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The effect of an acute bout of exercise on smoking topography

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A thesis submitted in partial fulfillment of the requirements for the Master of Arts degree in
Kinesiology

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THE EFFECT OF AN ACUTE BOUT OF EXERCISE ON SMOKING TOPOGRAPHY

(Spine title: Exercise and smoking topography)

(Thesis format: Monograph)

by

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Graduate Program in Kinesiology

A thesis submitted in partial fulfillment
of the requirements for the degree of
Master of Arts

The School of Graduate and Postdoctoral Studies
The University of Western Ontario
London, Ontario, Canada

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THE UNIVERSITY OF WESTERN ONTARIO
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The effect of an acute bout of exercise on smoking topography

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Abstract

This pilot study aimed to examine the effect of an acute bout of exercise on smoking behavior (topography) subsequent to a temporary period of smoking abstinence. Forty-three adult smokers (female = 34, $M_{\text{age}} = 43.14$), who had been smoking for an average of 23.90 years, were randomized to either an exercise ($n = 21$) or passive sitting group. Thirty-one smokers completed the study. The primary outcome variables included: puff count, puff volume, puff duration, inter-puff interval (IPI), and total cigarette duration. The effect of exercise on smoking topography was non-significant. Overall, the effectiveness of exercise as an additional harm reduction strategy was not supported.

Keywords: smoking, smoking topography, harm reduction, desire to smoke

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Chapter One: Literature Review

Introduction

Tobacco use is the foremost preventable cause of death and disease worldwide (WHO, 2011). In Canada, an estimated 4.7 million (16.7%) people aged 15 years or older are current smokers. Smoking prevalence is higher among males (19.7%) than females (13.8%), is highest among young adults (age 20-24), at 22.1% (CTUMS, 2010), and is related to socio-demographic factors, such as: socio-economic status, ethnicity, and education level (CTUMS, 2010; CDC, 2007). Cigarette smoking is a risk factor for long-term health consequences. The long-term health consequences of cigarette smoking include: cardiovascular disease (e.g., coronary heart disease, atherosclerosis), cancer (e.g., lung, kidney, esophageal), pulmonary disease (e.g., chronic obstructive pulmonary disease, pneumonia), and other health complications (e.g., delayed wound healing, osteoporosis, reproductive disorders). The evidence is sufficient to conclude that smoking damages nearly every organ of the body (USDHHS, 2004). Greater than 37 000 deaths each year in Canada are attributed to tobacco use (Peto, Lopez, Boreham, Thun, & Heath, 1992), and approximately one half of current smokers will become ill or die from continued use (Baliunas, Patra, Rehm, Popova, Kaiserman, & Taylor, 2007). The burden of smoking does not fall solely on the individual; smoking is associated with significant economic and health care costs. The estimated social cost of tobacco use is \$17 billion per year (Rehm et al., 2006), and tobacco-related illness costs Canadians approximately \$4.4 billion in direct health care costs each year (Rehm et al., 2006). Currently, the prevalence of smoking in Canada is a record low (16.7%); but, there is a trend towards smaller declines each year (CTUMS, 2010). Effective and economical smoking cessation

interventions are needed.

In this chapter, the literature will be reviewed on why it is difficult to quit smoking. Evidence for the acute effect of exercise on tobacco withdrawal symptoms and mood will also be reviewed and critiqued. Next, the literature on how a person smokes (i.e., smoking topography) will be summarized. Last, the literature on the utility of exercise as a harm reduction strategy, and research on the effect of an acute bout of exercise on smoking topography will be reviewed.

Why is it difficult to quit smoking?

There is short- and long-term health benefits associated with a successful quit smoking attempt. The short-term benefits of quitting smoking include: reduced heart rate, removal of carbon monoxide (CO), improved sense of taste and smell, and improved lung function. The long-term benefits of quitting smoking include a decreased risk of lung cancer, cardiopulmonary disease, and stroke, and prolonged life expectancy. The majority (60.2%) of smokers in Canada indicate an interest in quitting smoking in the next six months, and an estimated 46.6% of smokers have made at least one quit attempt in the past year (CTUMS,2010). Yet, among smokers who attempted to quit in the past year, only 1 in 10 were abstinent at time of survey (CTUMS, 2010). In addition, the success rate (6 to 12 months prolonged abstinence) of unaided stop smoking attempts is 3-5% (Hughes, Keely, & Naud, 2004). The low success rate of stop smoking attempts is strong evidence that quitting is difficult.

Nicotine is the cigarette constituent responsible for addiction (USDHHS, 1988). When tobacco smoke is inhaled, nicotine is distilled from a cigarette and crosses the blood-brain barrier. Nicotine accumulates in the brain rapidly. A high level of nicotine can reach the brain in 10-20 seconds (Benowitz, Hukkanen, & Jacob III, 2009). Nicotine binds to nicotinic cholinergic receptors (nAChRs) and causes the release of neurotransmitters, including: dopamine, glutamate, gamma-amino-butyric acid (GABA) (Benowitz, 2009). The release of neurotransmitters is important to the development of nicotine dependence. For example, dopamine is involved in drug induced reward (Dani & De Biasi, 2001) and pleasure (Nestler, 2005). The speed of nicotine delivery to the brain via smoking contributes to addiction.

Defining addiction and dependence. Addiction is defined as “a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors...It is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving” (Schnoll, Johnson, Lerman, 2007).

The Surgeon General’s report (USDHHS, 1988) outlined the criteria for drug dependence, including nicotine. According to this report, drug dependence is defined by primary and additional criteria. The criteria are presented in Table 1.

Table 1

Primary and additional criteria for drug (nicotine) dependence (USDHHS, 1988)

Primary Criteria	Additional Criteria
Highly controlled or compulsive use	Addictive behavior often involves:
Psychoactive effects	Stereotypic patterns of use
Drug-reinforced behavior	Use despite harmful effects
	Relapse following abstinence
	Recurrent drug cravings
	Dependence-producing drugs often produce:
	Tolerance
	Physical dependence
	Pleasant (euphoriant) effects

According to the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) (American Psychiatric Association, 2000), the term dependence is suggestive of a mental disorder. The symptoms of substance dependence include: (a) drug tolerance; (b) continued use despite harm; (c) loss of control; (d) unsuccessful attempts to decrease use; (e) salience; (f) reduced involvement in life; and (g) substance withdrawal (American Psychiatric Association, 2000). Substance dependence is diagnosed if at least three of the aforementioned symptoms have occurred in the preceding 12 months. The term dependence is used throughout this paper.

A hallmark of nicotine dependence is tobacco withdrawal symptoms, including cigarette cravings. A cigarette craving is the most common symptom of withdrawal. A craving (i.e., urge to smoke) is defined as a subjective emotional state; it is responsible for continued tobacco use in dependent smokers (Kozlowski & Wilkinson, 1987). Tobacco withdrawal symptoms emerge when a nicotine dependent person stops smoking. Withdrawal symptoms include: irritability, depressed mood, restlessness, anxiety, difficulty concentrating, increased hunger and eating, and insomnia (Hughes & Hatsukami, 1986). Overall, tobacco withdrawal is characterized by behavioral, cognitive, and physiological symptoms. People continue to smoke in order to avoid withdrawal symptoms (i.e., negative reinforcement) and to enhance positive affect (i.e., positive reinforcement) (USDHHS, 2010).

The environment and social situations reinforce cigarette smoking. A cigarette smoker may associate an environment, mood, and/or social situation with a subjective feeling of reward. For instance, due to repeated exposure, a cigarette smoker may develop a habit of smoking after a meal, with a cup of coffee, or with friends who smoke

(Benowitz, 2009). The association between cigarette smoking and positive affect (e.g., stimulation, arousal, and stress reduction) is also strengthened due to repeated exposure. Last, a smoker may integrate the behavior into their social life. Family, friends, and one's identity are often linked to smoking.

A dependence on cigarette smoking is a result of the product (e.g., addictive constituents), the host (person) response (e.g., physiological, psychological), and the environment or social setting (USDHHS, 2010). It is the complex relationship of the biological, psychological, and social pull of cigarettes that makes stopping smoking difficult. Treating nicotine dependence is an area of interest for researchers and health practitioners. Several pharmacological and counselling therapies have been and continue to be under investigation (e.g., nicotine replacement therapy (NRT) (Stead, Perera, Bullen, Mant, & Lancaster, 2008), varenicline (Gonzales et al., 2006), bupropion (Fiore et al., 2008; Jorenby et al., 2006), motivational interviewing (Butler, Rollnick, Cohen, Bachmann, Russell, Stott, 1999).

Exercise is a potential smoking cessation adjunct (Taylor, Ussher, & Faulkner, 2007; Ussher, Taylor, & Faulkner, 2008). Marcus and colleagues (1999) demonstrated that vigorous intensity exercise combined with cognitive behavioral support facilitates smoking cessation. In addition, Williams and colleagues (2010) demonstrated that moderate intensity exercise may enhance the efficacy of a combined nicotine replacement therapy (NRT) and cessation counseling program, but only with adequate adherence. In contrast, past research demonstrated that quit rates following a 12-week combined bupropion and exercise program were not significantly higher when compared to a placebo (Abrantes et al., 2009). Overall, the research does not consistently show that

exercise aided interventions improve long-term cessation rates (Ussher et al., 2008).

The current study is concerned with the impact of an acute bout of exercise on smoking outcomes. Hence, the remainder of this chapter will focus on current literature in this paradigm.

Acute Effect of Exercise on Smoking Outcomes

Taylor and colleagues (2007) conducted a systematic review on the acute effects of exercise on tobacco withdrawal, cravings, affect, and smoking behavior. To analyze the effect of exercise on smoking outcomes (e.g., cravings, withdrawal symptoms, and affect), a single bout of exercise is typically compared to a passive condition. In addition, smoking outcomes are usually assessed following a temporary period of smoking abstinence.

Withdrawal symptoms. Taylor and colleagues (2007) showed that a single session of exercise significantly decreased some tobacco withdrawal symptoms; namely, psychological stress, anxiety, tension, poor concentration, irritability, and restlessness (Taylor et al., 2007). A session of exercise, 5 to 10 minutes in duration, reduced tobacco withdrawal symptoms among smokers who were temporarily abstinent (Daniel, Cropley, Ussher, & West, 2004; Ussher, Nunziata, Cropley, & West, 2001). The magnitude of reduction in withdrawal symptoms was similar to the reduction in cravings. Tobacco withdrawal symptoms were significantly reduced both during and after exercise.

Cigarette cravings. A systematic review by Taylor and colleagues (2007) proved that a single session of exercise significantly decreased cigarette cravings. ‘Strength of desire to smoke’ was significantly reduced during and after exercise. In the

review, a moderate to large effect size (ES) was shown (.50 – 4.6; Taylor et al., 2007). This effect was present for different intensities, durations, and types of exercise. For example, Ussher and colleagues (Ussher, West, Doshi, & Sampuran, 2006) showed that isometric exercise for five minutes reduced the urge to smoke by .7 on a seven point scale (ES = .29). In addition, Taylor and colleagues (2005) showed that a self-paced brisk walk for one mile reduced the desire to smoke by 4.6 on a seven point scale (ES = 3.7). A significant reduction in cigarette cravings has been shown for walking (e.g., Taylor, Katomeri, & Ussher, 2006; Janes VanRensburg & Taylor, 2008); stationary cycling (e.g., Ussher et al., 2001; Daniel, Cropley, & Fife-Schaw, 2006), isometric exercise (e.g., Ussher et al., 2006), and Hatha yoga (Elibero, Janes Van Rensburg, & Drobles, 2011). Taylor and colleagues (2007) reported that craving reduction was most significant immediately subsequent to exercise; but, a significant post-treatment effect has also been found for up to 30 minutes post-treatment (Ussher, Cropley, Playle, Mohidin, & West, 2009; Scerbo, Faulkner, Taylor, & Thomas, 2010). The magnitude of reduction in cigarette cravings following a single session of exercise was comparable to the effect of oral nicotine replacement therapy (NRT) (West & Shiffman, 2001). Overall, the evidence clearly indicated that a single session of exercise reduced cigarette cravings.

General mood and affect. Researchers have shown that an acute bout of exercise enhanced mood and affect (e.g., Taylor et al., 2006; Thayer, Peters, Takahashi, & Birkhead-Flight, 1993; Elibero et al., 2011; Everson, Daley, & Ussher, 2006). An increase in activation and energy (Taylor et al., 2006; Thayer et al., 1993), and a reduction in tension have also been found in response to a solitary bout of exercise (Taylor et al., 2006). Last, Everson and colleagues (2008) demonstrated that a 10 minute

bout of moderate intensity cycling increased positive well-being and decreased psychological distress. Changes in mood and affect may mediate a reduction in cravings (Taylor et al., 2006; Roberts, Maddison, Simpson, Bullen, & Prapavessis, in press).

Possible mechanisms. A solitary session of exercise may be a coping strategy for temporary relief of tobacco withdrawal symptoms (Taylor et al., 2007). Previous research has examined factors that may affect this relationship. The mechanisms that have been examined include: distraction (Daniel et al., 2006; Ussher et al., 2006), mood and affect (Everson et al., 2008; Elibero et al., 2011), shifts in attention (Janse Van Rensburg, Taylor, & Hodgson, 2009), exercise expectancy (Daniel et al., 2006; Harper, Fitzgeorge, & Prapavessis, 2011), credibility (Harper et al., 2011), and neurobiological changes such as increases in dopamine (Wilson & Marsden, 1995) and catecholamines (Richter & Sutton, 1994; Ward, Garvey, Bliss, Sparrow, Young, & Landsberg, 1991). Overall, previous research has explored several mechanisms that may affect the exercise and craving relationship, however, the evidence is not clear.

Limitations of the acute paradigm. The acute exercise and smoking paradigm has two inherent pitfalls. First, research is often carried out in a laboratory. Smoking cues can be controlled in this setting; but, it does not resemble a 'real world' experience. Second, acute studies often consist of a temporary period of abstinence. Tobacco withdrawal symptoms may not align with symptoms experienced during a quit attempt. Overall, the ecological validity of studies in the acute paradigm is in question.

Overview of Smoking Behavior (topography)

Exposure to the elements of cigarette smoke (e.g., tar, carbon monoxide, and

nicotine) is associated with health consequences (Frederiksen, Martin, & Webster, 1979). The number of cigarettes per day (i.e., rate of cigarette consumption) is the common gauge of exposure; but, the way a person smokes a cigarette (i.e., smoking topography) is also significant (Frederiksen et al., 1979). A number of variables form smoking topography, including: puff count, puff volume, puff velocity, inter-puff interval, puff duration, and time to first puff.

The process of cigarette smoking is complex (Benowitz et al., 2009); the way a person smokes a cigarette is important for a number of reasons. First, exposure to carbon monoxide (Zacny, Stizer, Brown, Yingling, & Griffiths, 1987) and carcinogenic elements (Djordjevic, Stellman, & Zang, 2000) is influenced by puff indices, such as puff volume. The analysis of smoking topographical indices is an estimate of exposure to the harmful elements of a cigarette. Second, the analysis of smoking topographical indices has clinical implications (Perkins, Karelitz, Giedgowd, & Conklin, 2011). Previous research has demonstrated that some topographical variables (e.g., maximum puff velocity, puff volume, inter-puff interval) predicted abstinence after a stop smoking attempt using nicotine replacement therapy (NRT) (Strasser, Pickworth, Patterson, & Lerman, 2004). Third, smoking topography is a gauge of smoking reinforcement and reward. The assessment of topographical indices may be of use in helping researchers understand the factors that sustain cigarette smoking. Overall, the measurement of topography is of use in stop smoking interventions and in the gauge of harm from smoking.

The measurement of smoking behavior. Topographical variables can be measured by self-report, observation, or via an instrument.

A smoker is best positioned to monitor their smoking behavior across different

situations (Frederiksen et al., 1979). A self-report questionnaire is simple and efficient. But, self-report is a retrospective account of behavior, therefore it may not be accurate. A variation of self-report is self-monitoring. Self-monitoring is a practical and flexible method. Unfortunately, it is a burden to the subject. Overall, self-report assessment of smoking behavior is practical, but the accuracy is questioned.

Direct observation is the crux of behavior research. Researchers have examined topographical variables by observation. Observation by trained observers and videotaping of smoking patterns are the common forms of observation (Frederiksen, Miller, & Peterson, 1977; Frederiksen et al., 1979). Some topographical variables can be measured accurately by observation (e.g., puff count, total cigarette duration). But, it is difficult to measure intricate variables, such as inter-puff interval, puff volume, and puff duration. Smoking behavior is often observed in a laboratory setting. A smoker may take more and longer puffs, and smoke more quickly in a laboratory than in a natural setting (Ossip-Klein, Martin, Lomax, Prue, & Davis, 1983). Observation of topography is difficult; it is not an accurate reflection of normal smoking behavior.

A variety of instruments have been used to objectively measure topographical variables. Past research has used pneumotachographs (e.g., Zacny et al., 1987), pressure transducers (e.g., Ossip-Klein et al., 1983), portable recorders (e.g., Hatsukami, Morgan, Pickens, & Champagne, 1990), flowmeters (e.g., Ahijevych, Gillespie, Demirci, & Jagadeesh, 1996), and puff analyzers (e.g., Sutton, Russell, Iyer, Feyerabend, & Saloojee, 1982). Technological advances have resulted in the development of a sophisticated device called the CReSS Pocket (Clinical Research Support System; (CReSS; Plowshare Technologies®, Borgwalt, KC. Inc., Richmond, Virginia, USA). Previous research has

used the CReSS Pocket to quantify topographical variables (e.g., Lee, Malson, Waters, Moolchan, & Pickworth, 2003; Faulkner, Arbour-Nicitopoulos, & Hsin, 2010; Blank, Disharoon, & Eissenberg, 2009).

Variability in smoking topography. Cigarette smoking topography is influenced by several variables, including sex, and nicotine dependence. First, previous research provided evidence that mean puff volume, and mean puff duration were affected by sex (Eissenberg, Adams, Riggins III, & Likness, 1999). Puff volume and puff duration were greater in males than females (Eissenberg et al., 1999). Second, total volume and maximum puff volume were greater in smokers with a high level of nicotine dependence (Perkins et al., 2011). Third, previous research provided evidence that body mass index (BMI) and the length of deprivation influenced subjective reinforcement (Blendy et al., 2005; Zacny & Stitzer, 1985). Subjective reinforcement may be related to objective topographical variables. Overall, the consideration of variables such as, sex, nicotine dependence, BMI, and length of abstinence is warranted in topography research.

