotine quickly travels to the brain where it stimulates the release of chemicals that generate a pleasurable feeling. The resulting feeling of pleasure becomes associated with nicotine-containing substances such as tobacco, and thus smoking is associated with a reward. Nicotine is thought to act similarly to stimulants and facilitates rewarding addictive behaviors such as gambling. Nicotinic effects also include decreased appetite, increased energy, elevation of mood and increased concentration, all of which quickly diminish when a person stops ingesting nicotine. This need to regain the pleasurable effects of nicotine is what leads to regular
use of nicotinic-containing substances and addiction. Withdrawal from nicotine results in uncomfortable cravings that occur after the last dose is ingested and lasts until the next dose or until the individual fully breaks the nicotine addiction. These withdrawal symptoms can be particularly difficult to manage for homeless individuals who lack access to medical resources that could aid them during withdrawal.

Transdermal nicotine patches have been used as an effective tool for smoking cessation. The National Interagency Council on Smoking and Health defines a minimum of 7 days of smoking abstinence as successful smoking cessation. Mulligan et al examined transdermal nicotine patch pharmacokinetics and found that plasma nicotine levels from this patch quickly reach plasma nicotine levels comparable to smoking in the first 3 hours, and the highest mean concentration is achieved at eight hours. The half-life of transdermal patch nicotine is approximately 11 hours, thus with this patch, plasma nicotine concentrations are maintained for 24 hours. A substance’s half-life is the time it takes the body to eliminate one-half of the substance. This makes transdermal nicotine patches a useful smoking cessation tool because they require once per day replacement. This makes the patch a relatively easy-to-use treatment for homeless people as they would have to change it only once a day.

In 2015, approximately 500,000 people in America were considered homeless which is defined as when an individual sleeps outside or in an emergency shelter or is living in a transitional housing program. Across the United States, a variety of community-based programs serve the homeless, including emergency shelters, transitional housing, rapid re-housing and permanent supportive housing.
In the homeless population, smoking is alarmingly high with about 60-80% of the homeless reported to be regular smokers in contrast to 17.8% of the mainstream American population. A major contributor to this high smoking rate is the lack of ready access to primary health care. The homeless population also has higher rates of depression, alcohol abuse, and polysubstance abuse. All of these conditions have been correlated with higher smoking rates. The daily stress of finding food, water, shelter, and staying warm also promotes smoking. Also spending time with other homeless people who smoke makes it difficult to quit.

Factors leading to homelessness

A 2011 report of the National Health Care for the Homeless Council (NHCHC) outlines the various ways people become homeless. One of the greatest risk factors for homelessness is living below the poverty line. Additionally, lack of a high school education is correlated with homelessness. Heffron et al found that nearly 50% of their homeless sample did not graduate from high school. Low education levels also correlate with labor-intensive and physically demanding jobs, which present a high risk for injuries and illnesses that may require extended work absences. Eventually, if the health condition requires excessive time off from work, a worker often exhausts their sick leave, and becomes unable to maintain a regular schedule or perform work functions. In such cases, they exhaust their savings and without funds to pay for health care needs, an injured worker may not be able to regain his/her health and resume work. This is especially true for physically intensive jobs such as construction, dock work, mining, logging, iron work, plumbing, road work and manufacturing. This may result in the
loss not only of pay but also work-sponsored benefits including health insurance. In 2007, of the one million U.S. personal bankruptcies filed, 62% resulted from medical debt. Qualifying for social services is usually possible only if one has dependent children and an extremely low income, hence, many Americans who lose their jobs due to work injuries often lose medical insurance.

Medicaid, the government funded health insurance program, is usually limited to children, elderly, pregnant women, or those with proven permanent disabilities. In some states, it takes approximately 22 months to qualify for Medicaid. It is during this time when a person is at an extremely high risk for becoming homeless. As medical bills begin to rise, losing employment can have dire financial consequences. Monthly bills such as rent, electricity, and weekly groceries become extremely difficult to pay. Eventually, this results in eviction from their residence and homelessness.

Furthermore, high-risk populations for homelessness include those with mental health conditions or disabilities, post-traumatic stress disorder (PTSD), a history of domestic abuse, and/or drug and alcohol addiction. Other risk factors for homelessness include a childhood experience of living in a group home or a special nonfamily residence. Overall, being a male, and unmarried, unemployed, having a history of running away from home during childhood, having lived in a juvenile detention facility, or in jail, and having low formal education increase the chances of homelessness.

