Developing Effective Smoking Cessation Treatment Interventions for Individuals with Severe Mental Illness Who are Homeless or Vulnerably Housed

by

Donna L. Pettey MSW, RSW

A DISSERTATION SUBMITTED IN PARTIAL FULFILMENT OF

REQUIREMENTS FOR THE DEGREE OF

DOCTOR OF PHILOSOPHY POPULATION HEALTH

UNIVERSITY OF OTTAWA

Abstract

While tobacco use remains a leading preventable risk factor for mortality and morbidity in Canada (Patra, Rehm, Baliunas & Popova, 2007), the overall smoking prevalence rate of Canadians has decreased substantially from close to 50% of the population in 1965 to 16.1% of the population in 2012 (Canadian Tobacco Use Monitoring Survey (CTUMS) 2012; Reid, Hammond, Rynard & Burkhalter, 2014). However, up to 85% of individuals with a mental illness continue to use tobacco products (Harris, Parle & Gagne, 2007), contributing to an inequitable distribution of negative health outcomes for this population. Individuals with severe mental illness die an estimated twenty-five years earlier than the general population, with sixty per cent of these deaths due to cardiovascular, pulmonary and infectious disease (Parks, Svendsen, Singer, & Foti, 2006). A recent study that examined specific tobacco-attributable deaths in these populations found that tobacco accounted for 53% of deaths in individuals with schizophrenia, 50% of all deaths for those diagnosed with a depressive disorder, and 48% of all deaths for those with a diagnosis of bipolar disorder (Callaghan et al., 2014).

This research project is intended to increase our understanding of what constitutes an effective intervention for smoking cessation and smoking reduction in a population of individuals with severe mental illness who are homeless or vulnerably housed, living in a large urban setting. Two areas of inquiry were proposed. The first inquiry examined data collected as part of a needs assessment to determine the overall prevalence rate of smoking and related behaviours for a population of individuals with severe mental illness receiving services from a community mental health agency. We found that the tobacco use prevalence was 72%, and 62% of smokers had high or very high levels of nicotine dependence; however

almost half of respondents (47%) were interested in quitting or reducing tobacco within the next 6 months. Smokers were found to be over 9 times more likely to have a co-occurring substance use disorder (*OR*=9.44, 95%CI[6.33,14.08]).

The second inquiry was a pilot study conducting a randomized controlled trial design to evaluate smoking cessation and smoking reduction outcomes for two groups of individuals (*n*=61) with severe mental illness receiving different smoking cessation interventions. Clients randomly assigned to the routine Smoking Cessation group (SC-R) received up to 24 weeks of no-cost Nicotine Replacement Therapy (NRT) and clients assigned to the Smoking Cessation Plus group (SC+) received up to 24 weeks of no-cost Nicotine Replacement Therapy (NRT) plus two initial individual sessions of motivational interviewing followed by weekly psychosocial group interventions for up to 24 weeks. Primary outcomes were levels of tobacco use at the 3-month and 6-month follow-up. The 7-day point prevalence abstinence rate measured at 3 months was 21.9% (*n*=7) for the SC+ group and 13.8% (*n*=4) for the SC-R group (*OR*=1.75,95%CI[.46,6.74]). At 6 months, the 7-day point prevalence abstinence rate was 12.5% (*n*=4) for the SC+ group and 6.9% (*n*=2) for the SC-R group (*OR*=1.93, 95%CI[.33,11.41]). Secondary outcomes included change in reported quality of life, physical health and mental health status functioning over the course of the study. We found that there were no statistically significant differences in the smoking quit or smoking reduction rates between the two treatment groups. At the 3-month time point the overall quit rate for both groups combined was 18% (*n*=11) and at the 6-month time point the quit rate was 10% (*n*=6). Reduction in the number of daily cigarettes smoked was statistically significant over time (F [1.68, 98.90] = 55.13, $p < .001$, $\eta_p^2 = 0.48$) for both

groups, as was the overall reduction of the FTND score (F [2, 94] = 17.98, $p < .001$, $\eta_p^2 = 0.28$).