Exercise as a potential harm reduction strategy. There are ‘hardened’ smokers who are unable or unwilling to attain cessation. In addition to tobacco withdrawal symptoms and cravings, the social and psychological dependence on nicotine is difficult to overcome. A harm reduction strategy may be best suited for ‘hardened’ smokers. Harm reduction can refer to a strategy or intervention that involves continuation of a high risk behavior (e.g. smoking); but, the primary objective is to lower the risk of morbidity and mortality (Stratton, Shetty, Wallace, & Bondurant, 2001; Hatsukami, Henningfield, & Kotlyar, 2004). At present, nicotine replacement therapy (NRT) is the only strategy to satisfy all eight criterion of harm reduction (de Ruiter & Faulkner, 2006). However,

regular physical activity may be an *additional* harm reduction approach (de Ruiter & Faulkner, 2006; Hatsukami et al., 2004).

A harm reduction strategy should satisfy the following eight criterion: (1) reduce the occurrence of death and disease; (2) not present additional health or safety risks; (3) should not further contribute to an individual's level of nicotine dependence; (4) not increase the prevalence of tobacco dependence; (5) no reduce the likelihood of eventual cessation; (6) allow a smoker to become tobacco and nicotine free; (7) not lure adolescents or lead to misuse by adolescents; and (8) smoking cessation messages should be incorporated into promotion of the harm reduction approach (Hatsukami et al., 2004). de Ruiter and Faulkner (2006) postulate that regular physical activity may satisfy each principle.

A solitary session of exercise can provide cigarette craving and tobacco withdrawal relief (Taylor et al., 2007). A solitary session of exercise may also delay time to *ad libitum* smoking (Reeser, 1983; Katomeri & Taylor, 2006; Taylor & Katomeri, 2007; Thayer et al., 1993). In addition, there is emerging evidence for a positive change in smoking topography subsequent to exercise (Faulkner et al., 2010). Taken as a whole, an acute bout of exercise has the potential to contribute to smoking harm reduction. The effect of an acute bout of exercise on time to *ad libitum* smoking and objective topographical variables (Reeser, 1983; Mikhail, 1983; Faulkner et al., 2010) will be further discussed in the remainder of this chapter.

Exercise and Smoking Behavior (topography)

***Ad libitum* smoking behavior.** Four studies (Reeser, 1983; Thayer et al., 1993;

Katomeri & Taylor, 2006; Taylor & Katomeri, 2007) have investigated the effect of a single session of exercise on time to *ad libitum* smoking. The treatment effects range from a net time of 8 (Katomeri & Taylor, 2006) to 57 (Taylor & Katomeri, 2007) minutes. Post-treatment desire to smoke predicted the time to first cigarette. A lower desire to smoke ($r = -0.26, p < .05$) was associated with an increased time to first cigarette (Taylor & Katomeri, 2007). Overall, previous research has found that a 5 to 20 minute bout of exercise increased the time to a next cigarette (Reeser, 1983; Thayer et al., 1993; Katomeri & Taylor, 2006; Taylor & Katomeri, 2007).

There are two caveats of the aforementioned evidence that warrant discussion. First, the researchers used dissimilar experimental designs. For example, different lengths of smoking abstinence, and different types and intensities of exercise were reported. Also, the level of nicotine dependence was not congruent across studies. Second, time to first cigarette was based on self-report accounts. Self report accounts may have biased and/or contaminated the findings.

The evidence that a solitary session of exercise can delay the time to a next cigarette is encouraging. As the length of time between cigarettes is increased, the number of cigarettes smoked per day (i.e., rate of consumption) is decreased. A reduced rate of consumption is a type of harm reduction (de Ruiter & Faulkner, 2010). But, a delay in *ad libitum* smoking does not account for the complex nature of cigarette smoking. Thus, an in-depth evaluation of objective smoking topography is needed.

Acute effects of exercise on smoking topography. Two unpublished Master's Theses (Reeser, 1983; Mikhail, 1983) each investigated the effect of exercise on time to first cigarette, puff count, and duration of first cigarette following a 30 minute period of

smoking abstinence. Direct observation was used to measure the topographical variables.

Reeser (1983) equated data from two laboratory sessions. A randomized between subject design was used. There were three conditions: (a) cycling (60% maximum heart rate); (b) stretch and isometrics; and (c) passive. Each condition was succeeded by a 30 minute observation period; 28% of subjects in either the stretching and isometrics condition or the cycling condition did not smoke during the 30 minute observation period, compared to 15% in the passive condition. The stretching and isometric condition had fewer puffs with the first cigarette than the passive condition ($ES = .69$). Also, on average, the stretching and isometric condition smoked 31 minutes post-condition; whereas, the passive condition smoked a mean of 7 minutes post-condition. Interestingly, the cycling condition smoked a mean of 14 minutes post-condition.

Mikhail (1983) used a within subject experimental design. There were three conditions: (a) cycling (66-69% maximum heart rate); (b) cycling (82-85% maximum heart rate); and (c) passive (reading). Each condition was succeeded by a 60 minute observation period. The time length of the first cigarette was greater for the passive condition compared to either cycling condition. In a 23 hour post-laboratory period, participants also recorded the number of cigarettes smoked. Overall, the difference between the two cycling conditions was non-significant, and no other effects (e.g., number of puffs per cigarette, number of cigarettes in follow-up period) were reported (Mikhail, 1983).

The overall duration (Mikhail, 1983), and puff count (Reeser, 1983) of a cigarette were reduced subsequent to a solitary session of exercise compared to a passive condition. There were limitations of the aforementioned research. First, smoking

behavior was measured in a laboratory setting. Although exposure to smoking stimuli can be controlled within a laboratory, the setting is not ecologically valid (Frederiksen et al., 1979). Second, both Reeser (1983) and Mikhail (1983) only measured puff count and total duration. Total duration and puff count, along with time to first cigarette provide an incomplete depiction of smoking behavior. The investigation of more complex and objective topographical indices subsequent to exercise was needed.

Faulkner and colleagues (2010) provided the first evidence for the effect of an acute bout of exercise on objective smoking topography. Faulkner and colleagues (2010) used a within subject design, with two conditions: (1) passive sitting (control); and (2) brisk walking (experimental). The CReSS Pocket was used to measure puff volume, puff duration, puff count, inter-puff interval, and the time to first puff in a 20-minute post-condition period. In addition, desire for a cigarette was assessed pre-, during, and post-condition. Faulkner and colleagues (2010) reported that participants in the brisk walking condition smoked a lower volume per puff compared to the passive condition. Puff duration was also reduced for the brisk walking condition. The effects were present after controlling for the length of smoking abstinence. Also, the trends were in favor of the walking condition for the remaining topographical variables. Last, Faulkner and colleagues (2010) reported a correlation between craving reduction and time to first puff, such that the greater the reduction in cravings, the greater the time to first puff.

There are several caveats of the aforementioned study by Faulkner and colleagues (2010) that warrant discussion. First, a within subject design was used to investigate the effect of brisk walking on smoking topography. A within subject design has advantages (Maxwell & Delany, 2004), but it cannot show a cause and effect relationship. The

results may be strengthened with the use of a randomized between subject design. Second, the exercise condition was a ten minute session of light intensity walking. The time and intensity of exercise were insufficient to show an effect in an active sample. A moderate intensity session that is acclimated to each subjects resting heart rate may be more effective. Third, the average length of smoking abstinence reported by Faulkner and colleagues (2010) was 8.4 hours. Past research reported that a 15 hour period of smoking abstinence can give rise to heightened withdrawal symptoms (Ussher et al., 2001; Daniel et al., 2004). A longer period of smoking deprivation may be needed to show a significant change in smoking topography. Overall, future exercise and smoking topography research should consider the caveats of this study.

Objective and Hypothesis

Primary objective. The purpose of the current study was to investigate the effect of an acute bout of moderate intensity exercise on smoking topography variables (puff count, puff duration, puff volume, inter-puff interval, and total duration) following a temporary period of smoking abstinence, compared to a passive condition.

Primary hypothesis. Participants in the moderate intensity exercise condition will demonstrate positive changes in smoking topography (i.e., reduced puff count, puff duration, puff volume, total duration, and increased inter-puff interval) compared to a passive condition.

Chapter Two: The Current Study

Method

The subsequent methods are reported in accordance with CONSORT principles (www.consort-statement.org). The conduct of this study adhered to guidelines of the Declaration of Helsinki (World Medical Association, 2008) and the World Health Organization (WHO) 2002 Good Clinical Research Practice. This study was registered with Clinical Trials, a service of the United States National Institute of Health (NCT01417975). All participants read the Letter of Information (Appendix A), had his/her questions answered, and signed a Consent Form (Appendix A) prior to participation in this study.

Design

The research used a stratified (age, sex, physical activity level, nicotine dependence) two group randomized controlled trial design. Randomization was accomplished by a computer-generated numbers table for age (18-30 years, 31-50 years, 51-64 years), sex (male, female), physical activity level (active, inactive), and nicotine dependence (low, high). Participants were blinded to group allocation and were unaware of the existence of a second condition.

Participants

Inclusion criteria included: (1) aged 18 to 64 years; (2) smoke 10 or more cigarettes per day for at least two years; and (3) completion of the Physical Activity Readiness Questionnaire (PAR-Q; Canadian Society for Exercise Physiology (CSEP),

2002). Exclusion criteria included: (1) contraindication to physical activity (e.g., disability, unstable angina); (2) a positive answer to one or more questions on the PAR-Q; (3) pregnant or intending on becoming pregnant before completion of the study; (4) engaged in a quit attempt in past 6 months; and (5) suffering from a illness (e.g., cold) that would compromise normal smoking behavior. Forty-three participants ($M_{age} = 43.14$ years, $SD = 13.01$) who satisfied all criteria were randomized into one of two conditions: moderate intensity exercise or passive sitting. Participants included 34 females and nine males.

Demographic characteristics

Demographic information, including: age, gender, smoking status (e.g., number of cigarettes per day, current other substance use, date and time of last cigarette, and brand and type of cigarette smoked most often), and smoking history (e.g., number of years smoking regularly, age of first cigarette, and past other substance use) was collected. Height (cm) and weight (kg) were recorded and Body Mass Index (BMI) was calculated.

Primary Outcome Measure

Smoking behavior (topography). The CReSS Pocket (Clinical Research Support System; Plowshare Technologies®, Borgwalt, KC. Inc., Richmond, Virginia, U.S.A) measured smoking topography. The CReSS Pocket is a portable, battery-operated machine. The machine is a hand-held unit that consists of a specialized mouthpiece. The mouthpiece produces a pressure drop that is converted to a flow rate. All variables are derived from the measurement of flow and time (Hammond, Fong, &

Cummings, 2005). The topography markers acquired from the CReSS Pocket include: (1) puff count (number of puffs); (2) puff volume (ml); (3) puff duration (seconds); (4) inter-puff interval (IPI; seconds); and (5) time to first puff (seconds). In addition to the values acquired from the CReSS Pocket, total duration (minutes) was calculated. Total duration (minutes) was derived from the start and end time. Time to first puff was not included in the current study. Data were downloaded from the device immediately upon collection. A serial port computer interface was used to download the data. The CReSS Pocket has excellent test-retest reliability for puff duration ($\alpha \geq 0.75$) (Lee et al., 2003) and fair- to - good reliability for puff volume ($0.4 > \alpha < 0.75$) (Lee et al., 2003).

Topographical data were inspected for errors of measurement. Erroneous puffs can result from device misuse and/or imprecision. The first puff and any puffs with a volume less than 12 ml were deleted from the data set. The data for all remaining puffs were averaged to obtain one value for each topography marker. Data for the light-up puff was not included as it bears no resemblance to subsequent puff (in terms of volume and duration), and is often not inhaled by the smoker (Zacny & Stitzer, 1985). The criterion for false puffs has been previously used (Lee et al., 2003).

Other Measures

Desire to smoke. The single-item statement ‘I have a desire to smoke’ (Tiffany & Drobes, 1991) assessed desire to smoke. The item was scored on a seven-point Likert scale, from 1 (*strongly disagree*) to 4 (*neither agree nor disagree*), and 7 (*strongly agree*). Desire to smoke was measured at baseline (Session 1), the start of Session 2, and one-minute post-condition (Session 2).

Physical activity questionnaire. The short-form International Physical Activity Questionnaire (IPAQ; Craig et al., 2003) gauged current physical activity, including: (1) walking; (2) moderate-intensity; and (3) vigorous-intensity activities. The IPAQ is a self-report recall of physical activity in the previous seven days. The questionnaire was administered at baseline. Physical activity was defined by metabolic equivalent task (METs) units. A MET-minute was calculated by multiplying the MET unit by the number of minutes. One measure of activity was computed to yield a score of total MET-minutes/week. The MET scores used in the calculation of the IPAQ data include: (1) walking = 3.3 METs; (2) moderate physical activity = 4.0 METs; and (3) vigorous physical activity = 8.0 METs. The IPAQ also measured the number of sitting hours per day. Time spent sitting is an indicator of sedentary activity; therefore, it was not included in the total score of physical activity. Participants were classified as inactive (< 1500 MET-minutes per week) or active (≥ 1500 MET-minutes per week).

Fagerström test for nicotine dependence. Behavioral and physiological aspects of dependence were measured by the Fagerström Test for Nicotine Dependence (FTND; Heatherton, Kozlowski, Frecker, & Fagerström, 1991). The FTND was administered at baseline (Session 1). The FTND is a six-item, multi-dimensional scale, summarized as a single score. This study used a median split of FTND scores, with five or higher indicating high dependence and below five indicating low dependence. The FTND has good internal consistency ($\alpha = .64$, $p < .001$) and adequate test-retest reliability ($r = .88$) (Pomerleau, Carton, Lutzke, Flessland, & Pomerleau, 1994). In the current study, the FTND had adequate internal consistency ($\alpha = .65$).

Acceptability of the CReSS Pocket. The acceptability questionnaire assessed

participants' experience with the CReSS Pocket. The purpose built questionnaire consisted of 11-items that assessed the degree to which the CReSS Pocket "altered smoking behavior" (i.e. puff volume, time between puffs, puff duration, puff count, and cigarette duration), "reduced smoking enjoyment," "affected the taste of the cigarette," "made smoking more difficult," and "increased awareness of how much was smoked." Acceptability of puff velocity and likeliness to smoke were not included in the subsequent analysis because they did not represent smoking topography variables. The scale ranged from 0 (*strongly disagree*) to 100 (*strongly agree*). Acceptability of the CReSS Pocket was assessed following baseline (Session 1) and Session 2 smoking topography measurement. This questionnaire has not been validated. In the current study, the questionnaire had very good internal consistency at baseline ($\alpha = .942$) and Session 2 ($\alpha = .961$).

Intervention

Moderate intensity exercise. The experimental condition involved a single bout of moderate intensity exercise on a Woodway PPS treadmill (Woodway, Waukesha, WI). The activity bout included a warm-up, 10 minutes of exercise (equivalent to moderate intensity) and a cool-down. Moderate intensity was defined as 40-68% of heart rate reserve (HRR) (Karvonen, Kentala, & Mustala, 1957). Heart rate reserve (HRR) was calculated using the formula: maximum heart rate (HR_{max}) – resting heart rate (HR_{rest}) (CSEP). Maximum heart rate was equivalent to $220 - \text{age}$ (CSEP). Resting heart rate (RHR; beats per minute) was taken at baseline. After 11-15 hours of smoking abstinence, resting heart rate can drop by approximately 8.5 beats per minute (Perkins, Epstein,

Stiller, Marks, & Jacob, 1989). Resting heart rate was taken before abstinence because it is an indicator of normal heart rate. The calculation for 40% HRR was: $[(HR_{\max} - HR_{\text{rest}}) \times .4] + HR_{\text{rest}}$ (CSEP). The calculation for 68% HRR was: $[(HR_{\max} - HR_{\text{rest}}) \times .68] + HR_{\text{rest}}$ (CSEP). Heart rate (HR) was monitored using a Polar RS100 heart rate monitor.

Passive sitting. The control condition involved sitting on a chair in the testing facility for 10 minutes. Participants were alone in a room, had minimal contact with the investigator, and were not discouraged from reading.

Procedure

Ethics approval was granted by the University of Western Ontario Research Ethics Board for Health Sciences Research Involving Human Subjects (REB #18109, Appendix A). Participants were recruited via several sources. Posters were placed on the university campus, in the university newspaper, at the Middlesex London Health Unit, and at Kelloggs® Canada (Appendix A). In addition, electronic advertisements were mailed to students at the University of Western Ontario (UWO) and employees of the London Health Sciences Centre (LHSC).

A flow diagram of the design and procedure is presented in Figure 1. Eligibility was determined by an initial telephone or e-mail screen, followed by one screening visit (Session 1). Subsequent to an expression of interest, participants were contacted by phone or e-mail and asked their age, smoking status (e.g., number of cigarettes per day), smoking history (e.g., number of years as a regular smoker, previous quit attempts), and current physical health. Participants were screened with the PAR-Q (CSEP, 2002). Participants who answered “yes” to any question on the PAR-Q were required to seek

physician approval before participating in this study. The study involved participants completing two visits (Session 1 and Session 2) at the Exercise and Health Psychology Laboratory (EHPL; www.ehpl.uwo.ca) at the University of Western Ontario (London, Ontario).

Baseline assessments (Session 1) included: (1) verification of smoking status; (2) smoking topography; and (3) other variables. Smoking status was verified using the piCO+™ Smokerlyzer® carbon monoxide (CO) monitor (Bedfont Scientific Ltd., Kent, England). A carbon monoxide reading of 10 parts per million (ppm) was the threshold of inclusion (as used in previous research; Faulkner et al., 2010) ($M = 16.00$, $SD = 7.56$). First, participants completed the demographic questionnaire. Participants then completed an assessment battery, including: (1) International Physical Activity Questionnaire (IPAQ; Craig et al., 2003); (2) Fagerstrom Test for Nicotine Dependence (FTND; Heatherton et al., 1991); and (3) desire to smoke (Tiffany & Drobes, 1991). All questionnaires can be referred to in Appendix B.