Homeless persons report more problems related to mental health, drug abuse, and alcohol abuse compared to the general population. This, however, is complicated by various internal and external barriers to obtaining proper health care. Homeless people
often do not seek medical care for their mental health or substance abuse problems because they are often in denial given that they face social stigma and the intense stress of fulfilling competing needs such as obtaining food, clothing, and shelter on a daily basis.\textsuperscript{5–7,18} Externally, the barriers include misconceptions and prejudices on part of health care professionals and broader systems that address the needs of homeless people.\textsuperscript{6} This is further complicated by often difficult-to-access and fragmented health care services.\textsuperscript{6}

Government Efforts to Address Homelessness

In 2009, Congress passed the Homeless Emergency Assistance and Rapid Transition to Housing Act (the HEARTH Act), which aims to develop and provide permanent housing solutions for the homeless, rather than transitional housing or shelters, the traditional focus.\textsuperscript{18} The HEARTH Act amends and reauthorizes the McKinney-Vento Homeless Assistance Act of 1987, which provides federal money for homeless shelter programs.\textsuperscript{19} The HEARTH Act provides substantial changes such as increased foreclosure prevention resources and creation of the Rural Housing Stability Assistance Program.\textsuperscript{19}

The U.S. government spent approximately $4.5 billion in 2015 addressing homelessness primarily via the Department of Housing and Urban Development (HUD), the Veterans Affairs (VA), the Department of Health and Human Services (HHS), and Department of Education (DOE).\textsuperscript{18}

Between 2007 and 2014, homelessness decreased from 651,142 to 578,424, or approximately 12% decrease in homeless people, largely attributed to the HEARTH
ACT.\textsuperscript{18,19} Today, approximately 500,000 Americans remain homeless.\textsuperscript{18} One of the greatest barriers to eradicating homelessness is the fact that housing is unaffordable for approximately 46 million Americans who live below the poverty line, defined as an annual household income of $23,550 or below for a family of four.\textsuperscript{18,20}

**Disparities in the Homeless**

Homeless populations face much health-related adversity. The homeless have a life expectancy 20 years less than the general population because they are at a higher risk for unintentional injuries, homicides, suicides, and health problems related to alcohol, tobacco and other substance abuse, and communicable diseases and medical conditions.\textsuperscript{5–7,18,21}

Being homeless is stressful and is often worsened by exposure to communicable diseases.\textsuperscript{5} For example, homeless people are exposed to respiratory infections and tuberculosis often at overcrowded homeless shelters.\textsuperscript{5} In addition, they face common medical conditions such as high blood pressure, diabetes, and asthma, which are difficult for the general population to manage, and even more so in the homeless. Because they receive very little health care and medication these conditions often go untreated in the homeless population, and can progress to life-threatening status. Due to lack of money, insurance, or resources, homeless people often do not visit doctors, and if they do, they cannot fill their prescriptions or safely store their medications and syringes.\textsuperscript{5} Injuries resulting from violent trauma often fail to heal properly due to infrequent bathing and inadequate wound care.\textsuperscript{5} Proper recuperation from illnesses and injuries is not necessarily possible on the street or in shelters.\textsuperscript{5} Furthermore, superficial cuts and common colds can
develop into more severe infections. High stress, dangerous living conditions (both on the streets and in homeless shelters), inability to control food intake, and limited access to or inability to comply with medications frequently result in high frequency emergency room visits and hospitalizations compared to the general population.

Homeless persons also have greater healthcare needs and lifestyle problems compared to the general population. In the general population, the most common reasons for visiting a physician are respiratory complaints, hypertension, health maintenance, prenatal and well-child visits. In the homeless population, however, the most commonly reported health problems are related to respiratory, digestive, and psychiatric complaints, infectious conditions, alcohol and other substance abuse problems.

According to Heffron et al., the greatest discrepancy in reported medical problems between homeless and the general populations is that the homeless report more mental illness, and drug and alcohol abuse. A proposed key contributor to this discrepancy is the homeless population’s lower level of formal education. The results of this study show that homeless populations have higher number of people who do not graduate high school when compared to the general population. Given these circumstances, it can become very difficult to obtain and keep jobs that have higher education as a pre-requisite.