This research demonstrates that collecting vital tobacco prevalence and dependency information is a straightforward and important task for community mental health agencies. Individuals with mental illness have both the interest and ability to quit or reduce their use of tobacco. Practitioners need to be aware of alternative smoking practices that may contribute to understanding tobacco use patterns and dependence in this population. Other factors such as co-morbid substance use disorder and level of community functioning may influence smoking status and, consequently, how treatment is provided. The findings of the pilot trial demonstrate the feasibility of conducting smoking cessation research with the population. Findings also suggest that a larger definitive trial is warranted to examine the effectiveness of the SC+ intervention. This research adds to the limited but growing knowledge base of how to address tobacco use and provide treatment to this vulnerable group, and will contribute to advances in population health by informing effective interventions with the attendant implications for program and policy development.

Acknowledgements

This achievement is dedicated to my parents Bill and Rita Pettey. I was privileged to be raised by parents who valued education and who led by example in demonstrating the importance of contributing to your community.

It is with deep gratitude that I acknowledge the contribution of the individuals who agreed to participate in this study. Thank-you for bravely working toward, what many of you expressed as, one of the most difficult changes in your lives. I hope that I have properly captured your experiences.

It is with equal gratitude that I acknowledge the amazing mentorship, support, and patience that Dr. Tim Aubry has provided to me over these past years as my supervisor. I have no doubt that I would never have been able to undertake this project without his expertise, direction and encouraging approach. I would also like to thank my committee members: Dr. Robert Flynn, Dr. Robert Reid, and Dr. Robert Swenson for the time they have taken to support me in the completion of this project.

I would like to thank the board and staff of CMHA Ottawa, my 'second home' for the past 27 years, who have supported me, and this project. In particular, I would like to acknowledge and thank the "Take a Breath" team: Annette Bradfield, Joanne Haddad, Russell Sheridan, Andre Inkel, Derrick Shears, Danny Lang, Craig Defries, Carol Skinner, Jennifer Rae, Michael Whitteker, and Lucy Whitteker. This project happened, and, continues to happen, as a result of your collective energy and commitment.

I would like to thank my extended network of family and friends for their ongoing support, in particular, my sisters Carol DeDecker, Marie Hardy, and Sandra Pettey. I also thank my 'sisters in life' for their countless and unique hours of support: Kirsty Jackson, Lisa

Cormier, Helen Gottfried-UnRuh, Joanne Lowe, Mrs. King, Wendy Muckle, Cousin Dale Teangauba, Margaret Ireland, Juliana Bravo, and my 'little sister' Kerri-Anne Mullen. And of course Murray Krock, Vincent, and Hal.

In truth, there are many other people who have helped me along the way on this 'incredible journey'. *The Incredible Journey* was actually one of my favourite books as a child and provides an apt metaphor for embarking upon a PhD in your late forties. It tells the unlikely tale of two dogs and a cat who, through a series of unlikely circumstances, find themselves in unfamiliar territory, far from home. After much suffering and doubt, they persevere, and only with the assistance from a variety of characters along the way, they find their way back home. But of course, they are changed forever.

Statement of the Contributions of Thesis Supervisor and Committee Members

The proposal for the thesis research was reviewed and accepted by committee member, Drs. Robert Flynn, Robert Reid, and Robert Swenson. Donna L. Pettey conceptualized and conducted the research presented in the thesis under the supervision of Dr. Tim Aubry, who served as the primary thesis advisor. Dr. Aubry also reviewed and provided feedback on the thesis document. In addition, Dr. Robert Flynn was consulted and provided feedback on the two manuscripts presented in the thesis. Both manuscripts involved the work of Dr. Tim Aubry as primary thesis advisor. In addition, Dr. Robert Flynn was consulted and contributed to overall revisions and clarity of the final manuscripts.