Next, participants were trained on the proper use of the Clinical Research Support System (CReSS) Pocket smoking topography device (Plowshare Technologies®, Borgwaldt KC. Inc., Virginia, USA). Participants were briefed on proper use of the CReSS Pocket and were instructed to smoke the cigarette as normal. Subsequently, participants went outside of the laboratory building and smoked a cigarette (preferred own brand) using the CReSS Pocket. Participants were provided with an instruction sheet while in possession of the device. In addition, participants were required to bring their preferred brand of cigarette to all study procedures. To conclude, participants completed the acceptability questionnaire. Session 1 took roughly 45 minutes to

complete.

Participants who satisfied all inclusion and exclusion criteria were randomized to one of two conditions: experimental (moderate intensity exercise) or control (passive sitting) (Figure 1). The participants were randomized to maximize group equivalency. If willing to participate (voluntary basis), eligible participants provided informed consent.

Session 2 was scheduled for one week subsequent to baseline ($M = 7.42$ days, $SD = 2.45$). To control for within subject variation in desire to smoke, Session 2 was scheduled for the same time of day as baseline ($M_{\text{time}} = 1.47$ hours, $SD = 1.81$). Preceding Time 2, participants were directed to abstain from smoking for a minimum of 18 hours ($M_{\text{time}} = 14.8$ hours, $SD = 4.95$). Temporary smoking abstinence was verified using the piCO+™ Smokerlyzer® carbon monoxide (CO) monitor. A breath carbon monoxide level of less than 10 ppm was taken as evidence of smoking abstinence (as used in previous research; Daniel et al., 2006; Ussher et al., 2001) ($M = 6.03$, $SD = 6.78$). Desire to smoke (Tiffany and Drobes, 1991) was assessed one minute pre-condition: exercise or passive sitting. Subsequently, all participants completed their allocated ten minute condition. Desire to smoke (Tiffany & Drobes, 1991) was assessed one minute post-condition. Participants then left the laboratory building to smoke a cigarette (preferred own brand) using the CReSS Pocket (Time 2a). Upon return to the laboratory, participants in both conditions sat passively for 30 minutes. Subsequent to the 30 minute waiting period, participants once again left the laboratory to smoke a cigarette (preferred own brand) using the CReSS Pocket (Time 2b). This smoking protocol was followed to assess whether topography effects found at Time 2a would carry over to Time 2b. The acceptability questionnaire was completed to conclude the study. Session 2 took roughly

90 minutes to complete. All participants were debriefed at the end of Session 2.

Data from this study were entered into a Microsoft Excel database at the host institution's laboratory and extracted into IBM SPSS Statistics (Version 19) for analysis. For data security, all computers at the EHPL are linked to the host institutions' LEGATO backup system.

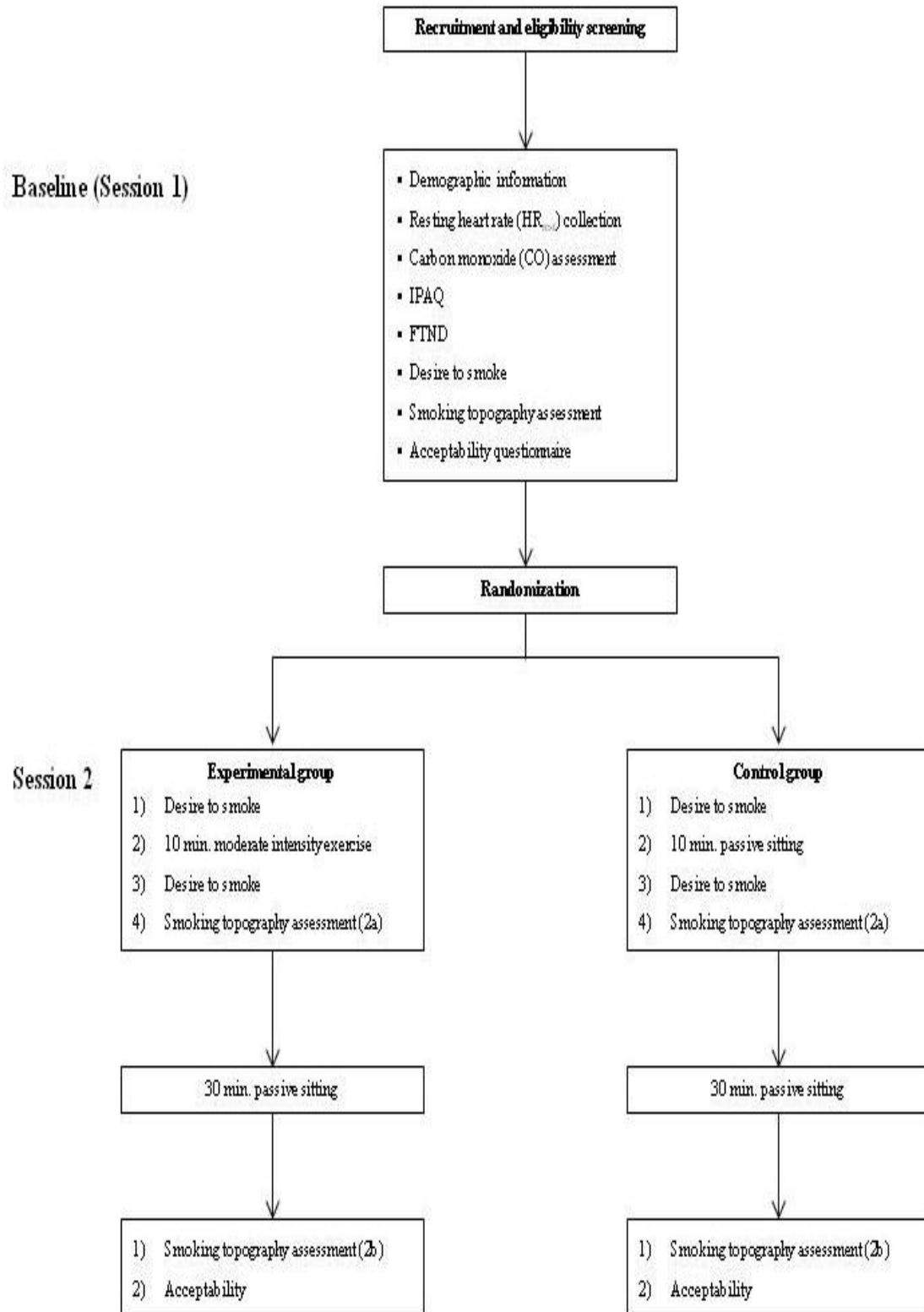


Figure 1. Flow diagram of design and overall procedure

Power Calculation

The current study was intended as a pilot study; hence no formal power calculation was computed.

Statistical Analyses

To assess group equivalency at baseline (Session 1), independent samples *t*-tests were conducted to compare the demographic markers, other measures, and the primary outcome variables (i.e., puff count, puff volume, puff duration, inter-puff interval, total duration). An independent samples *t*-test was also conducted to assess group equivalency for smoking abstinence (hours) prior to Session 2.

Desire to smoke was the manipulation check, and a repeated measures ANOVA was conducted to identify a condition (exercise vs. passive sitting) by time (pre- and post-condition) interaction effect. The relationship between desire to smoke and topography variables at Session 2a and Session 2b was investigated using Pearson product-moment correlation coefficients.

For the topography variables, a series of condition (exercise vs. passive sitting) by time (baseline, Session 2a, and Session 2b) repeated measures ANOVAs were conducted. Also, a series of one-way repeated measures ANOVAs were conducted to identify time effects (baseline, Session 2a, and Session 2b) using only the participants in the exercise condition who showed a desire to smoke reduction post-exercise.

The relationship between subjective acceptability and topography variables at baseline (Session 1) was investigated using Pearson product-moment correlation coefficients (Table 7).

The level of significance was accepted at $p < .05$ for all tests (Tabachnick & Fidell, 1996). Effect sizes (η^2) accompany all reported findings. In accordance with Cohen (1988), 0.01 is a small effect size, 0.06 is a moderate effect size, and 0.14 is a large effect size. Pearson product-moment correlation coefficients (r) of .10 to .29, .30 to .49, and .50 to 1.0 denote correlations of small, medium, and large, respectively (Cohen, 1988).

Results

Treatment of Data

Missing data. A participant who did not complete an outcome measure entirely was excluded on an analysis by analysis basis. Tabachnick and Fidell (1996) considered this the most conservative way to treat missing data. This occurred 6 times in total at baseline (Session 1). On the demographic questionnaire, four participants did not complete height and weight. One participant did not complete the household smoking question. Last, one participant did not complete the desire to smoke scale at baseline (Session 1). Missing data did not occur at Session 2.

Outliers. Outliers were identified based on inspection of the Boxplot. A data point was defined as an outlier if it extended more than 1.5 box-lengths from the edge of the box. A data point was defined as an extreme outlier if it extended more than 3 box-lengths from the edge of the box. The outliers and extreme outliers were removed from the subsequent analyses. Outliers were found for the subsequent demographic characteristics: BMI, number of cigarettes per day, age of first cigarette, and total MET min/week. Outliers were also found for the carbon monoxide reading at Session 2. At Session 1, outliers were found for the subsequent outcome variables: puff count, mean puff duration, mean inter-puff interval, and total duration. At Session 2a, outliers were found for the subsequent topography variables: puff count, and mean inter-puff interval. Last, at Session 2b, outliers were found for the subsequent topography variables: puff count, mean inter-puff interval, and total duration.

Assumptions of statistical techniques. The dependent variables that were studied were continuous (interval), and observations were independent. The data were

obtained using a random sample from the population. Normality was assessed by skewness and kurtosis values. The Kolmogorov-Smirnov statistic assessed the normality of the distribution of scores. Last, histograms were used to check the shape of the distribution.

Repeated measures ANOVAs were checked for the assumptions of homogeneity of variances (homoscedasticity) and homogeneity of inter-correlations (sphericity). Levene's test for equality of variances and Box's M statistic were used to check the assumptions respectively. Upon examination of the tests, the assumptions were not violated.

Last, bivariate correlations were checked for the assumptions of linearity and homoscedasticity. This was determined by visual inspection of the distribution of data points in the scatterplots.

Flow of Participants

The flow of participants is presented in Figure 2.

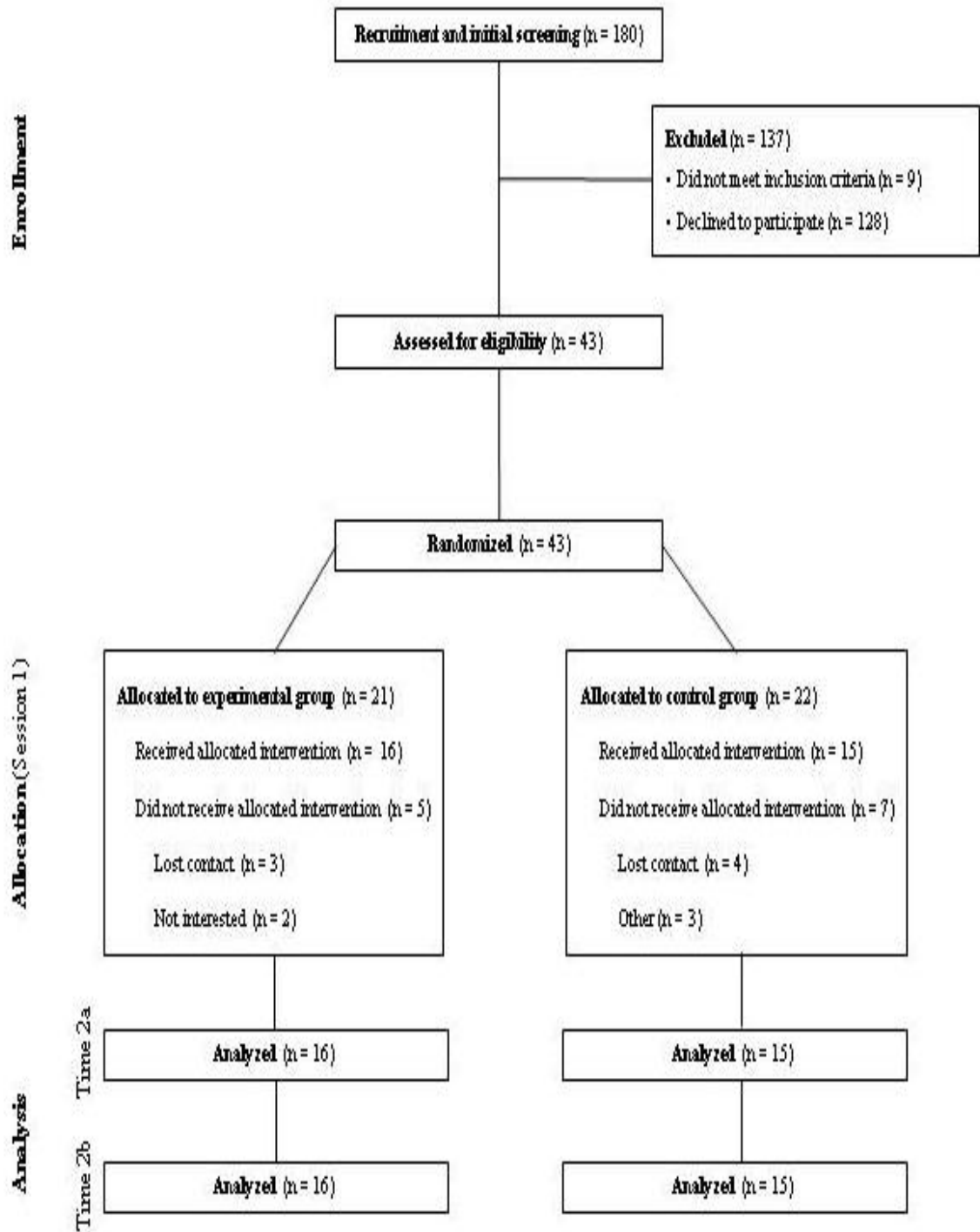


Figure 2. Flow of participants through the study.

Group Equivalency at Baseline

There was a significant difference in age for exercise ($M= 39.19$, $SD= 13.65$) and passive ($M= 47.86$, $SD= 10.64$) conditions; $t(41) = -2.584$, $p = .014$, $\eta^2 = .374$. There was a significant difference in total years smoked for exercise ($M= 19.26$, $SD= 13.05$) and passive ($M= 28.32$, $SD= 12.71$) conditions; $t(41) = -2.305$, $p = .026$, $\eta^2 = .339$. There was a significant difference in regular years smoked for exercise ($M= 16.14$, $SD= 12.53$) and passive ($M= 24.68$, $SD= 14.34$) conditions; $t(41) = -2.097$, $p = .041$, $\eta^2 = .311$. There was a significant difference in nicotine dependence (FTND) for exercise ($M= 4.10$, $SD= 1.92$) and passive ($M= 5.82$, $SD= 1.99$) conditions; $t(41) = -2.885$, $p = .054$, $\eta^2 = .411$. There was a significant difference in expired carbon monoxide (CO) for exercise ($M= 13.29$, $SD= 6.00$) and passive ($M= 18.59$, $SD= 8.10$) conditions; $t(41) = -2.448$, $p = .019$, $\eta^2 = .357$. There was no significant difference between groups for the remaining variables: BMI, age of first cigarette, number of cigarettes per day, total MET min/week, and time since last cigarette (Table 2).

There was no significant difference in number of hours abstained for exercise ($M= 13.47$, $SD= 5.91$) and passive ($M= 16.61$, $SD= 2.69$) conditions; $t(26) = -1.852$, $p = .079$, $\eta^2 = .341$.

There was no significant difference in desire to smoke at baseline for exercise ($M= 5.61$, $SD= .98$) and passive ($M= 6.05$, $SD= .90$) conditions; $t(38) = -1.461$, $p = .152$, $\eta^2 = .231$.

For the primary outcome variables, there was no significant difference in puff volume for exercise ($M= 53.08$, $SD= .18.34$) and passive ($M= 59.38$, $SD= 17.31$) conditions; $t(40) = -1.147$, $p = .258$, $\eta^2 = .178$. There was no significant difference in

puff duration for exercise ($M= 1.67, SD= .51$) and passive ($M= 1.61, SD= .50$) conditions; $t(40) = -1.147, p = .360, \eta^2 = .057$. Also, there was no significant difference in total cigarette duration for exercise ($M= 3.88, SD= .87$) and passive ($M= 3.93, SD= .93$) conditions; $t(38) = .330, p = .360, \eta^2 = .053$. But, there was a significant difference in puff count for exercise ($M= 15.00, SD= 5.22$) and passive ($M= 10.83, SD= 2.73$) conditions; $t(37) = 3.188, p = .003, \eta^2 = .464$. Last, there was a significant difference in inter-puff interval for exercise ($M= 12.78, SD= 4.41$) and passive ($M= 17.70, SD= 7.89$) conditions; $t(37) = -2.525, p = .016, \eta^2 = .371$.

For the acceptability variables, there were no significant differences between groups at baseline for alter puff count, puff volume, puff duration, IPI, and total duration. Also, there were no significant differences between groups at baseline for reduce smoking enjoyment, affect cigarette taste, increase smoking difficulty, and increase smoking awareness (Table 6).

The variables that were not equivalent at baseline were considered a potential covariate in the subsequent analyses. The assumptions of linearity, homogeneity of variances, and homogeneity of regression slopes were checked. Each demographic marker violated at least one of the assumptions. Therefore, the markers were not considered as covariates in the subsequent analyses. Baseline values for puff count and inter-puff interval satisfied the assumptions. These values were used as covariates in the subsequent analyses.