Higher incidences of depression are reported amongst the homeless because of pre-existing conditions and other confounding factors associated with homelessness. Homeless people also self-report more incidences of smoking. One of the challenges that health care professionals face in facilitating smoking cessation interventions for the homeless is the higher incidences of depression. Smokers with depression may
experience greater negative mood symptoms, relapses, cravings and withdrawal when attempting to quit. Furthermore, people with depression are twice as likely to smoke than people who are not depressed and they are more likely to relapse when they try to quit. A meta-analysis conducted by Gierisch et al on the comparative effectiveness of smoking cessation treatments for patients with depression found that combining group CBT with pharmacotherapy increased attempts to quit compared to pharmacotherapy with nicotine alone. This analysis suggests that behavioral therapy combined with pharmacotherapy could be successfully applied to the homeless population since it has high incidences of depression.

Existing research

The following section explores some empirically tested methods shown to be effective in aiding smoking cessation for the general population. Also discussed are whether they can be generalized beyond the general population cohort and applied to the special needs of the homeless population.

Mindfulness training has been used successfully as a stand-alone approach for smoking cessation. It usually involves mind and body awareness, emotion regulation, and training of attention regulation. Mindfulness has shown some efficacy in treatment of psychiatric disorders involving pain, anxiety and depression and many similar factors associated with smoking. Garrison et al suggested that mindfulness training may aid in smoking cessation by teaching individuals to pay attention to and be mindful of their cravings rather than simply indulging them. Mindfulness training has been associated with reduced consumption of alcohol, cocaine, amphetamines, marijuana, cigarettes and
Additionally, mindfulness training has also shown to help reduce cravings for nicotine smoking.\textsuperscript{27,28}

In a randomized controlled trial (RCT) Brewer et al., reported that mindfulness training is associated with a greater rate of cessation and reduction in cigarette use during treatment and those who received mindfulness training maintained cessation during a follow-up interview at week 17.\textsuperscript{29} Some of the challenges to mindfulness training are the necessity of trained personnel, therapists, and social stigma. Also one-on-one mindfulness training (or individual treatment) costs more than group mindfulness training.\textsuperscript{27,29}

Mindfulness training could be utilized to help the homeless population quit smoking although some major limitations could hinder its full potential for smoking cessation or a decrease in cravings, which can lead to decreased smoking rates. Furthermore, the costliness of individual (one-on-one) mindfulness training can be high and thus could be a barrier for the homeless population\textsuperscript{27} Additionally, some mindfulness training approaches use smart phone apps as a technique to deliver or supplemental mindfulness training and due to their costliness and high risk of theft, secondary to their high black market value, this poses an obstacle.

Motivational interviewing (MI), another smoking cessation approach, was first described by Miller in 1983 based on his experience in treating problem drinkers.\textsuperscript{9,30} MI is “a directive, client-centered counseling style for eliciting behavior change and helping clients to explore and resolve ambivalence.”\textsuperscript{9,30} MI involves a client-therapist conversation aimed to strengthen an individual’s motivation and commitment to
It differs from externally driven methods for motivating behavioral change as it supports change that is more consistent with an individual’s own values and concerns. Lindson-Hawley et al conducted a meta-analysis on motivational interviewing for smoking cessation. They found that MI helps people quit more effectively than brief advice or counseling regarding cessation when provided by primary care providers and MI counselors. Short 20-minute sessions are more beneficial and effective in comparison to longer MI sessions.

Okuyemi et al conducted a randomized controlled trial with 430 homeless smokers from emergency shelters and transitional housing units to compare combined NRT and MI to standard, stand-alone, 8-week, 21-mg nicotine patch therapy. Participants in the intervention group received six sessions of individual MI counseling geared to smoking cessation whereas the control group received one session of brief smoking cessation counseling. They found that adding MI to nicotine patch therapy did not significantly increase smoking cessation. One of the reasons attributed to this finding was the fact that the subjects had high rates of depression, alcohol and other substance abuse. MI has been used in smoking cessation trials with the general population in which participants were disqualified for having these co-morbidities. This study showed that MI may not be an effective tool for smoking cessation for the homeless population. A limitation of this study was that subjects received personal MI therapy sessions, which may not be feasible in studies that do not have enough personnel or funds to provide individual MI therapy sessions. Furthermore, MI is generally more effective in
participants who do not already have a high motivation to quit smoking. Other counseling therapies besides MI might be more effective for homeless population.  