Tables of Contents

List of Tables

Tobacco Use and Smoking Behaviours in a Sample of Individuals with Severe Mental Illness who are Homeless or Vulnerably Housed

Efficacy of Smoking Cessation Treatment Interventions for Individuals with Severe Mental Illness: A Pilot Randomized Controlled Clinical Trial

List of Figures

Efficacy of Smoking Cessation Treatment Interventions for Individuals with Severe Mental Illness: A Pilot Randomized Controlled Clinical Trial

List of Appendices

Developing Effective Smoking Cessation Treatment Interventions for Individuals with Severe Mental Illness Who are Homeless or Vulnerably Housed

While tobacco use remains a leading preventable risk factor for mortality and morbidity in Canada (Patra, Rehm, Baliunas & Popova, 2007), the overall smoking prevalence rate of Canadians has decreased substantially from close to 50% of the population in 1965 to 16.1% of the population in 2012 (Canadian Tobacco Use Monitoring Survey (CTUMS) 2012; Reid, Hammond, Rynard & Burkhalter, 2014). However, up to 85% of individuals with a mental illness[1] (Government of Ontario, 1999) continue to use tobacco products (Harris, Parle & Gagne, 2007), contributing to an inequitable distribution of negative health outcomes for this population. The extent of the inequity is revealed by the fact that individuals with severe mental illness die an estimated 25 years earlier than the general population, with 60% of these deaths due to cardiovascular, pulmonary and infectious disease (Parks, Svendsen, Singer, & Foti, 2006).

This research project is intended to increase our understanding of what constitutes an effective intervention for smoking cessation and smoking reduction in a population of individuals with severe mental illness. Two areas of inquiry were proposed. The first inquiry examined data collected as part of a needs assessment to determine the overall prevalence rate of smoking and related behaviours for a population of individuals with severe mental illness receiving services from a community mental health agency. The second inquiry utilized a randomized controlled trial design to evaluate smoking cessation and smoking reduction outcomes for two groups of individuals with severe mental illness

[1] The Ontario Ministry of Health and Long Term Care recognizes three dimensions to identify individuals with a serious mental illness/severe mental health problem - disability, anticipated duration and/or current duration and diagnoses.

receiving different smoking cessation interventions. Clients randomly assigned to the routine Smoking Cessation group (SC-R) received up to 24 weeks of no cost Nicotine Replacement Therapy (NRT) and clients assigned to the Smoking Cessation Plus group (SC+) received up to 24 weeks of no cost Nicotine Replacement Therapy (NRT) plus two initial individual sessions of motivational interviewing followed by weekly psychosocial group interventions for up to 24 weeks. This research adds to the limited but growing knowledge base of how to address tobacco use and provide treatment to this vulnerable group, and will contribute to advances in population health by informing effective interventions with the attendant implications for program and policy development.

Review of the Literature

Tobacco Use and Mental Illness

It is projected that by 2015 tobacco will kill 50% more people than HIV-AIDS and that 10% of all deaths globally will be attributable to tobacco (Mathers & Loncar, 2006). In Canada, more than 37,000 people will die this year due to tobacco use (Baliunas, Patra, Rehm, Popova, Kaiserman & Taylor, 2007), and up to half of all individuals who continue to smoke will die of tobacco-related disease (World Health Organization, 2014). Tobacco use is associated with numerous cancers as well as cardiovascular and respiratory diseases (U.S Department of Human Services, 2014; Baliunas et al., 2007) and accounts for over 12% of the total disease burden in Canada (Patra, Rehm, Baliunas & Popova, 2007). Despite these sobering figures, incredible gains have been made in the Canadian public health arena to reduce tobacco use and the related negative health consequences. Not only has overall smoking prevalence decreased substantially in all age cohorts in Canada, but other measures that predict severity of tobacco-related harm, such as number of cigarettes consumed by

smokers and levels of nicotine dependence, have also decreased (Canadian Tobacco Use Monitoring Survey (CTUMS) 2012; Reid, Hammond, Rynard & Burkhalter, 2014).