Table 2
Demographic characteristics and smoking status at baseline

	Experimental Group		Control Group	
Number of participants	21		22	
Male/Female	6/15		3/19	
<i>Variable</i>	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>
Demographics:				
Age (years)	39.19	13.65	47.86	10.64
BMI (kg/m ²)	25.21	5.89	27.42	6.37
Physical activity (IPAQ)	2603.33	2667.91	2053.19	2190.39
Smoking status				
Cigarettes per day	17.29	8.39	19.23	9.92
Fagerström test of nicotine dependence	4.10	1.92	5.82	1.99
Smoking history				
Age of first cigarette	15.62	8.52	13.68	3.72
Number of years smoking	19.26	13.05	28.32	12.71
Number of regular years smoking	16.14	12.53	24.68	14.34
Expired carbon monoxide (ppm)				
Baseline (Session 1)	13.29	6.00	18.59	8.10
Pre- condition (Session 2)	6.13	5.79	5.93	7.94
Length of smoking abstinence (hr.)	13.47	5.91	16.61	2.69

Note: BMI= Body Mass Index, IPAQ= International Physical Activity Questionnaire,

Manipulation Check

Desire to smoke. Desire to smoke was selected as the manipulation check because it is the most strong and consistently reported outcome in the acute literature (Taylor et al., 2007). Outliers were found for desire to smoke at baseline, Session 2a, and Session 2b. A significant effect for time ($F [2, 24] = .609, p = .003, \eta^2 = .391$) was found. The time by group interaction was also significant ($F [2, 24] = .670, p = .008, \eta^2 = .330$) (Figure 3). Overall, mean desire to smoke decreased to a greater degree for the exercise condition (Table 3).

Relationships. Bivariate correlations were used to examine the relationship between post-condition desire to smoke and the topography variables at Session 2a (Table 4a) and Session 2b (Table 4b). There was a strong, positive correlation between post-condition desire to smoke and total duration of cigarette at Session 2a. There was a strong, positive correlation between post-condition desire to smoke and total duration at Session 2b.

Table 3

Mean and standard deviations (SD) of desire to smoke by condition and time

Variable	Whole Sample		Exercise Condition		Passive Condition	
	Mean	SD	Mean	SD	Mean	SD
Desire to smoke						
Baseline	5.85	.95	5.61	.98	6.05	.90
Pre-condition	6.27	1.01	5.94	1.24	6.64	.50
Post-condition	5.10	1.88	4.06	1.88	6.38	.77

Table 4a

Correlations for desire to smoke post-condition and outcome variables at Session 2a

	Puff count 2a	Puff volume 2a	Puff duration 2a	IPI 2a	Total duration 2a
Desire to smoke Post-condition	-.029	.134	-.087	.228	.430*

* Correlation is significant, $p < .05$

Table 4b

Correlations for desire to smoke post-condition and outcome variables at Session 2b

	Puff count 2b	Puff volume 2b	Puff duration 2b	IPI 2b	Total duration 2b
Desire to smoke Post-condition	.042	.209	.174	.285	.405*

* Correlation is significant, $p < .05$

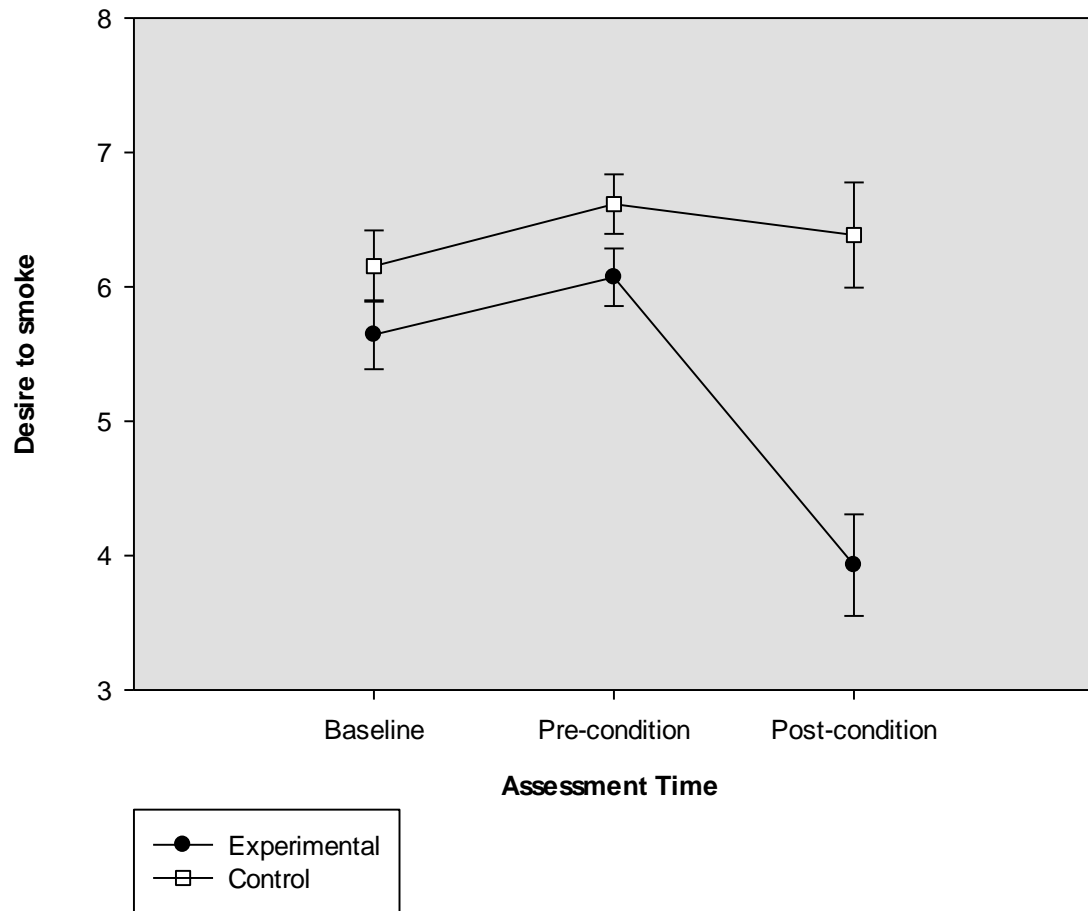


Figure 3. Mean desire to smoke at baseline, pre-condition, and post-condition.

Descriptive Statistics of the Primary Outcome Variables

The descriptive statistics (mean, standard deviations (SD)) for the outcome variables (puff count, puff volume, puff duration, IPI, and total duration) by condition and time are presented in Table 5.

Table 5

Mean and standard deviations (SD) of outcome variables by condition and time

Variable	Whole Sample		Exercise Condition		Passive Condition	
	Mean	SD	Mean	SD	Mean	SD
Puff count						
Baseline	13.08	4.70	15.00	5.22	10.83	2.73
Time 2a	12.86	4.80	14.00	5.97	11.46	2.33
Time 2b	12.21	3.60	13.53	4.27	10.69	1.80
Puff volume (ml)						
Baseline	56.23	17.90	53.08	18.34	59.38	17.31
Time 2a	56.81	16.92	55.99	17.08	57.70	17.29
Time 2b	55.60	18.16	52.94	17.37	58.44	19.15
Puff duration (sec.)						
Baseline	1.64	.50	1.67	.51	1.61	.50
Time 2a	1.65	.46	1.71	.53	1.60	.37
Time 2b	1.66	.45	1.64	.51	1.68	.41
IPI (sec.)						
Baseline	15.36	6.86	12.78	4.41	17.70	7.89
Time 2a	16.56	6.76	15.42	6.78	17.86	6.74
Time 2b	16.16	8.28	13.57	5.19	18.75	10.03
Total duration (min.)						
Baseline	3.90	.89	3.88	.87	3.93	.93
Time 2a	4.00	1.19	3.85	1.29	4.15	1.09
Time 2b	3.69	1.12	3.60	1.14	3.78	1.14

Note: IPI= Inter-puff interval, SD= standard deviation.

Group Differences

Puff count. Puff count at baseline was used as a covariate in this analysis.

Preliminary checks were conducted to ensure there was no violation of the assumptions of normality, linearity, homogeneity of variances, and homogeneity of regression slopes. After adjusting for baseline values, the difference between groups for puff count at Time 2b was non-significant ($F [1, 25] = .886, p = .356, \eta^2 = .034$) (Figure 4). After adjusting for baseline values, the difference between groups for puff count at Time 2b was non-significant ($F [1, 24] = .300, p = .589, \eta^2 = .012$) (Figure 4).

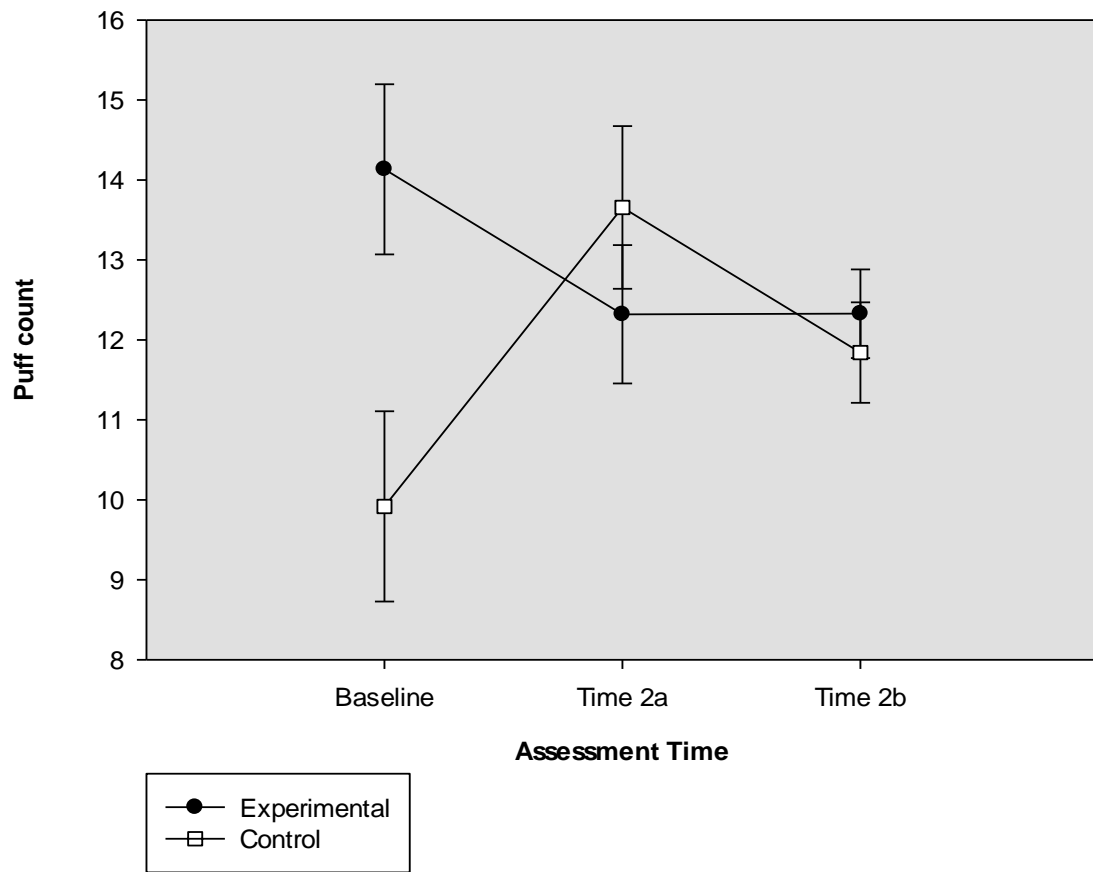


Figure 4. Mean puff count at baseline, Time 2, and Time 2b.

Puff volume. The effect for time was non-significant ($F [2, 28] = .939, p = .414, \eta^2 = .061$), and the time by group effect was non-significant ($F [2, 28] = .889, p = .192, \eta^2 = .111$) (Figure 5).

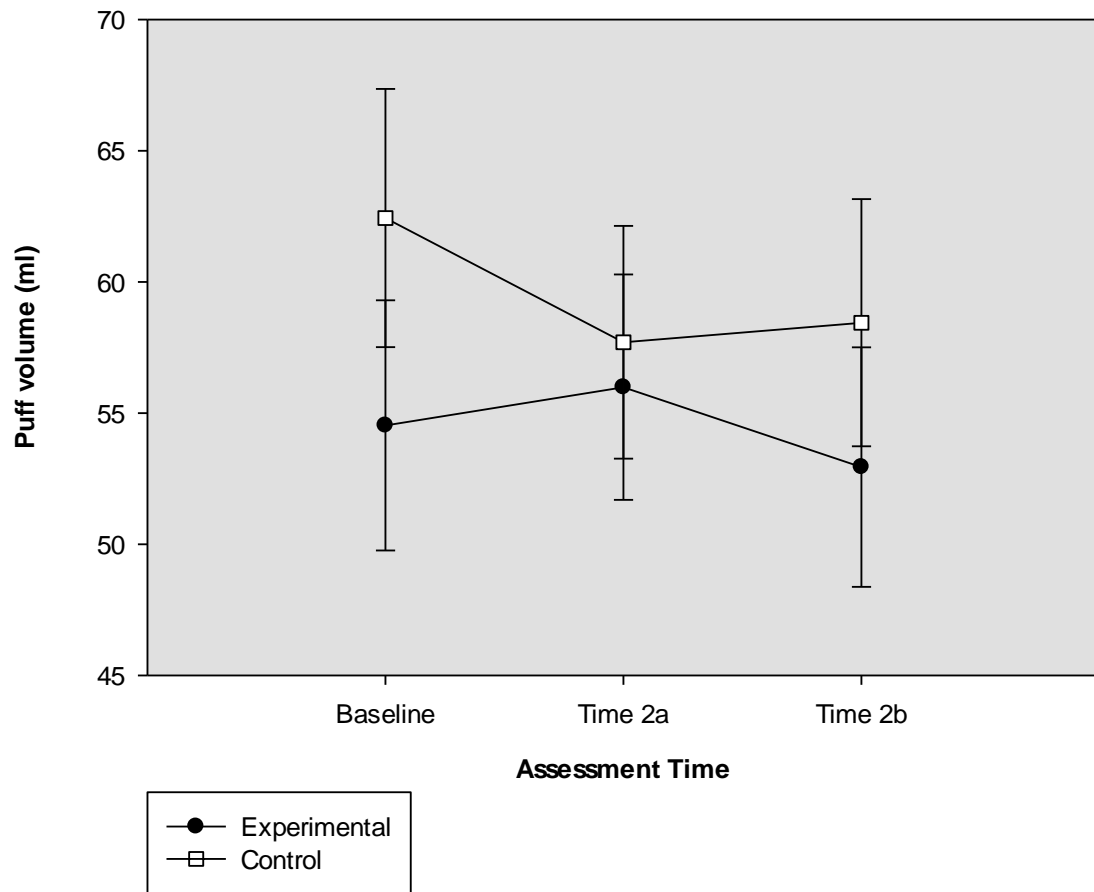


Figure 5. Mean puff volume (ml) at baseline, Time 2a, and Time 2b.

Puff duration. The effect for time was non-significant ($F [2, 28] = .986, p = .820, \eta^2 = .014$). The time by group interaction was also non-significant ($F [2, 28] = .902, p = .238, \eta^2 = .098$) (Figure 6).

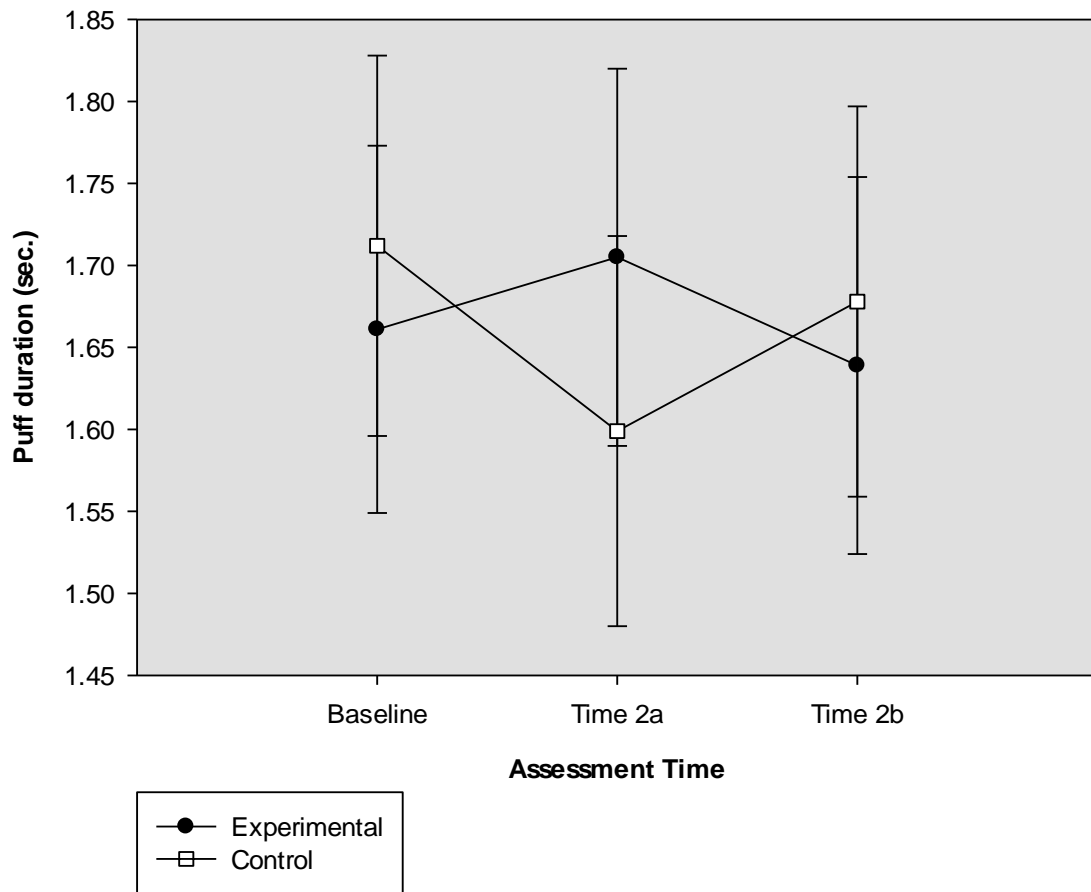


Figure 6. Mean puff duration (sec.) at baseline, Time 2a, and Time 2b.

Inter-puff interval. Inter-puff interval at baseline was used as the covariate in this analysis. Preliminary checks were conducted to ensure there was no violation of the assumptions of normality, linearity, homogeneity of variance, and homogeneity of regression slopes. After adjusting for baseline values, the difference between groups for inter-puff interval at Time 2a was non-significant ($F [1, 26] = .023, p = .881, \eta^2 = .001$) (Figure 7). After adjusting for baseline values, the difference between groups for inter-puff interval at Time 2b was non-significant ($F [1, 26] = .710, p = .407, \eta^2 = .027$) (Figure 7).