Another frequently used and effective therapy for smoking cessation is Cognitive Behavioral Therapy (CBT), developed by psychotherapist Aaron Beck in the 1960s. CBT combines cognitive therapy and behavioral therapy. Cognitive therapy focuses on an individual’s thoughts and beliefs and how they affect his/her mood and actions, and aims to facilitate a change in thinking to positively affect moods and actions. Behavioral therapy, on the other hand, focuses on a person’s actions and behavior, instead of thoughts, and aims to change negative behavioral patterns. In both of these techniques, a therapist guides patients to identify distorted or unhelpful thinking patterns and behaviors that the individual can change to positively impact their lives.

Stead et. al conducted a meta-analysis on the effects of adjunct CBT on pharmacotherapy, showing that behavioral support for people enrolled in smoking cessation programs increased their chances of long-term abstinence by 10 to 25%. Raja et al conducted a randomized clinical trial of smokers in India in which CBT was used, and compared this approach to basic health education for tobacco cessation in a cohort. They found that CBT was slightly more effective in helping smokers quit compared to basic health education. CBT was found to be more effective in long-term abstinence because it focuses on behavioral changes to help participants understand their reasons for smoking which has been shown to aid individuals in quitting. The CBT group was found to be more likely to be motivated to quit smoking. Additionally, CBT has been shown
to be highly efficacious in aiding smoking cessation in the African American population and those with PTSD.\textsuperscript{34,35}

Dedert et al conducted a series of pilot studies to assess the use of CBT for smokers with PTSD and found that indeed CBT can be effective for this population.\textsuperscript{35} They found that CBT helps subjects by preventing them from avoiding trauma processing through negative smoking behavior.\textsuperscript{35} Dedert et al also found that CBT helped to mitigate PTSD symptoms and to quit smoking.\textsuperscript{35} In regards to the homeless population, which has higher rates of PTSD and other psychosocial problems than the general population, this study provides evidence for implementing CBT for smoking cessation for populations with PTSD.\textsuperscript{5}

Andersson et al investigated smokers’ motivation and perception of smoking cessation activities in the dentistry to determine whether dentistry could aid patients in smoking cessation.\textsuperscript{34} This study spanned a 12-month period from 2010 to 2011 and involved subjects from four dental clinics in Stockholm, Sweden.\textsuperscript{36} Patients received necessary dental treatment, after which, 237 patients were asked to complete a questionnaire concerning tobacco use; of these 167, who were smokers, were selected for the study. This questionnaire surveyed sociodemographic data, including gender, age, educational level, marital status, country of origin, and self-perceived general health, along with a smoking assessment such as number of cigarettes smoked daily, number of years of smoking, importance of smoking, experience of quitting, and reasons to quit smoking.\textsuperscript{36} The questionnaire also assessed whether patients’ dental hygienists and dentists asked them about smoking habits, quitting smoking or smoking cessation.\textsuperscript{36} This
study found that patients were aware of the deleterious effects of smoking on their oral and general health, but that none of the subjects had received support to quit smoking from their dental team.\textsuperscript{36} The authors also found that discolored teeth and periodontal problems were the most common complaints from the patients who smoked; this line of questioning then offered a segue for dental staff to discuss with patients their smoking habit, its health effects, their feelings about it and cessation options.\textsuperscript{36} This study also found that the patients motivated to quit smoking were facing periodontal problems.\textsuperscript{36}

The Andersson et al study may shed light on options to aid the homeless in smoking cessation. The homeless often do not receive proper dental care, which can cause significant periodontal disease. Because smoking is a major contributor of periodontal disease, the negative dental effects of smoking may be motivators to assist in smoking cessation.\textsuperscript{36} While smoking cessation counseling conducted during dental care visits has been shown to help smokers decide to quit, one of the barriers to this method for the homeless population is lack of access to dental care.

Filion et al conducted a study to promote a text-message–based sleep and physical activity intervention to aid in smoking cessation. Although an unlikely option for the homeless population, the study provided some important results. Cigarette smoking was shown to be associated with poor sleep.\textsuperscript{37} Another study by Jaehne et al using polysomnography found that compared to nonsmokers, smokers have poor subjectively reported sleep, higher levels of sleep apnea, more leg movements in sleep and longer sleep latency (i.e., longer time required to fall asleep).\textsuperscript{38} Furthermore, smoking compromises cardiopulmonary function, which contributes to reduced physical activity.\textsuperscript{37}
They found that improving sleep and physical activity habits can aid in smoking cessation. Additionally, increased physical activity can assist in improved sleep and weight control amongst those trying to quit smoking; it can also help alleviate stress, and assist with managing food intake. Finally, improved physical activity can help to mitigate nicotine cravings and withdrawal symptoms, which can aid in smoking cessation. This study shows that proper sleep habits and regular physical activity can help individuals achieve a healthier lifestyle and assist in smoking cessation.