By most standards of analysis this reduction of tobacco use is a population health intervention success story. However, the inadequacies of current practice are revealed by examining who is represented within the populations of remaining smoking cohorts. Individuals with mental illness not only use tobacco at a much higher prevalence rate, but 40% of individuals with mental illness smoke more than 40 cigarettes a day (Horsfall, Cleary, Hunt & Walter, 2009) contributing to the established early mortality of this population (Kilbounre et al., 2009; Parks et al., 2006; Colton & Manderscheid, 2006). For individuals with schizophrenia in particular, coronary heart disease is now the primary cause of premature death, resulting in a 20% reduced life expectancy compared to the general population (Hennekens, 2007; Hennekens, Hennekens, Hollar & Casey, 2005). A recent study that examined specific tobacco attributable deaths in these populations found that tobacco accounted for 53% of deaths in individuals with schizophrenia, 50% of all deaths for those diagnosed with a depressive disorder, and 48% of all deaths for those with a diagnosis of bipolar disorder (Callaghan et al., 2014).

Increased smoking prevalence is also endemic in associated and frequently concurrently diagnosed disadvantaged groups such as people who are homeless, individuals with substance use disorders, aboriginal populations and the 'working poor', resulting in overall tobacco-related health disparities (Baggett et al., 2013a; Baggett, Tobey & Rigotti, 2013b; Bonevski, Baker, Tywman, Paul & Bryant, 2012; Guydish et al., 2011; Baggett & Rigotti, 2010; Hwang, Wilkens, Tjepkema, O'Campo & Dunn, 2009; Chesterman, Judge, Bauld & Ferguson, 2005; Murray, Bauld; Hackshaw & McNeill, 2009; Elton-Marshall,

Leathersdale & Burkhalter, 2011; Moolchan, Fagan, Fernander, Velicer, Hayward, King & Clayton, 2007). A recent study has reported the tobacco-attributable death rate for homeless men and women in Boston between the ages of 50-64 years old to be three times that of the general population of Massachusetts in that same age group, and three to five times that for individuals in the 35-49 age group (Baggett, Chang, Singer, Porneala, Gaeta, O'Connell & Rigotti, 2014).

Complicit in elevated smoking prevalence rates is the successful targeted marketing of marginalized populations by the tobacco industry that has been well documented and explored in the literature (Prochaska, Hal & Bero, 2008; Bero, 2005; Bero, 2003; Vagg & Chapman, 2005; Apollonia & Malone, 2005). As evidence of this marketing success, it has been determined that individuals with mental illness comprise over 44% of the U.S. tobacco market (Lasser et al., 2000), accounting for 39 billion dollars in annual sales (Hall & Prochaska, 2009).

The distinct role of tobacco use as a contributing factor in the fragile health status of individuals with a serious mental illness is complex, given the high prevalence of multiple co-morbidities such as alcohol and drug use disorders (Rush et al, 2008; Rush & Koegl, 2008; Regier, Farmer, Rae, Locke, Keither, Judd & Goodwin, 1990), chronic disease (Brown et al., 2010; Drake et al., 2001) and complex health conditions (McEvoy et al., 2005; Phutane et al., 2011). Additionally, individuals with mental illness remain one of the most economically marginalized populations within Canadian society, often ending up homeless or in jail, with poor social connections, living in poverty and without access to appropriate health interventions to address the range of serious physical health conditions to which they are vulnerable. This is a population that consumes enormous public health and social

services (Canadian Institute of Health Information, 2007) and within the prevailing climate of health care restructuring, mental health and addiction services have become a priority focus for potential health dollar investment with the goal of reducing demand on the acute and tertiary health care sectors (Government of Ontario, 2011; Champlain Local Health Integration Network, 2009). Developing tobacco use and other substance abuse treatment services to address the health care needs of this population has been difficult however, with a continuing divergence between the recommended evidenced based treatment approach and actual practice. This has been reinforced by a deficient research agenda to investigate interventions specific to the population of individuals with severe mental illness. In 2008 there were close to 8,800 peer reviewed studies on tobacco interventions that informed the development of clinical practice (Fiore et al., 2008). By 2010, only 8 RCT's of tobacco treatment interventions for individuals with severe mental illness were identified for a systematic review (Banham & Gilbody, 2010), and less than two dozen RTC's were identified in a recent study (Prochaska, Hall, Delucchi & Hall, 2014).