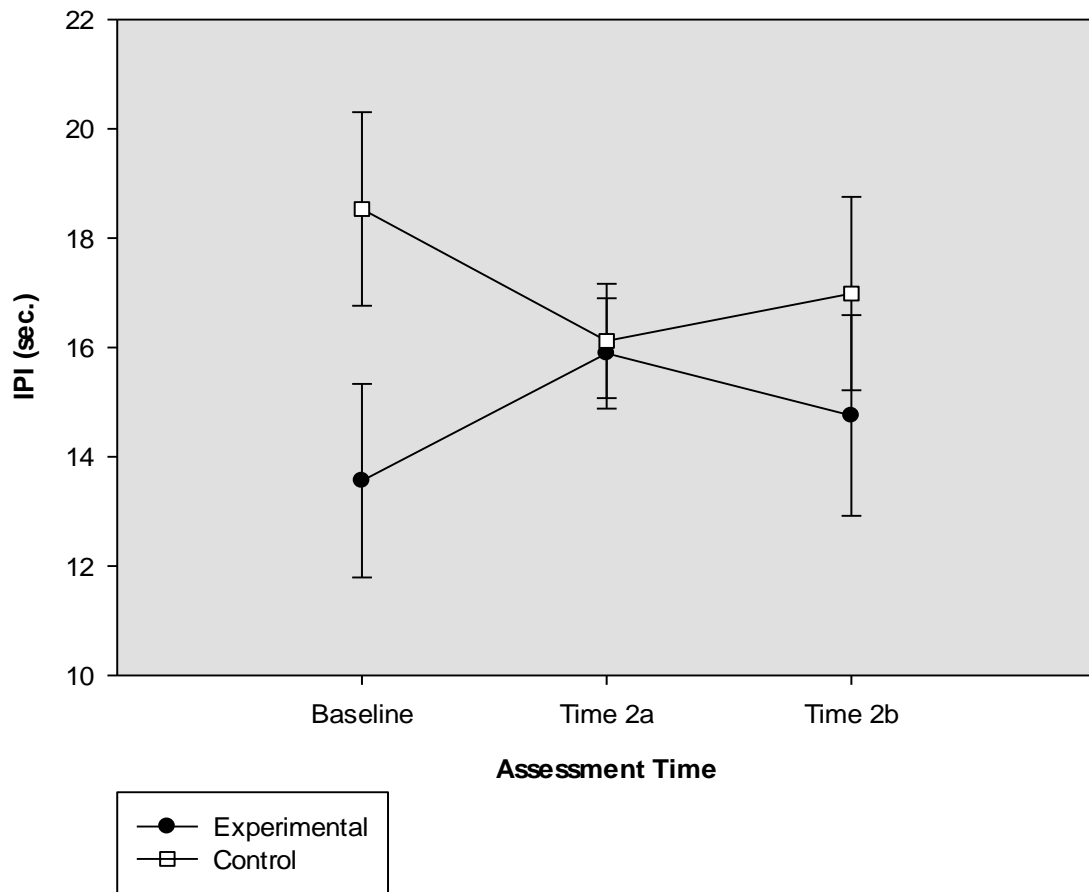


Figure 7. Mean IPI (sec.) at baseline, Time 2, and Time 2b. *IPI = inter-puff interval.*

Total duration. The effect for time was non-significant ($F [2, 26] = .865, p = .379, \eta^2 = .135$). The time by group interaction was also non-significant ($F [2, 26] = .759, p = .165, \eta^2 = .055$) (Figure 8).

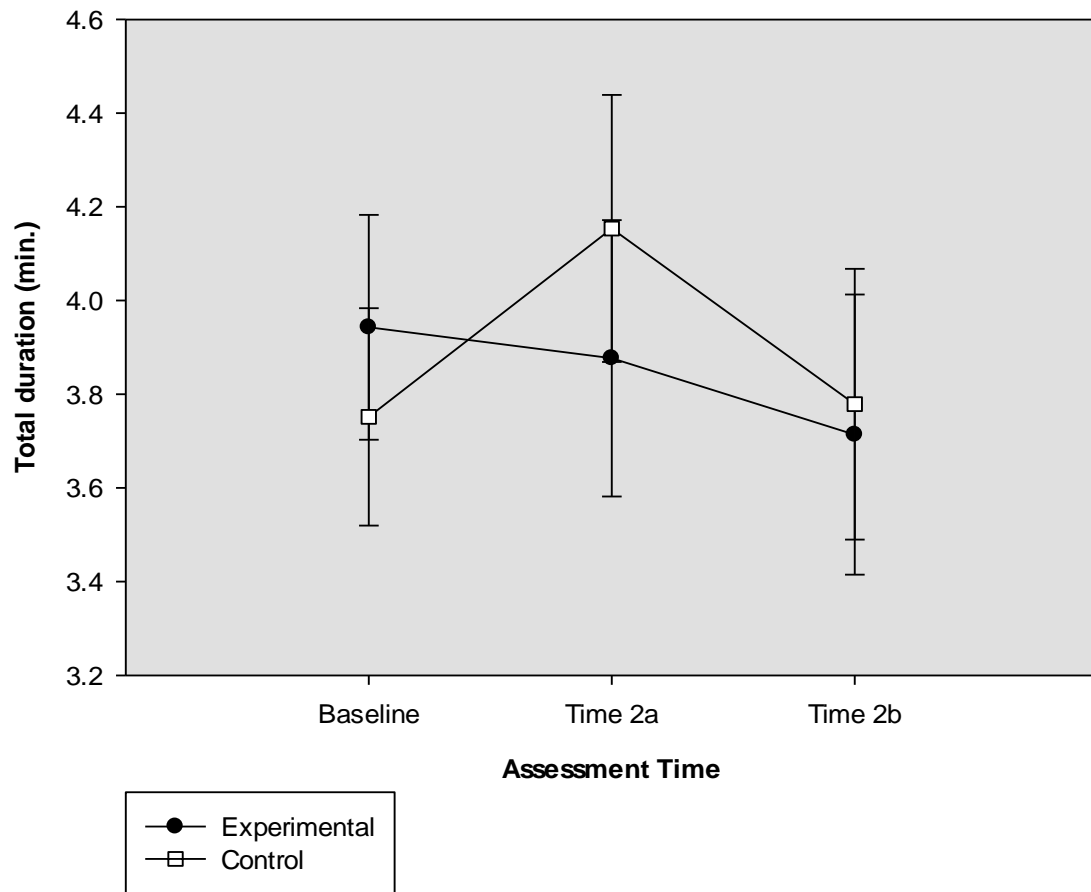


Figure 8. Mean total duration (min.) at baseline, Time 2a, and Time 2b.

Ancillary Analyses for Desire to Smoke Reduction

The subsequent analyses were conducted using only participants in the exercise condition who reported a minimum one point desire to smoke reduction post-condition ($n = 11$).

Puff count. For puff count, the one-way repeated measures ANOVA showed a non-significant effect for time ($F [2, 9] = .740, p = .258, \eta^2 = .260$). However, the effect was large, and visual inspection of the data indicated that puff count decreased after exercise.

Puff volume. For puff volume, the one-way repeated measures ANOVA showed a non-significant effect for time ($F [2, 10] = .711, p = .182, \eta^2 = .289$). The effect was large, and visual inspection of the data indicated that puff volume increased after exercise.

Puff duration. For puff duration, the ANOVA showed a non-significant effect for time ($F [2, 10] = .876, p = .517, \eta^2 = .124$). The effect was large, and visual inspection of the data indicated that puff duration increased after exercise.

IPI. For IPI, the ANOVA showed a non-significant effect for time ($F [2, 9] = .675, p = .170, \eta^2 = .325$). However, the effect was large, and visual inspection of the data indicated that IPI increased after exercise.

Total duration. For total duration, the ANOVA showed a non-significant effect for time ($F [2, 8] = .674, p = .674, \eta^2 = .094$). However, the effect was moderate-large, and visual inspection of the data indicated that total duration decreased after exercise.

Acceptability of the CReSS Pocket

Table 6

Mean and standard deviations (SD) of acceptability variables by condition and time

Acceptability Item	Whole Sample		Exercise Condition		Passive Condition	
	Mean	SD	Mean	SD	Mean	SD
Alter puff count						
Baseline	49.53	27.74	40.00	28.98	44.09	27.02
Session 2	47.10	34.76	46.88	37.54	47.33	32.83
Alter puff volume						
Baseline	49.53	31.54	44.76	33.11	54.09	30.03
Session 2	52.58	30.98	50.63	32.55	54.67	30.21
Alter puff duration						
Baseline	49.53	29.35	43.33	31.68	55.45	26.32
Session 2	50.97	31.34	51.88	35.82	50.00	26.99
Alter IPI						
Baseline	43.95	27.44	43.33	30.01	44.55	25.40
Session 2	48.71	33.94	46.25	36.31	51.33	32.26
Alter total duration						
Baseline	40.70	27.81	40.48	27.83	40.91	28.44
Session 2	52.58	34.35	50.63	37.14	54.67	32.26
Reduce smoking enjoyment						
Baseline	62.79	28.81	58.57	30.54	66.81	27.15
Session 2	61.29	31.17	58.13	34.10	64.67	28.50
Affect cigarette taste						
Baseline	52.56	33.03	47.14	35.52	57.73	30.38
Session 2	48.06	31.56	38.75	29.18	58.00	31.89
Increase smoking difficulty						
Baseline	53.26	34.14	44.30	37.09	61.81	29.38
Session 2	50.65	32.14	44.38	35.40	57.33	27.89
Increase smoking awareness						
Baseline	60.93	32.57	57.62	37.00	64.09	28.23
Session 2	62.90	32.88	59.38	37.14	66.67	28.45

Note: IPI = inter-puff interval

Table 7

Correlations for acceptability and topography variables at Time 1

	Puff count 1	Puff volume 1	Puff duration 1	IPI 1	Total duration 1
Alter puff count	.043	.004	.031	-.061	.051
Alter puff volume	-.011	.004	.059	-.124	-.022
Alter puff duration	-.130	-.051	.087	.150	.093
Alter IPI	-.049	-.041	.040	-.156	-.091
Alter total duration	-.021	-.088	.039	-.027	.093
Reduce smoking enjoyment	-.048	.182	.289	-.081	-.115
Affect cigarette taste	.024	.127	.298	-.138	-.044
Increase smoking difficulty	.114	.109	.235	-.033	-.003
Increase smoking awareness	.175	-.150	.078	-.141	-.015

* Correlation is significant, $p < .05$

Chapter Three: Discussion

Effect of Exercise on Smoking Topography

This pilot study investigated the effect of an acute bout of exercise on objective smoking topography. It was hypothesized that compared to a passive condition, there would be positive changes in topography subsequent to exercise. The current study was designed to overcome limitations of previous research (Faulkner et al., 2010).

Overall, topography differences between conditions and across assessment times were negligible. To begin, subsequent to controlling for baseline, the between group differences effect for puff count was small and non-significant. The exercise condition showed decreased puff count, whereas the passive increased puff count. Faulkner and colleagues (2010) showed a similar trend for reduced count subsequent to exercise.

Second, with respect to puff volume, the effect was moderate-large and non-significant. There was a marginal increase in volume after exercise, whereas volume decreased after sitting for the first cigarette. The trend is not consistent with Faulkner and colleagues (2010) and was contrary to the hypothesis. Volume was in the hypothesized direction for the subsequent cigarette (Time 2b).

Third, the results for puff duration showed a moderate, non-significant effect. The pattern found was similar to puff volume, and hence not consistent with the work of Faulkner and colleagues (2010). Perhaps the effect of exercise on volume and duration is delayed; such that, time is required to see a positive change on these indices.

Fourth, with respect to inter-puff interval the effect was small and non-significant. The time between puffs increased for the exercise condition, compared to baseline. The pattern is not consistent with Faulkner and colleagues (2010) which found reduced inter-

puff interval.

Last, with respect to total duration, the effect was small and non-significant. Compared to baseline, total duration decreased subsequent to exercise, whereas duration increased after sitting. Despite being under-powered, the trend is congruent with the hypothesis.

Compared to baseline, there was a trend for decreased puff count and total duration subsequent to exercise. Also, inter-puff interval increased subsequent to exercise. The patterns indicate harm reduction. However, the volume and duration of each puff increased. In essence, the outcome was a null result. Taking bigger and longer puffs to offset decreased puff count is a form of compensation. Past research showed evidence of compensatory smoking when cigarettes with a lower nicotine yield were used (Strasser, Lerman, Sanborn, Pickworth, & Feldman, 2007). Future exercise and topography research ought to consider the nicotine yield of the cigarettes that participants smoke during the study. Also, total puff volume is a key determinant of tobacco exposure (Zacny et al., 1987). Hence, it should be considered in future research.

The findings of this study support the null hypothesis. But, the question is why? Why are the current findings not congruent with those reported by Faulkner and colleagues (2010)? One explanation for the inconsistent findings between studies is sampling. Specifically, there are demographic and smoking history differences between the samples used in the respective studies. For instance, compared with the sample in the Faulkner et al. (2010) study, the sample of this study was older ($M_{\text{age}} = 43.1$ vs. 24.6), smoked more cigarettes per day ($M = 18.3$ vs. 15.2), and had likely smoked for a greater number of years ($M = 23.8$ vs. unknown). In addition, the current sample was 79%

female. In contrast, the sample of Faulkner and colleagues (2010) was 58% males. As mentioned previously, males and females smoke a cigarette differently. Taken together, the differences suggest that topography was less malleable for the sample in the current study compared to the sample in the Faulkner and colleagues (2010) study.

There were also methodological differences amongst the two studies. First, the current study used a 10-minute bout of moderate intensity exercise on a treadmill. The heart rate zone, based on the pre-abstinence resting heart rate value, was unique to each participant. In contrast, Faulkner and colleagues (2010) used a 10-minute bout of brisk walking. At this stage of research, the impact of exercise intensity and/or duration (if any) on smoking topography is unknown. Second, the mean length of smoking deprivation in the current study was 14.8 hours, compared to 8.4 hours in the Faulkner and colleagues (2010) study. Pre-condition desire to smoke was higher in this study, but the impact of deprivation length on topography is unknown. Last, the two studies used the CReSS Pocket to measure topography. All topography measurements are limited, to some degree, by the false act of smoking with a mouthpiece (Williams et al., 2011). Previous research has found that mouthpiece-based devices increase smoking difficulty, reduce smoking enjoyment, and affect cigarette taste (Blank et al., 2009). Although the CReSS Pocket allows for measurement of complex smoking markers, the device may be a limiting factor. However, this is unlikely in the current study given the neutral response among participants regarding the acceptability of the device.

Finally, there are design differences between the two studies. Faulkner and colleagues (2010) used a within-subject design. In contrast, the current study was a randomized controlled trial (RCT). A discussion of the strengths and limitations of these

designs is necessary. To begin, random allocation to a condition minimized the influence of known and unknown confounders (Peat, 2001). Hence, a randomized controlled trial “provides the highest level of evidence for the effects of an intervention and for causation” (Peat, 2001). A randomized controlled trial was the most appropriate design for this research question. The strengths of a within-subject design include: (a) power; and (b) reduction of error variance associated with individual difference. Using a within-subject design, Faulkner and colleagues (2010) showed that a bout of brisk walking may positively change topography. While this outcome was encouraging, the design of the current study is stronger and the evidence should be appraised accordingly.

Effect of exercise on desire to smoke

It is a well-established finding that an acute bout of low to moderate intensity exercise regulates desire to smoke in temporarily abstinent smokers (Taylor et al., 2007; Roberts et al., 2012). The findings from the present study will add to the existing body of literature. Further, the present study examined the relationship between desire to smoke and topography markers.

In the present study, the condition by time effect was significant. Participants reported lower desire to smoke in the exercise condition compared to the passive sitting condition. In congruence with past research (e.g. Daniel et al., 2004; Faulkner et al., 2010), this study demonstrates that an exercise bout of short duration and moderate intensity reduces desire to smoke, compared to a passive sitting condition.

Post-condition desire to smoke was correlated with the topography variable, total duration. The correlation was significant at Time 2a and Time 2b; as post-condition

desire to smoke increased, total duration of cigarette increased. Despite being non-significant, desire to smoke was also correlated with puff volume and duration; as desire to smoke increased, volume and duration increased. Also non-significant, desire to smoke was correlated with inter-puff interval (IPI); as desire to smoke increased, the time between puffs increased. The correlation of post-condition desire to smoke to smoking topography should be further examined. Faulkner and colleagues (2010) investigated the relationship between craving reduction and topography markers. This research could be refined with the use of a between-subject design.

Ancillary Analyses for Desire to Smoke Reduction

A series of post-hoc tests were conducted once the main findings were found to be non-significant. The aim was to examine topography change using only a sub-group of participants in the exercise condition who reported a desire to smoke reduction post-condition. It was postulated that participants in the exercise condition who reported a desire to smoke reduction would show a more pronounced change in smoking topography. A series of one-way repeated measures ANOVAs were conducted. The time effect for topography (i.e., puff count, puff volume, puff duration, inter-puff interval, and total duration) was non-significant.

The sub-group was under-powered to detect a change in topography. However, upon visual inspection of the data, a number of trends were present. First, the number of puffs was reduced subsequent to exercise. On average, this sub-group took 1.5 less puffs compared to baseline. Second, volume increased for the first cigarette after exercise, but volume returned to baseline for the subsequent cigarette. Puff volume is correlated with

puff duration ($r = .628$), thus, it follows that puff duration followed a similar trend.

Third, IPI increased for the first cigarette after exercise. On average, the time between puffs increased by 1.5 seconds. This trend did not hold for the second cigarette. Fourth, the total duration decreased subsequent to exercise. On average, the sub-group spent 12 fewer seconds with the first cigarette, compared to baseline. The trends for this sub-group were congruent with the previously reported patterns of the total sample. Overall, the results do not change dramatically when assessing only participants in the exercise group who reported a lower desire to smoke post-condition.