Kwon et al examined the effects of disease detection (i.e., diagnosis) on changes in smoking behavior. Their study population comprised 153,518 individuals who participated in a disease-screening program in 2007 and 2009 in China. They conducted multiple logistic regression analyses that considered sex, socioeconomic status, body mass index (BMI), diabetes, hypertension, hyperlipidemia and family history of cardiovascular disease. The results showed that men who were diagnosed with newly diagnosed hyperlipidemia were more likely to show positive behavior such as smoking cessation and less likely to engage in negative behavior such as smoking. This study also showed that those with BMI ≥ 25 had higher rates of positive health behavior compared to those with BMI < 23.

Kwon et al’s study, can be generalized to the homeless population, which often presents with multiple comorbidities, such as diabetes, hyperlipidemia, and hypertension similar to the general population. This study suggests that disease detection in the homeless population can potentially aid in smoking cessation by promoting positive behavior and discouraging negative behavior.
Schnoll et al conducted a randomized clinical trial that assessed whether the use of nicotine patches beyond 24 week period provided additional therapeutic benefit.\textsuperscript{41} The use of the transdermal nicotine patch continues to be one of the most popular pharmacotherapies used for smoking cessation, due to its easy access, low side effects and low cost.\textsuperscript{40} Six month cessation rates rarely exceed 20% in 8 week nicotine patch groups.\textsuperscript{40} Generally, health care providers prescribe NRT patch 21mg for 8 weeks of daily use. Schnoll et al found that extending the nicotine patch from 8 to 24 weeks increased point prevalent rates.\textsuperscript{41}

Furthermore, this study found that extended transdermal nicotine therapy produced end-of-treatment quit rates similar to those reported for other cessation pharmacotherapies approved by U.S. FDA such as the standard 10-week Bupropion.\textsuperscript{41}

The transdermal nicotine patch appears to be an appropriate pharmacotherapy choice for the homeless population as they can be purchased without a prescription, has fewer contraindications than other standard pharmacotherapeutic drugs, and are relatively low cost. Their relative low cost and availability make them a good choice for the homeless population who often do not or cannot comply with many prescription drugs.

To assess whether an intervention is effective, nicotine measurements are often used in smoking cessation studies. The Society for Research on Nicotine and Tobacco (SRNT) published a report on the biochemical verification of tobacco use and cessation. Under this report’s guidance, Benowitz et al discussed various ways to measure nicotine and carbon monoxide. Nicotine is used as a biomarker to assess a person’s blood nicotine levels from smoking.\textsuperscript{42} While nicotine can readily be measured in blood plasma, saliva...
and urine, using nicotine as a biomarker for tobacco use and cessation has some drawbacks. For instance, dietary sources of nicotine could confound results, and monitoring nicotine concentrations is expensive. Plasma levels of nicotine are found only if subjects smoke on the day of measurement, because nicotine has a short half-life. Nicotine measurements are accurate only when serum taken within 8-12 hours of smoking. Additionally, nicotine measurements cannot be used in studies in which subjects receive NRT because of inaccurate measurements.

Carbon monoxide, an exhaled byproduct of smoking, on the other hand, can be measured relatively inexpensively. Devices that measure the breath rate of conversion of CO to carbon dioxide as it passes over an active electrode are readily available. Although monitoring CO levels is useful in smokers because of its high sensitivity and specificity of about 90%, it is not useful in light smokers. Initially, monitoring CO levels requires a one-time expense of approximately $300-$1,000 for a CO monitor. CO levels are available immediately. One major limitation of using CO levels, for assessment of smoking, is that breath CO levels are the same as non-smokers after 1 day. Expired air CO of 8-10 ppm is considered as a positive biomarker.