This situation is further complicated by the historic health system 'silos' of the mental health, addiction and primary health care treatment worlds and the fact that many of the solutions to address the needs of this population, such as poverty reduction, clearly lie 'upstream' outside of the established historical purview of health interventions. The final report for the most recent strategic planning initiative for mental health and addiction services in the province of Ontario by the Ministry of Health and Long Term Care, *Navigating the Journey to Wellness: The Comprehensive Mental Health and Addictions Action Plan for Ontarians* (Government of Ontario, 2010), does not mention tobacco use or treatment. Tobacco use not only disproportionably affects individuals with mental illness

with particularly deadly consequences, but the record of investment in treatment, intervention, and even acknowledgement by the health system in targeting the problem, is demonstrably inadequate.

Tobacco Use and the Mental Health System

While smoking rates have consistently declined over the past forty years in the general population, why would so many individuals with severe mental illness continue to smoke? Both neuropsychiatric and psychosocial factors are most frequently cited in the literature, specifically the neurobiological vulnerabilities of the population (Leonard et al., 2001), heightened impact of nicotine withdrawal on psychiatric symptoms (Fagerstrom & Aubin, 2009), and theories of the primary of stress and reduced coping capacity for individuals with schizophrenia in particular (Leon & Diaz, 2005; Diaz, Veasquez, Susce & Leon, 2008). However, other factors or 'causal pathways' need to be considered in order to explain why, in both in-patient and community settings, individuals with serious mental illness are less likely to even be offered information or support to address their tobacco use (Johnson et al., 2009).

Hall and Prochaska (2009) identify a range of individual and systemic factors that help to explain why this vulnerable population continues to smoke at alarming levels, specifically that the "prioritization of mental health treatment, lack of an appreciation of the health effects of cigarette smoking, and beliefs among clinicians that persons with mental illness are not able or willing to quit have contributed to a culture in many treatment settings that accepts and 'normalizes' cigarette smoking" (p. 411). A recent Canadian study that examined community mental health care practitioner attitudes and practices toward smoking cessation for clients with mental illness revealed a higher level of smoking among the

practitioners than in the general population and that these staff were less likely to engage in conversation with clients about their tobacco use (Johnson et al., 2009).

An additional factor that will influence whether mental health clients are exposed to possible smoking cessation treatment is if their particular care provider believes that addressing tobacco use is part of their role. Psychiatrists have been found to provide cessation counseling during only 12% of visits with their patients as opposed to general health physicians where the rate is 38% of visits (Ziedonic et al. 2008; Himelhoch & Daumit, 2003). In examining mental health practitioner attitudes, Johnson et al. (2009) were able to demonstrate that "providers who perceived that they did not have the time or resources to engage in cessation activities and did not think it was part of their role were less likely to engage in smoking cessation activities. Similarly, providers who indicated clients were not interested in stopping, were less likely to engage in cessation activities" (p. 294). This aspect of suspected motivation is also at the core of a health system that systematically neglects to offer treatment, based on the assumption that individuals with mental illness are not interested in, or capable of, quitting. Research has demonstrated however, that smokers with psychiatric disorders have similar levels of expressed desire to quit or reduce smoking as the general population (Siru, Hulse & Tait, 2009; Hall & Prochaska, 2009; Moeller-Saxon, 2008).

A recent longitudinal study of 174 individuals with co-occurring mental illness and substance use disorders, assessed smoking cessation behaviors and quit attempts yearly for over 11 years (Ferron, Brunette, He, Xie, McHugo & Drake, 2011). Each year, up to one-third had one or more quit attempts and, in the 11 years that individuals were followed, over 75% attempted to quit. These quit attempts were typically undertaken without medication or

psychosocial intervention and, at the 11 year follow-up, 83% of the cohort remained smoking. The authors concluded that the clients with co-occurring substance use and mental health disorders in their study had similar numbers of quit attempts as the general population, but in the absence of any supportive treatment, they did not experience sustained smoking cessation success and many remained smokers (Ferron et al., 2011). An additional study that examined smoking cessation outcomes between groups based on socioeconomic status reported that quit attempts and use of smoking cessation medications were the same for both groups, but that smokers with a more deprived socioeconomic profile experienced less success in quitting (Kotz & West, 2008).