A desire to smoke reduction may be needed to change objective topography. But, it is not known what amount of reduction is needed. The current study included participants who reported a minimum one point reduction of desire to smoke. This criterion was chosen because the sample size was small. A greater reduction of desire to smoke (e.g., 3 point reduction on 7 point scale) may be required to change topography. In future trials, a desire to smoke reduction that is relative to pre-condition values should be considered. Future research also ought to consider if a critical level of desire to smoke must be reached to see topography change. The aforementioned questions should be honed in on in the early stage of exercise and topography research.

Strengths and Limitations

The present study had a number of strengths. First, the CReSS Pocket was used to measure topography. The CReSS Pocket is a portable, user-friendly device which allowed for measurement in a “natural” setting. Second, the setting where topography was assessed was held constant. A past study showed that topography can change across

social and non-social settings (Miller, Frederiksen, & Hosford, 1979). This study was designed to minimize natural topography change. Third, the design was strong; valid assessments were used, subjects were randomized according to stratification criteria, group allocation was concealed, and the randomization criteria minimized contamination of extraneous factors.

It is important to acknowledge the limitations of the current study. First, this study was a pilot study and was under-powered to detect a difference in smoking topography. Research with a larger sample size may contribute to the findings. Second, random allocation was based on a number of stratification criteria; yet, there were significant differences between the exercise and passive condition (e.g., age, FTND, puff count, inter-puff interval). Therefore, the groups were not comparable on known and unknown factors that may have influenced the findings. Third, the sample of this study was 79% female. Eissenberg and colleagues (1999) demonstrated that sex effects topography. The sex profile of the current study does not represent the general smoking population. Last, the intervention was a supervised exercise session in a laboratory. The dose of exercise was closely monitored, which strengthened the internal validity of this study. But, it is unknown how the findings would generalize to a natural environment.

Future Directions

The present study did not find support that a solitary session of exercise alters smoking topography. Future research should revise the exercise dose (i.e., type, time, intensity) in order to assess what exercise dose is most effective. Also, future work using a larger sample may overcome the issue surrounding lack of power and disparity between

groups at baseline. Other limitations identified above should also be addressed.

Sub-groups of smokers should also be examined. One's level of nicotine dependence and/or gender may have an effect on topography. Also, future research should use a less active sample (< 600 MET – minutes/week). A session of exercise may be more effective for this sub-group. Examination of topography in a sub-group of smokers who experience extreme desire to smoke relief may also be beneficial. This research may assist in delineating factors that affect exercise-related topography change, and ultimately harm reduction.

Past research found that the CReSS Pocket influenced subjective measures of smoking (e.g., increased smoking difficulty) (Blank et al., 2009). There is limited research on smokers' perceptions of the CReSS Pocket and its influence on smoking behavior. Future work should compare self-reported acceptability of the CReSS Pocket to objective smoking topography.

There are logistical concerns associated with use of the CReSS Pocket (e.g., cost). The past evidence for a delay in *ad libitum* smoking subsequent to exercise (Reeser, 1983; Taylor & Katomeri, 2007; Thayer et al., 1993) is more fruitful than the evidence presented here for topography change. Once a person returns to smoking, the change in objective smoking topography is non-significant. Exercise as a harm reduction strategy may therefore only apply to delaying *ad libitum* smoking and ultimately reducing the number of cigarettes per day.

Smokers' motives for smoking and stage of readiness to quit should also be considered. A smoker who is unwilling to quit may smoke in a different way than a smoker who plans to quit in the near future. Also, a smoker may lower their rate of

consumption prior to a quit date. But, it is unknown if a change in topography occurs concurrently with smoking reduction. It would also be interesting to examine topography in relation to ones smoking motives. For example, an exercise session may alter topography to a greater degree in people who smoke for pleasure versus those who smoke to cope with stress. This work would provide insight into factors that influence exercise-related smoking topography change.

A solitary session of exercise can decrease desire to smoke. Desire to smoke is related to smoking topographical indices (i.e., total duration), and may also be the mechanism behind smoking topography change. But, from this study it is not clear if topography changes are more pronounced after a desire to smoke reduction. This study was under-powered, therefore future research is needed. Future research should also consider the critical level of reduction needed. It is not likely that a control group will report a desire to smoke reduction. Therefore, investigating this issue may be a challenge.

General Summary and Conclusions

There are 'hardened' smokers who do not want to quit or find it very difficult to quit. 'Hardened' smokers will continue to smoke regardless of the life-threatening consequences. Moreover, the success rate of unaided attempts is 3-5% (Hughes et al., 2004). A harm reduction approach, which minimizes the risk of morbidity and mortality, is well-suited for this population. The general objective of this study was to examine if exercise, as it relates to smoking behavior change, is an efficacious harm reduction strategy. To do this, the effect of an acute bout of exercise on objective smoking

topography was examined. A sophisticated assessment device, the CReSS Pocket, was used. The present study provides the first randomized controlled trial evidence that exercise-related smoking topography change is small. Hence, the efficacy of exercise as a harm reduction strategy is not supported. Moving forward, in order to help ‘hardened’ smokers, a top priority of researchers and health care providers ought to be the development and evaluation of effective harm reduction strategies. By addressing the limitations of this research, the role of exercise as a harm reduction strategy can be better understood.

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Appendix A



Use of Human Participants - Ethics Approval Notice

Principal Investigator: Prof. Harry Prapavessis
 Review Number: 18109
 Review Level: Full Board
 Approved Local Adult Participants: 100
 Approved Local Minor Participants: 0
 Protocol Title: Dose an acute bout of exercise affect smoking satisfaction?
 Department & Institution: Kinesiology, University of Western Ontario
 Sponsor:
 Ethics Approval Date: July 19, 2011 Expiry Date: March 31, 2012

Documents Reviewed & Approved & Documents Received for Information:

Document Name	Comments	Version Date
UWO Protocol		
Letter of Information & Consent	Exercise	2011/06/29
Advertisement		
Letter of Information & Consent	Control	2010/06/29
Letter of Information & Consent	Debriefing	2011/07/12

This is to notify you that the University of Western Ontario Health Sciences Research Ethics Board (HSREB) which is organized and operates according to the Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans and the Health Canada/ICH Good Clinical Practice Practices: Consolidated Guidelines; and the applicable laws and regulations of Ontario has reviewed and granted approval to the above referenced study on the approval date noted above. The membership of this HSREB also complies with the membership requirements for REB's as defined in Division 5 of the Food and Drug Regulations.

The ethics approval for this study shall remain valid until the expiry date noted above assuming timely and acceptable responses to the HSREB's periodic requests for surveillance and monitoring information. If you require an updated approval notice prior to that time you must request it using the UWO Updated Approval Request form.

Member of the HSREB that are named as investigators in research studies, or declare a conflict of interest, do not participate in discussions related to, nor vote on, such studies when they are presented to the HSREB.

The Chair of the HSREB is Dr. Joseph Gilbert. The UWO HSREB is registered with the U.S. Department of Health & Human Services under the IRB registration number IRB 00000940.

Signature

Ethics Officer to Contact for Further Information

This is an official document. Please retain the original in your files.

The University of Western Ontario
 Office of Research Ethics



Use of Human Participants - Ethics Approval Notice

Principal Investigator: Prof. Harry Prapavessis
Review Number: 18109
Review Level: Delegated
Approved Local Adult Participants: 100
Approved Local Minor Participants: 0
Protocol Title: Dose an acute bout of exercise affect smoking satisfaction?
Department & Institution: Kinesiology, University of Western Ontario
Sponsor:
Ethics Approval Date: December 08, 2011 **Expiry Date:** August 31, 2032
Documents Reviewed & Approved & Documents Received for Information:

Document Name	Comments	Version Date
Revised UWO Protocol	Revised study objectives and hypothesis, Revised study methodology, Revised study instruments, Revised recruitment	
Revised Letter of Information & Consent	Exercise	2011/11/01
Revised Letter of Information & Consent	Control	2011/11/01
Other	Telephone script	
Revised Study End Date		

This is to notify you that The University of Western Ontario Research Ethics Board for Health Sciences Research Involving Human Subjects (HSREB) which is organized and operates according to the Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans and the Health Canada/ICH Good Clinical Practice Practices: Consolidated Guidelines; and the applicable laws and regulations of Ontario has reviewed and granted approval to the above referenced revision(s) or amendment(s) on the approval date noted above. The membership of this REB also complies with the membership requirements for REB's as defined in Division 5 of the Food and Drug Regulations.

The ethics approval for this study shall remain valid until the expiry date noted above assuming timely and acceptable responses to the HSREB's periodic requests for surveillance and monitoring information. If you require an updated approval notice prior to that time you must request it using the UWO Updated Approval Request Form.

Members of the HSREB who are named as investigators in research studies, or declare a conflict of interest, do not participate in discussion related to, nor vote on, such studies when they are presented to the HSREB.

The Chair of the HSREB is Dr. [Joseph Gilbert](#). The UWO HSREB is registered with the U.S. Department of Health & Human Services under the IRB

Signature _____

This is an official document. Please retain the original in your files.

The University of Western Ontario
Office of Research Ethics

LAWSON HEALTH RESEARCH INSTITUTE**FINAL APPROVAL NOTICE**

RESEARCH OFFICE REVIEW NO.: R-11-603

PROJECT TITLE: Does an acute bout of exercise affect smoking satisfaction?

PRINCIPAL INVESTIGATOR: Dr. Harry Prapavessis

DATE OF REVIEW BY CRIC: November 19, 2011

Health Sciences REB#:18109

Please be advised that the above project was reviewed by the Clinical Research Impact Committee and the project:

Was Approved

PLEASE INFORM THE APPROPRIATE NURSING UNITS, LABORATORIES, ETC. BEFORE STARTING THIS PROTOCOL. THE RESEARCH OFFICE NUMBER MUST BE USED WHEN COMMUNICATING WITH THESE AREAS.

Dr. David Hill
V.P. Research
Lawson Health Research Institute

All future correspondence concerning this study should include the Research Office Review Number and should be directed to Sherry Paiva, CRIC Liaison, LHSC, Rm. C210, Nurses Residence, South Street Hospital.

cc: Administration



LETTER OF INFORMATION

Study Title: Does an acute bout of exercise affect smoking satisfaction?

Principal Study Investigator:

Harry Prapavessis, Ph.D. (School of Kinesiology, Western University)

Co-Investigators:

Terri Schneider, B.A. (School of Kinesiology, Western University)

Stefanie De Jesus, Ph.D. (cond.), M.A., B.Sc. (School of Kinesiology, Western University)

You are being invited to participate in a research study looking at the effects of a short period of exercise on smoking behaviour. This is a randomized control trial (a type of research study), which includes eligible volunteers who choose to take part. Please take your time to make a decision, and discuss this proposal with your personal doctor, family members and friends as you feel inclined. The purpose of this letter is to provide you with the information you require to make an informed decision on participating in this research. This letter contains information to help you decide whether or not to participate in this research study. It is important for you to know why the study is being conducted and what it will involve. Please take the time to read this carefully and feel free to ask questions if anything is unclear or there are words or phrases you do not understand. We are asking you to take part because you are an adult between 18 and 64 years of age who smokes.

Purpose of the study

Exercise has been shown to help with traditional cessation strategies. A single bout of exercise, low to moderate in intensity, can help regulate cravings, withdrawal symptoms and smoking topography. Smoking topography refers to the measurement of smoking behaviour, which includes puff volume, maximum puff velocity, inter-puff interval, puff duration, number of puffs per cigarette, and the time to smoke a single cigarette.

The primary objective of this study is to examine the effects of an acute bout of moderate intensity exercise on smoking satisfaction and smoking behaviour (smoking topography) following a period of smoking abstinence. The second purpose of this study is to assess the influence of nicotine metabolism rate (how quickly your body breaks down nicotine) on smoking satisfaction and topography.

Participants

One hundred participants will be asked to take part in this research. To be eligible to participate, you must meet the following criteria: 18 and 64 years of age, smoke 10 or more cigarettes per day for more than 2 years, have not been engaged in a serious quit

attempt in the last six months, must not be suffering from an illness (e.g. cold) that would affect your typical smoking behavior, do not have a medical condition that prevents you from exercising, not be pregnant or intending on becoming pregnant. You must also be able to read and write in English and have a telephone or e-mail account that the investigators can contact you at.

Research Procedure

If you choose to take part in this study, you will be asked to complete three study components: A) the first laboratory session, B) abstain from smoking, C) the second laboratory session.

The laboratory sessions will be held at the Exercise and Health Psychology Laboratory (EHPL) at The University of Western Ontario (UWO). The EHPL is located in Room 408 of the Labatt Health Sciences Building. Prior to the first meeting you will be asked to complete the Physical Activity Readiness Questionnaire (PAR-Q). The pre-screening period, including the completion of the PAR-Q will take approximately 20 minutes to complete. Each laboratory meeting will take approximately 75 minutes.

A) First laboratory session

During your first laboratory session, you will complete a questionnaire package (see Item 1) and the following information will be collected: resting heart rate (see Item 2), weight, height, breath carbon monoxide levels (see Item 3) and saliva samples (see Item 4) for nicotine metabolism analysis. Afterwards, you will be asked to familiarize yourself with the CReSS Pocket (see Item 5) by taking a few puffs of an electronic cigarette (see Item 6). Following this, you will be asked to smoke a cigarette (of your regular brand) with the CReSS Pocket, at a minimum of 10 metres from any building entrance of the Labatt Health Sciences Building. It is within your rights to refuse a cigarette at any point during this research study and we will honour your rights. At the end of your first laboratory session, we will schedule your second laboratory session within seven days of your first laboratory session.

B) Abstain from smoking

You will be asked to abstain from smoking for at least 18 hours prior to your second laboratory visit (see Item 7). We will confirm that you have not smoked in the last 18 hours by asking you to complete a second carbon monoxide test (see Item 3).

C) Second laboratory session

During your second laboratory session, smoking abstinence will first be confirmed by breath carbon monoxide levels (see Item 3), and then you will be asked to passively sit on a chair for 10 minutes. Approximately 5 minutes after you will smoke a cigarette using the CReSS Pocket (see Item 5) and complete a questionnaire package (see Item 1). You will then sit passively for approximately 30 minutes and then once again smoke a cigarette using the CReSS Pocket (see Item 5) and complete a questionnaire packaged (see Item 1). You will be asked to smoke outside the Labatt Health Sciences building, at a minimum of 10 meters away from any building entrance. It is within your rights to refuse a cigarette at any point during this research study and we will honour your rights.

Experimental description (items 1-10)

Item 1: Questionnaire package

Time Involvement: 30 minutes

The questionnaire package will include: a demographic questionnaire, dependence on nicotine questionnaire, physical activity questionnaire, smoking withdrawal questionnaire, smoking motives questionnaire, stage of change questionnaire, and questions about your cravings and comfort using the CReSS device.

Item 2: Measuring Resting Heart Rate

Time Involvement: 5 minutes

Heart rate will be measured by a Polar heart rate transmitter, which consists of a watch and a strap held in place under your bust line by an elastic strap.

Item 3: Carbon monoxide assessments

Time Involvement: 15 seconds each

We will measure your smoking status twice by using a breath carbon monoxide analyzer: once at each laboratory session. We will ask you to breathe into a machine called the Bedfont Smokerlyzer. This machine measures the amount of carbon monoxide (CO) as you breathe out. It does not cause any harm or discomfort to you. This Smokerlyzer measures how much you have smoked in the past several hours. The second test (just prior to treatment at the second laboratory session) will be done to verify that you have abstained from smoking for at least 18 hours.

Item 4: Provide saliva sample on cotton swab

Time Involvement: 2 minutes

From this saliva sample we will measure the 3-hydroxycotinine and cotinine within your body to determine a 3-hydroxycotinine/cotinine ratio. This ratio tells us about the rate at which your body metabolizes (breaks down) nicotine.

Item 5: CReSS Pocket Device

Time Involvement: 15 minutes

We will measure your smoking topography using the CReSS Pocket. This hand-held, computer-based machine measures how you smoke a cigarette (puff count, puff volume, puff duration, inter-puff interval and time to first puff) by placing your cigarette in the device and breathing through the sterilized orifice of the device. The CReSS Pocket does not cause any harm or discomfort to you.

Item 6: Electronic cigarette

Time Involvement: 10 minutes

Electronic cigarettes, also known as e-cigarettes, are electrical devices that attempt to simulate the act of tobacco smoking. This e-cigarette may mimic an actual cigarette except it does not contain nicotine (0mg of nicotine). When a smoker draws air through the e-cigarette, an airflow sensor activates the battery that turns the tip of the cigarette red to simulate smoking and heats the atomizer to vaporize the propylene glycol into a mist. The vapour is odorless and vanishes quickly. Propylene glycol is an FDA-approved

compound that is used in many food products, cosmetics, and toothpaste. Upon inhalation, the aerosol vapor evaporates and vanishes.

Item 7: Abstain from smoking for 18-24 hours

We ask that prior to your second laboratory session you abstain from smoking for at least 18 hours (18-24hours).

Risks

While in the study, you may experience side effects. Known side effects are listed below, but other effects may occur that we cannot predict. If you are or become pregnant you must notify the investigator as smoking involves risks to the foetus.

Temporary Smoking Abstinence: You may experience withdrawal symptoms during the time you are abstaining from cigarettes. Such symptoms may include feeling edgy and nervous, dizzy, sweaty, having trouble concentrating, headaches, insomnia, increased appetite and weight gain, muscular pain, constipation, fatigue, or having an upset stomach. All of these symptoms are common for those who quit smoking so you should not be alarmed, as these symptoms will go away within a few days. Moderate intensity exercise has been shown to reduce smoking withdrawal symptoms, so it could be that those in the moderate intensity exercise treatment condition experience relief from some of these symptoms. Another common side effect of quitting smoking is that your “smoker’s cough” gets worse for the first few days after you quit. This is your body’s way of attempting to rid the lungs of excess toxins. Your smoker’s cough will improve to a great extent after you have become smoke-free for a number of days.

Benefits

Involvement in this study could assist you in becoming smoke free. You may not get a personal benefit from participating in this study but your participation may help us get knowledge to shape the development of future exercise and smoking cessation programs.