One challenge in developing effective smoking cessation programs is that there is no single measurable outcome utilized by all investigators. This is largely attributed to the fact that smoking cessation programs are developed by members of various disciplines. Two main outcome measures are currently used in the literature: self-report cessation milestones and biochemical verification. Velicer et al.’s analysis of self-reported measures found that the decision as to which outcome measure should be
utilized is often predicated by logical arguments rather than empirical evaluations of specific measures.\textsuperscript{17}

Point prevalence abstinence of 24 hours is a good choice for measuring outcomes because it can be biochemically verified.\textsuperscript{17} This method aids to rectify results that are measured after an intervention, such as 6 or 12 months, which is beneficial in situations where smokers take months to quit.\textsuperscript{17} It is preferred over a continuous abstinence measure because it can shed light on the dynamic process of quitting more efficiently.\textsuperscript{17} Furthermore, measuring the point prevalence rate can take into account brief and extended relapses because it allows for the intervention to not be considered as a failure, when used in interventional studies.\textsuperscript{17} The concept of point prevalence is also easy to communicate to non-scientists, which adds to its benefits.\textsuperscript{17}

The limitations of this method is that given the high rates of smoking relapse during the first 3 months following quitting, participants who are former smokers at one point can become current smokers at another point. Additionally, since this measurement method requires a minimum duration of 7 days of nonsmoking for an intervention to be considered effective, it is not as stable of a measure as continuous abstinence rates for subjects that have not been abstinent for at least 7 days.\textsuperscript{17} Continuous abstinence rates and point prevalence rates are shown to be equally effective in the long run.

An intervention that uses combined NRT and CBT would be appropriate for the homeless population because, as noted earlier, NRT is relatively low-cost, readily available over the counter, and is easy to store, making it a useful tool for this population. Additionally, CBT has been shown to be effective in smoking cessation and in treating
mental illness in the general population. The homeless population, as previously noted, also has higher incidences of mental illness thus CBT could be an effective means to facilitate smoking cessation in the homeless. Based on these findings, pharmacotherapy coupled with group behavioral therapy could reduce tobacco smoking among homeless adults.
METHODS

Study design

This is a smoking cessation program proposal for a community health project to assist the homeless population at the Boston Health Care for the Homeless Program (BHCHP).

Study population and sampling

BHCHP, which treats the homeless population in the Boston area, will provide the source population for this study. In 2015, BHCHP treated 9,590 homeless individuals. Of these, 4,789 or approximately 50% reported polysubstance abuse; 6,232 or approximately 65% of its treatment population, currently smoke. One or more health care providers at BHCHP have counseled 6,063 patients, or 63%, on tobacco cessation during medical visits [personal email communication with BHCHP staff 2/11/2016]. This project will recruit individuals who have been homeless for at least 3 months and who have smoked at least 10 cigarettes per day for the past 6 months or more based on self-reports. Eligible subjects will be homeless adults over the age of 18, of both genders and all races and ethnicities. Subjects will be asked if they have a desire to quit tobacco for at least six months. Prior failed attempts at smoking cessation will not exclude subjects from this study.

Subjects who self-report being homeless for less than 3 months prior to the start of the study will be excluded in order to focus on individuals suffering from prolonged homelessness. Subjects currently enrolled in other smoking cessation programs or studies will be ineligible for this study. Subjects who do not speak English will be excluded from
this study. One to two subjects will be recruited for this study for the first month for a total of 30–60 participants. This study will be 3 months in duration.

**Treatment (or intervention)**

The primary intervention for this study will include pharmacotherapy with daily 21 mg nicotine patch for 24 weeks and group behavioral therapy to assist with smoking cessation.\(^{41}\) Given this population’s difficulty in storing medication, NRT was chosen because the nicotine patch is available over the counter, is relatively affordable and is easy to store. This population is eligible for Medicaid, which would provide the necessary funds for over-the-counter nicotine patch. Additional support would be provided to subjects to assist in obtaining nicotine patches.

Therapy sessions will be held three times per week for 1 hour per session early in the day to effectively support subjects through cravings and withdrawal. Subjects will be asked to attend group behavior therapy at least one time per week but can attend three times per week for three months. There will be a time sheet that will be kept to record and track the attendance of subjects. Attending a minimum of 12 sessions over three months will be considered compliant.

Daily therapy sessions will be provided to ensure a maximum of 10 participants to one therapist per session for five therapy sessions per week. Participants will be guided through cravings, triggers, and helped decide on behavioral adjustments that could help them ignore their cravings and avoid cigarettes and during these sessions. Reinforcing success will also happen at these sessions.
Study variables and measures

Number of cigarettes smoked per day and nicotine patch usage will be initially obtained and recorded from each participant by self-report at the weekly group therapy sessions. Participants will be considered compliant if they use six or more patches per week. Behavior therapy attendance will be tracked weekly. Table 1 lists study variables and measures.