Part of challenging the myth that individuals with mental illness are not interested in addressing their tobacco use involves tackling a pervasive belief that smoking provides a singular source of pleasure for clients who have few material comforts (National Association of State Mental Health Program Directors, 2007). There are also persistent beliefs that quitting smoking will worsen the symptoms of mental illness and interfere with the ability to maintain abstinence from alcohol or drugs (Hall & Prochaska, 2009). Research in this area indicates however, that smoking cessation interventions do not endanger abstinence (Khara & Okoli, 2010; Currie, Nesbitt, Wood & Lawson, 2003), and do not increase psychiatric symptoms (Banham & Gilbody, 2010; Hall & Prochaska, 2009), or induce psychological distress (Steinberg, Bover, Richardson, Schmelzer, Williams & Foulds, 2011).

Paucity of treatment opportunities aside, even with stringent smoking in the workplace legislation now in place, many Canadian hospitals continue to have separate smoking policies for psychiatric patients (Bardell & Brown, 2006). By 2008 in the U.S., only one-third of non-federal acute care hospitals had adopted smoke free campus policies

(Goldstein, Steiner, McCullough, Kramer & Okun, 2009) but as of 2011, 83% of state psychiatric facilities reported being smoke-free (Ortiz, Schacht & Land, 2013). While staff safety and fear of escalation of violence is often cited as a rationale for lenient smoking regulations in psychiatric hospitals, research has demonstrated that facilities that continue to permit smoking have significantly higher incidents of conflict related to smoking than non-smoking facilities (Lane, Werdel, Schacht, Ortiz & Parks, 2009; Harris et al., 2007).

In most residential treatment programs for substance abuse treatment smoking is still permitted on site, and only 10% of these treatment facilities in Canada reported providing on-site smoking cessation treatment (Currie et al., 2003). A survey of 3,800 out-patient substance abuse treatment facilities in the U.S., that assessed capacity to treat tobacco dependency, found close to 90% of the programs reported that the majority of their clients smoked, but only 23% reported that clients received counseling for their tobacco dependency, and only 18% advised clients to use smoking cessation medications (Cupertino et al., 2013). This led to the conclusion that "drug treatment facilities and staff lack the policies, leadership, and financial resources to provide evidence-based tobacco treatment" (Hunt et al, 2013. p. 1800). A 2010 survey of addiction treatment agencies in Ontario, Canada, reported that 23.4% of agencies provided smoking cessation treatment (Center for Addiction and Mental Health, 2010).

Smoking Cessation Interventions for Individuals with Severe Mental Illness

In general, smoking cessation intervention programs recommend a combination therapy of pharmacological intervention including nicotine replacement therapy (NRT) which comes in the form of patches, inhalers, lozenges, nasal spray and gum; psychotropic medications such as varenacline and buproprion; and psychosocial interventions.

Psychosocial interventions include individual and group counselling, typically utilizing motivational interviewing (MI) and cognitive behavioural therapy (CBT) approaches that address a broad range of issues related to smoking behavior, with most programs consisting of eight to twelve weekly sessions.

There are many challenges with this standard approach in meeting the smoking cessation needs of a population with serious mental illness. First and foremost, the therapy itself is cost-prohibitive, as NRT is not routinely paid for as part of the Ontario government provincial drug plan[2] for individuals receiving either the Ontario Disability Support Plan (ODSP) or Ontario Works (OW). A broad initiative that provides free NRT treatment, the Smoking Treatment for Ontario Patients (STOP) program, has been rolled out in the province of Ontario for enrolled patients of Family Health Teams and Community Health Centres, with a more recent addition to include clients of addiction treatment programs (Center for Addiction and Mental Health, 2014). Community mental health programs are currently not eligible to participate in the program, limiting the reach of this intervention for this particular population. These types of health initiatives, while certainly helpful for some populations, highlight how continuing to compartmentalize service sectors within health care services can leave vulnerable populations, such as individuals who are not receiving treatment from designated services, further marginalized and excluded from service.