Participation

Participation in this study is voluntary. You may refuse to participate, refuse to answer any questions or withdraw from the study at any time with no effect on your academic or employment status. If you decide to take part you will be given this Letter of Information to keep and be asked to sign the consent form. If you withdraw from the study, you maintain the right to request that any data collected from you not be used in the study. If you make such a request, all of the data collected from you will be destroyed. Please contact the study coordinator, Terri Schneider, if you wish to withdraw from the study. If you are participating in another study at this time, please inform the study researchers right away to determine if it is appropriate for you to participate in this study.

Biological Specimens

The sample we are asking of you during the course of this study is saliva. This saliva sample will be used for the current study only. The saliva sample will be frozen in our laboratory freezer, then shipped and analyzed at the University of Toronto in Canada for an indication of how quickly you metabolize (break down) nicotine in your body (3-

hydroxycotinine: cotinine ratio). Bar codes will be used to label your saliva samples, so the laboratory technicians analyzing your saliva will have no information as to who provided the saliva sample. The samples will be stored for a minimum of 3 years. Usage and potential research value will be reviewed annually thereafter. It is typical to keep the samples collected from a research study for 6 years after the study has been conducted. Once the research value is deemed lower than sufficient to justify storage costs, the samples will be destroyed by standard disposal of biohazardous waste laboratory policies and procedures. If we would like to use your saliva for a different study or for a different purpose in this study, we will send you a new letter of information and ask your permission.

Any specimen(s) obtained for the purposes of this study will become the property of the study researchers and once you have provided the specimens you will not have access to them. The specimen(s) will be discarded or destroyed once they have been used for the purposes described in the protocol. The specimen(s) will be used for research and such use may result in inventions or discoveries that could become the basis for new products or diagnostic or therapeutic agents. In some instances, these inventions and discoveries may be of potential commercial value and may be patented and licensed by the researcher. It is not the purpose of this study to use specimens for any inventions or patents, so it is very unlikely that this will occur as an outcome of a sample you provide us with. You will not receive any money or other benefits derived from any commercial or other products that may be developed from use of the specimens.

New Findings

If, during the course of this study, new information becomes available that may relate to your willingness to continue to participate, this information will be provided to you by the investigator.

Confidentiality

We will be collecting information from 100 participants for this study. All the information you provide to the researcher will be kept in the strictest confidence. You will be assigned an identification number and all data collected from you will be recorded and stored under this number only. All data will be stored in coded form on computers accessible only to research staff in a secure office. You will not be identified in any documents relating to the research. No information obtained during the study will be discussed with anyone outside of the research team. If the results of the study are published, your name will not be used.

Representatives of the University of Western Ontario Health Sciences Research Ethics Board and regulatory bodies (Health Canada) may contact you or require access to your study-related records to monitor the conduct of the research. If we find information we are required by law to disclose, we cannot guarantee confidentiality. We will strive to ensure the confidentiality of your research-related records. Absolute confidentiality cannot be guaranteed as we may have to disclose certain information under certain laws.

Compensation

Free parking will be provided for your visits to the laboratory. If public transportation is required for participation in this study you will be reimbursed to a maximum of \$10.00.

If you have private medical or life insurance, you should check with your insurance company before you agree to take part in the study to confirm your participation in this study will not affect your insurance coverage and/or access to benefits.

This study is covered by an insurance policy and if during the course of the study any injury should occur to you, not due to your fault or negligence, all medical expenses necessary to treat such injury will be paid provided: a) you comply at all times with the study researcher's instructions b) you promptly report any such injury to the study researchers conducting the study, and c) the expenses are not otherwise covered by your provincial health care. Financial compensation for such things as lost wages, disability or discomfort due to this type of injury is not routinely available. You do not waive any legal rights by signing the consent form.

Alternative treatments

If you decide not to participate or if you withdraw from the study before it is completed, the alternative course of treatment could be to see your family physician for advice on how to quit smoking. Another alternative to the procedures described above is not to participate in the study and continue on just as you do now.

Optional Follow-Up Telephone Interviews

At the completion of the study, you will be given the option of participating in the follow-up phase of this study, consisting of a yearly update of your health and/or the re-use of your smoking behavior information. This will consist of a short telephone interview (less than 15 minutes) conducted once a year, for twenty years, where we will ask you if you have had any major health complications in the past year, such as heart disease or cancer. This research has the same purpose as the original study with a focus on comparing these issues between males and females and identifying potential contributors to future health status. If you choose to provide consent, your smoking topography, nicotine metabolism, and questionnaire data will be used in future smoking-related research. Your confidentiality will be protected as outlined above (refer to page 5).

If you would like to have your name and contact information kept on file, we can ask you about the possibility of participating in future studies. If you agree to participate in the study follow-up and/or be contacted for participation in other studies, you may refuse to answer any questions or withdraw your consent at any time by informing a member of the research team. Your name and contact information will not be shared with anyone outside of the research team. The potential risks and discomfort, benefits and confidentiality and privacy issues are identical to those outlined in the confidentiality section of this Letter of Information. You will not be compensated financially for participation in the follow-up phase of this study. If you have any questions or concerns about this research, you should contact study investigators.

Contact person(s)

If you have any questions about your rights as a research participant or the conduct of the study you may contact Dr. David Hill, Scientific Director, Lawson Health Research Institute. If you have any questions about the study, please contact the study coordinator, Terri Schneider.

This letter is for you to keep. You will be given a copy of this letter of information and consent form once it has been signed. If you have any concerns, please feel free to contact one of the researchers below. You may request the general findings of this research study from the researchers after the study is complete. You do not waive any legal rights by signing the consent form.

Terri Schneider
Graduate Student
School of Kinesiology,
Western University

Stefanie De Jesus
Graduate Student
School of Kinesiology,
Western University

Dr. Harry Prapavessis
Professor
School of Kinesiology,
Western University



LETTER OF INFORMATION

Study Title: Does an acute bout of exercise affect smoking satisfaction?

Principal Study Investigator:

Harry Prapavessis, Ph.D. (School of Kinesiology, Western University)

Co-Investigators:

Terri Schneider, B.A. (School of Kinesiology, Western University)

Stefanie De Jesus, Ph.D. (cond.), M.A., B.Sc. (School of Kinesiology, Western University)

You are being invited to participate in a research study looking at the effects of a short period of exercise on smoking behaviour. This is a randomized control trial (a type of research study), which includes eligible volunteers who choose to take part. Please take your time to make a decision, and discuss this proposal with your personal doctor, family members and friends as you feel inclined. The purpose of this letter is to provide you with the information you require to make an informed decision on participating in this research. This letter contains information to help you decide whether or not to participate in this research study. It is important for you to know why the study is being conducted and what it will involve. Please take the time to read this carefully and feel free to ask questions if anything is unclear or there are words or phrases you do not understand. We are asking you to take part because you are an adult between 18 and 64 years of age who smokes.

Purpose of the Study

Exercise has been shown to help with traditional cessation strategies. A single bout of exercise, low to moderate in intensity, can help regulate cravings, withdrawal symptoms and smoking topography. Smoking topography refers to the measurement of smoking behaviour, which includes puff volume, maximum puff velocity, inter-puff interval, puff duration, number of puffs per cigarette, and the time to smoke a single cigarette.

The primary objective of this study is to examine the effects of an acute bout of moderate intensity exercise on smoking satisfaction and smoking behaviour (smoking topography) following a period of smoking abstinence. The second purpose of this study is to assess the influence of nicotine metabolism rate (how quickly your body breaks down nicotine) on smoking satisfaction and topography.

Participants

One hundred participants will be asked to take part in this research. To be eligible to participate, you must meet the following criteria: 18 to 64 years of age, smoke 10 or more cigarettes per day for more than 2 years, have not engaged in a serious quit attempt

in the last six months, must not be suffering from an illness (e.g. cold) that would affect your typical smoking behavior, do not have a medical condition that prevents you from exercising, not be pregnant or intending on becoming pregnant. You must also be able to read and write in English and have a telephone or e-mail account that the investigators can contact you at.

Research Procedure

If you choose to take part in this study, you will be asked to complete three study components: A) the first laboratory session, B) abstain from smoking, C) the second laboratory session.

The laboratory sessions will be held at the Exercise and Health Psychology Laboratory (EHPL) at The University of Western Ontario (UWO). The EHPL is located in Room 408 of the Labatt Health Sciences Building. Prior to the first meeting you will be asked to complete the Physical Activity Readiness Questionnaire (PAR-Q). The pre-screening period, including the completion of the PAR-Q will take approximately 20 minutes to complete. Each laboratory meeting will take approximately 75 minutes.

A) First laboratory session

During your first laboratory session, complete a questionnaire package (see Item 1) and the following information will be collected: resting heart rate (see Item 2), weight, height, breath carbon monoxide levels (see Item 3) and saliva samples (see Item 4) for nicotine metabolism analysis. Afterwards, you will be asked to familiarize yourself with the CReSS Pocket (see Item 5) by taking a few puffs of an electronic cigarette (see Item 6). Following this, you will be asked to smoke a cigarette (of your regular brand) with the CReSS Pocket, at a minimum of 10 metres from any building entrance of the Labatt Health Sciences Building. It is within your rights to refuse a cigarette at any point during this research study and we will honour your rights. At the end of your first laboratory session, we will schedule your second laboratory session within seven days of your first laboratory session.

B) Abstain from smoking

You will be asked to abstain from smoking for at least 18 hours prior to your second laboratory visit (see Item 7). We will confirm that you have not smoked in the last 18 hours by getting you to complete a second carbon monoxide test (see Item 3).

C) Second laboratory session

During your second laboratory session, smoking abstinence will first be confirmed by breath carbon monoxide levels (see Item 3), and then you will be asked to exercise at a moderate intensity on a treadmill for 10 minutes. Approximately 5 minutes after exercise you will smoke a cigarette using the CReSS Pocket (see Item 5) and complete a questionnaire package (see Item 1). You will then sit passively for approximately 30 minutes and then once again smoke a cigarette using the CReSS Pocket (see Item 5) and complete a questionnaire package (see Item 1). You will be asked to smoke outside the Labatt Health Sciences Building, at a minimum of 10 meters away from any building

entrance. It is within your rights to refuse a cigarette at any point during this research study and we will honour your rights.

Experimental description (items 1-10)

Item 1: Questionnaire package

Time Involvement: 30 minutes

The questionnaire package will include: a demographic questionnaire, dependence on nicotine questionnaire, physical activity questionnaire, smoking withdrawal questionnaire, smoking motives questionnaire, stage of change questionnaire, and questions about your cravings and comfort using the CReSS device.

Item 2: Measuring Resting Heart Rate

Time Involvement: 5 minutes

Heart rate will be measured by a Polar heart rate transmitter, which consists of a watch and a strap held in place under your bust line by an elastic strap.

Item 3: Carbon monoxide assessments

Time Involvement: 15 seconds each

We will measure your smoking status twice by using a breath carbon monoxide analyzer: once at each laboratory session. We will ask you to breathe into a machine called the Bedfont Smokerlyzer. This machine measures the amount of carbon monoxide (CO) as you breathe out. It does not cause any harm or discomfort to you. This Smokerlyzer measures how much you have smoked in the past several hours. The second test (just prior to treatment at the second laboratory session) will be done to verify that you have abstained from smoking for at least 18 hours.

Item 4: Provide saliva sample on cotton swab

Time Involvement: 2 minutes

From this saliva sample we will measure the 3-hydroxycotinine and cotinine within your body to determine a 3-hydroxycotinine/cotinine ratio. This ratio tells us about the rate at which your body metabolizes (breaks down) nicotine.

Item 5: CReSS Pocket Device

Time Involvement: 15 minutes

We will measure your smoking topography using the CReSS Pocket. This hand-held, computer-based machine measures how you smoke a cigarette (puff count, puff volume, puff duration, inter-puff interval and time to first puff) by placing your cigarette in the device and breathing through the sterilized orifice of the device. The CReSS Pocket does not cause any harm or discomfort to you.

Item 6: Electronic Cigarette

Time Involvement: 10 minutes

Electronic cigarettes, also known as e-cigarettes, are electrical devices that attempt to simulate the act of tobacco smoking. This e-cigarette may mimic an actual cigarette except it does not contain nicotine (0mg of nicotine). When a smoker draws air through

the e-cigarette, an airflow sensor activates the battery that turns the tip of the cigarette red to simulate smoking and heats the atomizer to vaporize the propylene glycol into a mist. The vapour is odorless and vanishes quickly. Propylene glycol is an FDA-approved compound that is used in many food products, cosmetics, and toothpaste. Upon inhalation, the aerosol vapor evaporates and vanishes.

Item 7: Abstain from smoking for 18-24 hours

We ask that prior to your second laboratory session you abstain from smoking for at least 18 hours (18-24hours).

Risks

While in the study, you may experience side effects. Known side effects are listed below, but other effects may occur that we cannot predict. If you are or become pregnant you must notify the investigator as smoking involves risks to the foetus.

Exercise: There are some inherent risks of injury associated with exercise participation, particularly among people who are not used to exercising. You may, for example, feel mild muscle “tightness” or soreness that lasts for a couple of days. The possible benefits associated with exercise may outweigh the potential minor discomfort of beginning a supervised, laboratory-based exercise program. To minimize the physical risks of exercise, proper warm-up/cool-down and stretching protocols will be performed by a trained exercise counsellor. Additionally, the exercise program delivered will be tailored to your individual fitness level, and modified according to your comfort level. Furthermore, you will only be allowed to participate in this exercise program if you complete the PAR-Q (Physical Activity Readiness Questionnaire) forms to ensure that it is safe for you to begin an exercise program. The exercise facilitator will be both CPR and First Aid trained, and experienced in working with previously inactive populations. If any physical or mental risks arise during treatment, The Student Emergency Response Team (SERT) will be available to provide immediate assistance. SERT will assist the exercise supervisor until the 911 emergency services arrive. Should you have a minor injury while exercising you will receive medical treatment onsite as required. A first aid kit and ice packs will be available for minor injuries.

Temporary Smoking Abstinence: You may experience withdrawal symptoms during the time you are abstaining from cigarettes. Such symptoms may include feeling edgy and nervous, dizzy, sweaty, having trouble concentrating, headaches, insomnia, increased appetite and weight gain, muscular pain, constipation, fatigue, or having an upset stomach. All of these symptoms are common for those who quit smoking so you should not be alarmed, as these symptoms will go away within a few days. Moderate intensity exercise has been shown to reduce smoking withdrawal symptoms, so it could be that those in the moderate intensity exercise treatment condition experience relief from some of these symptoms. Another common side effect of quitting smoking is that your “smoker’s cough” gets worse for the first few days after you quit. This is your body’s way of attempting to rid the lungs of excess toxins. Your smoker’s cough will improve to a great extent after you have become smoke-free for a number of days.

Benefits

Involvement in this study could assist you in becoming smoke free. You may not get a personal benefit from participating in this study but your participation may help us get knowledge to shape the development of future exercise and smoking cessation programs.

Participation

Participation in this study is voluntary. You may refuse to participate, refuse to answer any questions or withdraw from the study at any time with no effect on your academic or employment status. If you decide to take part you will be given this Letter of Information to keep and be asked to sign the consent form. If you withdraw from the study, you maintain the right to request that any data collected from you not be used in the study. If you make such a request, all of the data collected from you will be destroyed. Please contact the study coordinator if you wish to withdraw from the study. If you are participating in another study at this time, please inform the study researchers right away to determine if it is appropriate for you to participate in this study.

Biological Specimens

The sample we are asking of you during the course of this study is saliva. This saliva sample will be used for the current study only. The saliva sample will be frozen in our laboratory freezer, then shipped and analyzed at the University of Toronto in Canada for an indication of how quickly you metabolize (break down) nicotine in your body (3-hydroxycotinine: cotinine ratio). Bar codes will be used to label your saliva samples, so the laboratory technicians analyzing your saliva will have no information as to who provided the saliva sample. The samples will be stored for a minimum of 3 years. Usage and potential research value will be reviewed annually thereafter. It is typical to keep the samples collected from a research study for 6 years after the study has been conducted. Once the research value is deemed lower than sufficient to justify storage costs, the samples will be destroyed by standard disposal of biohazardous waste laboratory policies and procedures. If we would like to use your saliva for a different study or for a different purpose in this study, we will send you a new letter of information and ask your permission.

Any specimen(s) obtained for the purposes of this study will become the property of the study researchers and once you have provided the specimens you will not have access to them. The specimen(s) will be discarded or destroyed once they have been used for the purposes described in the protocol. The specimen(s) will be used for research and such use may result in inventions or discoveries that could become the basis for new products or diagnostic or therapeutic agents. In some instances, these inventions and discoveries may be of potential commercial value and may be patented and licensed by the researcher. It is not the purpose of this study to use specimens for any inventions or patents, so it is very unlikely that this will occur as an outcome of a sample you provide us with. You will not receive any money or other benefits derived from any commercial or other products that may be developed from use of the specimens.

New Findings

If, during the course of this study, new information becomes available that may relate to

your willingness to continue to participate, this information will be provided to you by the investigator.

Confidentiality

We will be collecting information from 100 participants for this study. All the information you provide to the researcher will be kept in the strictest confidence. You will be assigned an identification number and all data collected from you will be recorded and stored under this number only. All data will be stored in coded form on computers accessible only to research staff in a secure office. You will not be identified in any documents relating to the research. No information obtained during the study will be discussed with anyone outside of the research team. If the results of the study are published, your name will not be used.

Representatives of the University of Western Ontario Health Sciences Research Ethics Board and regulatory bodies (Health Canada) may contact you or require access to your study-related records to monitor the conduct of the research. If we find information we are required by law to disclose, we cannot guarantee confidentiality. We will strive to ensure the confidentiality of your research-related records. Absolute confidentiality cannot be guaranteed as we may have to disclose certain information under certain laws.

Compensation

Free parking will be provided for your visits to the laboratory. If public transportation is required for participation in this study you will be reimbursed to a maximum of \$10.00.

If you have private medical or life insurance, you should check with your insurance company before you agree to take part in the study to confirm your participation in this study will not affect your insurance coverage and/or access to benefits.

This study is covered by an insurance policy and if during the course of the study any injury should occur to you, not due to your fault or negligence, all medical expenses necessary to treat such injury will be paid provided: a) you comply at all times with the study researcher's instructions b) you promptly report any such injury to the study researchers conducting the study, and c) the expenses are not otherwise covered by your provincial health care. Financial compensation for such things as lost wages, disability or discomfort due to this type of injury is not routinely available. You do not waive any legal rights by signing the consent form.