<table>
<thead>
<tr>
<th>STUDY VARIABLES AND MEASURES</th>
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<tbody>
<tr>
<td>Number of cigarettes smoked daily</td>
</tr>
<tr>
<td>Number of nicotine patches used weekly</td>
</tr>
<tr>
<td>Number of weekly therapy sessions attended</td>
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<tr>
<td>Likert Scale for Cravings</td>
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<tr>
<td>Gender</td>
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<tr>
<td>Race</td>
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<tr>
<td>Age</td>
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<tr>
<td>Number of participants with pre-existing mental illness</td>
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Recruitment

Subjects will be recruited from BHCHP. Subjects will be approached in the waiting room and asked if they use tobacco and if they would like to quit smoking. If they affirm the desire to quit smoking, they will be given a questionnaire that will assess their eligibility for this study. This questionnaire will be provided to the subjects by a project coordinator at BHCHP in the waiting room. Assistance will be provided to
subjects who are unable to read. They will be asked their age, gender, if they would like to quit, how many cigarettes they currently smoke daily, and how long they have been smoking, and to describe any previous smoking cessation attempts. Finally, the questionnaire will ask the subjects their desired target cigarette goals at 3 months, 6 months, 12 months, and 24 months. Those that meet inclusion criteria will have the option to give consent to be included in the study.

Data collection

Subjects will be provided an initial questionnaire and follow up once per week during their weekly session. The questionnaire will be similar to the original one at the start of the study (in the waiting room) to assess their therapy. Assistance will be provided for subjects who are unable to read. This questionnaire will ask subjects the number of cigarettes they are currently smoking daily and their daily nicotine patch usage. To assess their cravings, subjects will be asked to rate their cravings on a Likert scale, ranging from 1, “no desire to smoke”, to 5, an immediate/ a current and strong desire to smoke”. Additionally, this questionnaire will ask subjects to subjectively assess their therapy since the start of the study. This will be a Likert scale, with 1 being “not helpful” to 5 being “very helpful with cravings” and overall therapy.

Data analysis

Descriptive statistics will be reviewed on an ongoing basis for program evaluation and quality control. Demographics such as age, gender, and ethnicity will be described by mean and proportions. Other quantitative variables such as number of cigarettes smoked and number of nicotine patches used per day will be analyzed on a run chart to explore
changes over time. Pre- and post-averages will be analyzed with a paired t-test. Likert scale items will be analyzed by mean scores, with the standard deviation and mean scores over time to be plotted on run charts to explore changes. Data entry and statistical analysis will be performed with Microsoft Excel 2010 software (or a similar version).

**Timeline and resources**

- **Resources**
  - Project coordinator
  - Smoking cessation counselor
  - Clerical assistant

This study will take place over four months: the first month for recruitment and three consecutive months for the intervention (weekly counseling and NRT patch). For the intervention phase, a study coordinator will be hired to assist subjects with the initial questionnaires. All data will be collected electronically in an Excel program so a computer with Microsoft Excel will be required. For the group behavioral therapy, a therapist will be required for the 3-month treatment stage) of the study. Table 2 outlines the project’s timeline.

<table>
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<tr>
<th>TIME LINE FOR PROJECT</th>
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<tr>
<td>MONTH</td>
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<tr>
<td>MONTH 1</td>
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<tr>
<td>MONTHS 2-4</td>
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</tbody>
</table>
Institutional Review Board

A protocol will be submitted to the Boston University Medical Campus Institutional Review Board for expedited approval. This will indicate the minimal risk to participants from the smoking cessation intervention as well as a minimal risk for personal health information exposure. If the IRB determines that the project does not meet the criteria for expedited approval, a request for full board approval will then be submitted.
CONCLUSION

Discussion

The homeless population has higher rates of smoking, psychiatric illness, and drug and alcohol abuse compared to the general population. Nicotine replacement therapy (NRT) alone and cognitive behavior therapy (CBT) alone have been shown to be effective.\textsuperscript{33,41} Ideally, this proposed study would have a 100\% cessation rate but the literature indicates that most smoking cessation programs with homeless participants have a ‘quit’ or non-compliance rate of 20–40\%.\textsuperscript{4} Based on this data, smoking reduction by 25\% would make this a successful study. If this study is successful, NRT combined with group CBT could help other homeless populations reduce or quit smoking because it is cost effective and cheap.