Alternative treatments

If you decide not to participate or if you withdraw from the study before it is completed, the alternative course of treatment could be to see your family physician for advice on how to quit smoking. Another alternative to the procedures described above is not to participate in the study and continue on just as you do now.

Optional Follow-Up Telephone Interviews

At the completion of the study, you will be given the option of participating in the follow-up phase of this study, consisting of a yearly update of your health and/or the re-

use of your smoking behaviour information. This will consist of a short telephone interview (less than 15 minutes) conducted once a year, for twenty years, where we will ask you if you have had any major health complications in the past year, such as heart disease or cancer. This research has the same purpose as the original study with a focus on comparing these issues between males and females and identifying potential contributors to future health status. If you choose to provide consent, your smoking topography, nicotine metabolism, and questionnaire data will be used in future smoking-related research. Your confidentiality will be protected as outlined above (refer to page 5).

If you would like to have your name and contact information kept on file, we can ask you about the possibility of participating in future studies. If you agree to participate in the study follow-up and/or be contacted for participation in other studies, you may refuse to answer any questions or withdraw your consent at any time by informing a member of the research team. Your name and contact information will not be shared with anyone outside our Research Team. The potential risks and discomfort, benefits and confidentiality and privacy issues are identical to those outlined in the confidentiality section of this letter of information. You will not be compensated financially for participation in the follow-up phase of this study. If you have any questions or concerns about this research, you should contact study investigators.

Contact person(s)

If you have any questions about your rights as a research participant or the conduct of the study you may contact Dr. David Hill, Scientific Director, Lawson Health Research Institute. If you have any questions about the study, please contact the study coordinator, Terri Schneider.

This letter is for you to keep. You will be given a copy of this letter of information and consent form once it has been signed. If you have any concerns, please feel free to contact one of the researchers below. You may request the general findings of this research study from the researchers after the study is complete. You do not waive any legal rights by signing the consent form.

Terri Schneider
Graduate Student
School of Kinesiology,
Western University

Stefanie De Jesus
Graduate Student
School of Kinesiology,
Western University

Dr. Harry Prapavessis
Professor
School of Kinesiology,
Western University

INFORMED CONSENT

Study Title: Does an acute bout of exercise effect smoking satisfaction?

I have read the Letter of Information, have had the nature of the study explained to me and I agree to participate. All questions have been answered to my satisfaction.

Please send me the overall conclusions from this trial: Yes No

I consent for my study related data to be used in future research studies: Yes No

I would like to be contacted for other research studies: Yes No

I would like to participated in the follow-up phase of the study: Yes No

Consenting Signature:

Participant: _____
Please Print Name

Participant: _____
Please Sign Name

Date: _____



Researcher Signature:

Person obtaining informed consent: _____
Please Print Name

Person obtaining informed consent: _____
Please Sign Name

Date: _____



DEBRIEFING LETTER OF INFORMATION

Study Title: Does an acute bout of exercise affect smoking satisfaction?

Principal Study Investigator:

Harry Prapavessis, Ph.D. (School of Kinesiology, Western University)

Co-Investigators:

Terri Schneider, B.A. (School of Kinesiology, Western University)

Stefanie De Jesus, Ph.D. (cond.), M.A., B.Sc. (School of Kinesiology, Western University)

The purpose of this study was to examine the effects of an acute bout of moderate intensity exercise on smoking satisfaction and smoking behaviour (smoking topography) following a period of smoking abstinence. The second purpose of this study was to assess the influence of nicotine metabolism rate (how quickly your body breaks down nicotine) on smoking topography. Previous research has shown that a single bout of exercise, low to moderate in intensity, can help regulate cravings, withdrawal symptoms and smoking topography. Smoking topography refers to the measurement of smoking behaviour, which includes puff volume, maximum puff velocity, inter-puff interval, puff duration, number of puffs per cigarette, and the time to smoke a single cigarette.

In this study, participants were asked to become familiar with the CReSS device using an electronic cigarette (0mg of nicotine), complete a questionnaire package, provide carbon monoxide levels, saliva samples, and smoking topography information using the CReSS Pocket. The purpose of these measures was to examine your smoking behaviour, confirm smoking abstinence and assess the influence of nicotine metabolism rate (how quickly your body breaks down nicotine) on smoking topography.

There were two groups in this study assigned at random (like the flip of a coin): 1) a Moderate Exercise Group and 2) a Passive Sitting Group. Participants in the Moderate Exercise Group exercised at a moderate intensity for 10 minutes on a treadmill at the Exercise and Health Psychology Laboratory (EHPL). Participants in the Passive Sitting Group sat passively for 10 minutes on a chair in the EHPL. You were not informed of the two groups at the beginning of the study in order to eliminate potential bias and contamination. This simply means that having knowledge of the two conditions (Moderate Exercise Group and Passive Sitting Group) may have influenced your responses and smoking topography.

Continued participation in this study was voluntary. You may refuse to participate, refuse to have your information used in the study, and refuse to answer any questions or withdraw from the study at any time with no effect on your academic or employment status.

If you have any additional questions, comments or concerns about the study, please do not hesitate to contact Terri Schneider, Stefanie De Jesus, or Harry Prapavessis.

I have read the Debriefing Letter of Information, have had the nature of the study explained to me and I agree for my data to be used in the study analysis. All questions have been answered to my satisfaction.

Consenting Signature:

Participant: _____
Please Print Name

Participant: _____
Please Sign Name

Date: _____



Researcher Signature:

Person obtaining informed consent: _____
Please Print Name

Person obtaining informed consent: _____
Please Sign Name

Date: _____

**Are you a *smoker* between
18 – 64 years of age?**

**You may be eligible to participate in a
research study being conducted at the
Exercise and Health Psychology Laboratory at
the University of Western Ontario**

**This FREE one week study evaluates smoking
behaviours in response to physical activity levels**

If you are interested, or have any questions, please contact Stefanie or Terri



We look forward to hearing from you!



Appendix B

Physical Activity Readiness
Questionnaire - PAR-Q
(revised 2002)

PAR-Q & YOU

(A Questionnaire for People Aged 15 to 69)

Regular physical activity is fun and healthy, and increasingly more people are starting to become more active every day. Being more active is very safe for most people. However, some people should check with their doctor before they start becoming much more physically active.

If you are planning to become much more physically active than you are now, start by answering the seven questions in the box below. If you are between the ages of 15 and 69, the PAR-Q will tell you if you should check with your doctor before you start. If you are over 69 years of age, and you are not used to being very active, check with your doctor.

Common sense is your best guide when you answer these questions. Please read the questions carefully and answer each one honestly: check YES or NO.

YES	NO	
<input type="checkbox"/>	<input type="checkbox"/>	1. Has your doctor ever said that you have a heart condition <u>and</u> that you should only do physical activity recommended by a doctor?
<input type="checkbox"/>	<input type="checkbox"/>	2. Do you feel pain in your chest when you do physical activity?
<input type="checkbox"/>	<input type="checkbox"/>	3. In the past month, have you had chest pain when you were not doing physical activity?
<input type="checkbox"/>	<input type="checkbox"/>	4. Do you lose your balance because of dizziness or do you ever lose consciousness?
<input type="checkbox"/>	<input type="checkbox"/>	5. Do you have a bone or joint problem (for example, back, knee or hip) that could be made worse by a change in your physical activity?
<input type="checkbox"/>	<input type="checkbox"/>	6. Is your doctor currently prescribing drugs (for example, water pills) for your blood pressure or heart condition?
<input type="checkbox"/>	<input type="checkbox"/>	7. Do you know of <u>any other reason</u> why you should not do physical activity?

If
you
answered

YES to one or more questions

Talk with your doctor by phone or in person BEFORE you start becoming much more physically active or BEFORE you have a fitness appraisal. Tell your doctor about the PAR-Q and which questions you answered YES.

- You may be able to do any activity you want — as long as you start slowly and build up gradually. Or, you may need to restrict your activities to those which are safe for you. Talk with your doctor about the kinds of activities you wish to participate in and follow his/her advice.
- Find out which community programs are safe and helpful for you.

NO to all questions

If you answered NO honestly to all PAR-Q questions, you can be reasonably sure that you can:

- start becoming much more physically active — begin slowly and build up gradually. This is the safest and easiest way to go.
- take part in a fitness appraisal — this is an excellent way to determine your basic fitness so that you can plan the best way for you to live actively. It is also highly recommended that you have your blood pressure evaluated. If your reading is over 144/94, talk with your doctor before you start becoming much more physically active.

DELAY BECOMING MUCH MORE ACTIVE:

- if you are not feeling well because of a temporary illness such as a cold or a fever — wait until you feel better; or
- if you are or may be pregnant — talk to your doctor before you start becoming more active.

PLEASE NOTE: If your health changes so that you then answer YES to any of the above questions, tell your fitness or health professional. Ask whether you should change your physical activity plan.

Informed Use of the PAR-Q: The Canadian Society for Exercise Physiology, Health Canada, and their agents assume no liability for persons who undertake physical activity, and if in doubt after completing this questionnaire, consult your doctor prior to physical activity.

No changes permitted. You are encouraged to photocopy the PAR-Q but only if you use the entire form.

NOTE: If the PAR-Q is being given to a person before he or she participates in a physical activity program or a fitness appraisal, this section may be used for legal or administrative purposes.

"I have read, understood and completed this questionnaire. Any questions I had were answered to my full satisfaction."

NAME _____

SIGNATURE _____

DATE _____

SIGNATURE OF PARENT
or GUARDIAN (for participants under the age of majority) _____

WITNESS _____

Note: This physical activity clearance is valid for a maximum of 12 months from the date it is completed and becomes invalid if your condition changes so that you would answer YES to any of the seven questions.



© Canadian Society for Exercise Physiology www.csep.ca/forms

At what age did you smoke your first cigarette? _____

What brand of cigarette do you smoke most of the time? _____

Do you smoke Filter cigarettes Non-filter cigarettes

Do you smoke regular king size extra large cigarettes

Do you smoke your cigarette about 1/4 of the length
 1/2 of the length
 3/4 of the length
 all the way to the end (the filter)

Do you simply puff your cigarette without inhaling the smoke? Yes No

Do you inhale the smoke seldom
 occasional
 often
 always

How long have you been smoking regularly? _____

INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. The questions will ask you about the time you spent being physically active in the **last 7 days**. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Think about all the **vigorous** activities that you did in the **last 7 days**. **Vigorous** physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Think *only* about those physical activities that you did for at least 10 minutes at a time.

1. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, digging, aerobics, or fast bicycling?

_____ **days per week**

No vigorous physical activities → **Skip to question 3**

2. How much time did you usually spend doing **vigorous** physical activities on one of those days?

_____ **hours per day**

_____ **minutes per day**

Don't know/Not sure

Think about all the **moderate** activities that you did in the **last 7 days**. **Moderate** activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal. Think *only* about those physical activities that you did for at least 10 minutes at a time.

3. During the **last 7 days**, on how many days did you do **moderate** physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.

_____ **days per week**

No moderate physical activities → **Skip to question 5**

4. How much time did you usually spend doing **moderate** physical activities on one of those days?

_____ **hours per day**

_____ **minutes per day**

Don't know/Not sure

Think about the time you spent **walking** in the **last 7 days**. This includes at work and at home, walking to travel from place to place, and any other walking that you might do solely for recreation, sport, exercise, or leisure.

5. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time?

_____ **days per week**

No walking → ***Skip to question 7***

6. How much time did you usually spend **walking** on one of those days?

_____ **hours per day**

_____ **minutes per day**

Don't know/Not sure

The last question is about the time you spent **sitting** on weekdays during the **last 7 days**. Include time spent at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading, or sitting or lying down to watch television.

7. During the **last 7 days**, how much time did you spend **sitting** on a **week day**?

_____ **hours per day**

_____ **minutes per day**

Don't know/Not sure

ID: _____

FAGERSTROM TEST FOR NICOTINE DEPENDENCE

1. How soon after you wake up do you smoke your first cigarette?
 - a) After 60 minutes
 - b) 31-60 minutes
 - c) 6-30 minutes
 - d) Within 5 minutes

2. Do you find it difficult to refrain from smoking in places where it is forbidden?
 - a) No
 - b) Yes

3. Which cigarette would you most hate to give up?
 - a) The first in the morning
 - b) Any other

4. How many cigarettes per day do you smoke?
 - a) 10 or less
 - b) 11-20
 - c) 21-30
 - d) 30 or more

5. Do you smoke more frequently during the first hours after awakening than during the rest of the day?
 - a) No
 - b) Yes

6. Do you smoke even if you are so ill that you are in bed most of the day?
 - a) No
 - b) Yes

\

ID: _____

Desire to Smoke

Using a seven-point scale, please respond to the following statement: *'I have a desire to smoke'*

1	2	3	4	5	6	7
Strongly agree			Neither agree nor disagree			Strongly

PHYSIOLOGICAL DATA

Carbon Monoxide

Visit 1 Micro Smokerlyzer: _____

Visit 2 Micro Smokerlyzer: _____

Visit 2 Number of hours abstained: _____

Exercise Prescription

HR_{rest}: _____

Age: _____

HR_{max}: 220bpm - _____ (age) = _____

HRR: _____ (HR_{max}) - _____ (HR_{rest}) = _____

45% of HRR is calculated as follows:

68% of HRR is calculated as follows:

$[(HR_{max} - HR_{rest}) \times \%] + HR_{rest}$

$[(HR_{max} - HR_{rest}) \times \%] + HR_{rest}$

$[(\text{---}) - (\text{---}) \times 0.45] + \text{---} = \text{---}$

$[(\text{---}) - (\text{---}) \times 0.68] + \text{---} = \text{---}$

Exercise session:

Warm up Length: _____

Total duration: _____ Speed: _____ Incline: _____ HR: _____

Nicotine Metabolism

Saliva sample taken: Yes No

CYP2A6 genotype (polymorphism): _____

CYP2A6 phenotype: High metabolism
 Intermediate metabolism
 Slow metabolism

ACCEPTABILITY QUESTIONNAIRE

ID: _____

Please put a mark on the line that best describes the question being asked in regards to your experience with the Portable Smoking Topography Measurement Device (CReSS Pocket) that used during your laboratory visits compared to smoking a cigarette without the CReSS Pocket.

The CReSS Pocket altered how *much* I puffed (i.e. puff volume)

0	10	20	30	40	50	60	70	80	90	100
STRONGLY DISAGREE				NEUTRAL			STRONGLY AGREE			

The CReSS Pocket altered how *fast* I puffed (i.e. puff velocity)

0	10	20	30	40	50	60	70	80	90	100
STRONGLY DISAGREE				NEUTRAL			STRONGLY AGREE			

The CReSS Pocket altered the *time* between my puffs

0	10	20	30	40	50	60	70	80	90	100
STRONGLY DISAGREE				NEUTRAL			STRONGLY AGREE			

The CReSS Pocket altered how *long* I puffed (i.e. puff duration)

0	10	20	30	40	50	60	70	80	90	100
STRONGLY DISAGREE				NEUTRAL			STRONGLY AGREE			

The CReSS Pocket altered the number of puffs I took per cigarette

0	10	20	30	40	50	60	70	80	90	100
STRONGLY DISAGREE				NEUTRAL			STRONGLY AGREE			

The CReSS Pocket altered the time to smoke my single cigarette

0	10	20	30	40	50	60	70	80	90	100	
STRONGLY DISAGREE				NEUTRAL				STRONGLY AGREE			

The CReSS Pocket made smoking less likely

0	10	20	30	40	50	60	70	80	90	100	
STRONGLY DISAGREE				NEUTRAL				STRONGLY AGREE			

The CReSS Pocket reduced smoking enjoyment

0	10	20	30	40	50	60	70	80	90	100	
STRONGLY DISAGREE				NEUTRAL				STRONGLY AGREE			

The CReSS Pocket affected the taste of the cigarettes

0	10	20	30	40	50	60	70	80	90	100	
STRONGLY DISAGREE				NEUTRAL				STRONGLY AGREE			

The CReSS Pocket made smoking more difficult

0	10	20	30	40	50	60	70	80	90	100	
STRONGLY DISAGREE				NEUTRAL				STRONGLY AGREE			

The CReSS Pocket increased my awareness of how much was smoked

0	10	20	30	40	50	60	70	80	90	100	
STRONGLY DISAGREE				NEUTRAL				STRONGLY AGREE			

Curriculum Vitae for Terri L. Schneider

Education

Master of Arts, Kinesiology	Western University London, ON, Canada	2010-2012
Bachelor of Arts (Honors), Kinesiology	Western University London, ON, Canada	2006-2010

Honors and Awards

Western Graduate Research Scholarship		2010-2012
Dean's List, Western University		2008-2010
The Western Scholarship of Distinction		2006

Teaching Experience

Graduate Teaching Assistant Positions

KIN2230B Research Design in Human Movement Science The University of Western Ontario		2012
KIN1088A Introduction to Sport Psychology The University of Western Ontario		2010

Research Experience

Research Assistant to Dr. Harry Prapavessis Faculty of Health Sciences, Western University		2011-present
<ul style="list-style-type: none"> ▪ Planned and applied a strategy for participant recruitment, delivered participant information sessions, monitored the group exercise program, and supervised research volunteers for the Getting Physical on Cigarettes (Canadian Cancer Society) Clinical trial. 		
Research Assistant to Dr. Harry Prapavessis Faculty of Health Sciences, Western University		2010-present
<ul style="list-style-type: none"> ▪ Applied a physical activity and healthy lifestyle behavior change program to assist cancer survivors in the Colon Health and Life-Long Exercise Change (CHALLENGE) trial. 		

Research Assistant to Amy Kossert 2009-2010
 Faculty of Health Sciences, Western University

- Conducted pre-program health assessments and provided coaching and teaching in rehabilitative physical activity and healthy living for the Exercise and Breast Cancer Clinical Trial.

Membership in Academic or Professional Societies

Canadian Society for Exercise Physiology (CSEP), Certified Personal Trainer 2011

Canadian Action Network for the Advancement, Dissemination and Adoption of Practice- informed Tobacco Treatment (CAN-ADAPTT) 2011

Ontario Kinesiology Association (OKA), Certified Member 2011

Service

ESCEPS Conference Organizing Committee, The University of Western Ontario 2011-2012