A recruitment challenge for this study would be the willingness of subjects to have smoking cessation. Of the population treated at BHCHP, 64\% have received previous smoking cessation counseling. BHCHP patients who have not been counseled on the deleterious effects of smoking may not be interested in this intervention.

One of the limitations of this study will be lack of biochemical verification. A carbon monoxide breath monitor would be a useful tool because it provides accurate results within seconds. These devices can be expensive, ranging from $300-$1,000. Because of this, a carbon monoxide (CO) breath monitor will not be used in this study. This means that primary data will be self-reported and no biochemical verification will be used. Given that this study will primarily use questionnaires there is a potential for response bias.
Another bias for this study is that BHCHP is a homeless care center. This makes participants who are not a part of BHCHP ineligible for this study. Furthermore, the transient nature of the population and low compliance rates might pose challenges for subjects to complete the intervention phase of the study. Subjects may not have the motivation to attend weekly therapy sessions, which would compromise the intervention.

As noted throughout this proposal, the homeless population has a higher prevalence of mental illness compared to the general population; however, the mental health data for this population subset is not currently available. Smoking cessation amongst people that have mental illness has been shown to be difficult when compared to the general population. Another challenge is that we currently do not know the percentage of people with mental illness in this subset and it may be higher compared to the general population, which may affect the likelihood of quitting.

**Summary**

Since the 1964 release of the Surgeon General’s Report, smoking has significantly declined from 43% to 17.8% in 2015. The homeless population continues to have disturbingly high smoking rates, estimated between 60 and 80%, which calls for more smoking cessation studies and programs geared for this often overlooked population. The daily stresses of finding food, water, safe shelter, and a stable home, and of coping with co-morbid psychiatric and medical conditions and psychosocial problems relating to homelessness, and lack of access to affordable health care are the major contributors for high smoking rates in this population.
NRT alone via the nicotine patch has been shown to be effective for smoking cessation. Given the homeless population’s psychosocial problems and psychiatric illnesses, adjunctive CBT with NRT via the nicotine patch would likely be more effective than NRT alone.

**Clinical and/or public health significance**

The primary goal of this study is smoking cessation amongst a targeted population of homeless people in the Boston area. The secondary goal is a decreased number of cigarettes smoked daily by this target population. If these goals are met, this study can be implemented in other smoking cessation studies for the homeless. This study requires Medicaid funding for daily nicotine patches and a smoking cessation counselor for group therapy sessions, which makes it cost effective and less expensive than other interventions that require prescription medication and one-on-one behavioral therapy sessions.

Smoking causes significant cardiovascular disease, cancer, morbidity and mortality and places a great financial burden on the U.S. health care system. Increased smoking cessation would positively affect public health in general, and more specifically, it would help improve the health of the often overlooked populations such as the homeless. Furthermore, smoking cessation rates for the homeless would decrease their morbidity, mortality, and aid in decreasing their health care costs.

Lowered smoking rates would also help lower health care costs in general. State governments spend on average $607 million yearly on smoking related illness. A study conducted in 2010 found that insurers would save between $1.90 and $5.75 for each
dollar spent on smoking cessation. A decrease in smoking will lower cancer incidences, risks of heart attacks and strokes, and bronchitis and mitigate the financial burden of health care systems in treating smoking related illnesses. This project can be applied to the general population if successful because it is relatively low-cost, requires minimal personnel, and the NRT medication required is available over the counter.
### LIST OF JOURNAL ABBREVIATIONS

<table>
<thead>
<tr>
<th>Journal Abbreviations</th>
<th>Full Journal Name</th>
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<tbody>
<tr>
<td>Acta Odontol Scand</td>
<td>Acta Odontologica Scandinavica</td>
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<tr>
<td>Addict Behav</td>
<td>Addictive Behaviors</td>
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<tr>
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<td>Drug and Alcohol Dependence</td>
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<td>JAMA: Internal Medicine</td>
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<td>J Clin Diagn Res</td>
<td>Journal of Clinical and Diagnostic Research</td>
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<td>Subst Use Misuse</td>
<td>Substance Use &amp; Misuse</td>
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<td>Yonsei Med J</td>
<td>Yonsei Medical Journal</td>
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Desai, V, Numerical Investigations of Methods to Model Spinal Injuries, Army Research Laboratory, Aberdeen, Maryland, August 2011