Additionally, there has not been widespread uptake of the medical practice guidelines available to provide the actual 'dose' of nicotine replacement therapy that may be required

[2] The government of British Columbia currently provides no cost NRT for up to 12 weeks to any resident. All other provinces and territories, with the exception of Newfoundland and New Brunswick where no subsidization is provided, offer various levels of subsidy for NRT products and other smoking cessation medications. In August 2011 the Ontario Government added 12 weeks of varenicline and bupropion to the Ontario Drug Benefits Plan and currently makes NRT available to patients of specific health funded services under the Smoking Treatment for Ontario Patients (STOP) Program.

for this population. A study by Fagerström and Furgburg (2008) examined level of nicotine dependence in relation of overall smoking prevalence across 13 countries. They found that countries with lower overall smoking prevalence inversely had higher levels of nicotine dependence in the remaining smokers, supporting the notion that the diminishing population of smokers may require more intensive interventions due to higher levels of dependence (Fagerström & Furgburg, 2008). This work followed a much earlier study documenting the same phenomena (Fagerström et al, 1996). While it is already well documented that individuals with severe mental illness are extremely 'heavy' and 'efficient' smokers (Harris et al., 2007; Dixon et al., 2007), the labelling directives for NRT are for populations that do not typically have such extreme levels of dependence. The existing recommended dosage and titration schedules included on the NRT packaging will not necessarily be appropriate for the heavily addicted who may benefit from higher doses of NRT, combination NRT therapies, and longer periods of NRT treatment. Borelli (2009) has proposed that vulnerable populations of smokers may need to have evidence based smoking cessation treatment practices modified or adapted if they differ from the general population of smokers in ways such as an inequitable burden of tobacco related health disease, having additional risk factors that would predict smoking and a paucity of protective factors that might aid quitting smoking (Borelli, 2009).

In the United States, such modified clinical guidelines for smoking cessation for individuals with mental illness have been produced by the Department of Health and Human Services (Fiore, Jaén, Baker et al., 2008), but there has been a slow uptake and implementation of these guidelines in treating individuals with mental health and/or substance use disorders (Hall & Prochaska, 2009). In Canada, there are widely accepted

smoking cessation guidelines for the general population, and the Canadian Action Network for the Advancement, Dissemination and Adoption of Practice-informed Tobacco Treatment (CAN-ADAPTT) has recently produced treatment guidelines for "Specific Populations: Mental Health and/or Other Addiction(s)". The three summary statements recommend screening, offering of counseling and pharmacotherapy at appropriate dosages, and monitoring of mental health status with possible adjustment of psychotropic medications as needed (CAN-ADAPTT, 2011). The Ontario medical association has also produced a position paper that addresses myths surrounding the use of stop-smoking medications (OMA, 2008).

There is a clear divergence though between the community of practitioners who have developed these evidenced-based clinical guidelines for use of NRT, and the entities such as Health Canada and the Federal Drug Administration in the U.S., that govern the use of medications. Altering the recommended dosing and packaging directives is considered 'off label' use by Health Canada. The Association for the Treatment of Tobacco Use and Dependence and the Society for Research on Nicotine and Tobacco (SRNT) published a policy statement in July 2014 advising the Federal Drug Administration in the U.S. to allow pharmaceutical companies to revise their labelling of NRT packaging (Fucito et al., 2014). In 2013, the FDA had approved some alterations of NRT labelling (Food and Drug Administration, 2013a; Food and Drug Administration, 2013b), but based on a review of the evidence, the SRNT is urging further changes that would allow for combination NRT dosing, extended treatment times without needing to consult with a healthcare professional, and the use of NRT prior to a quit date (Fucito et al., 2014).

Intensity of psychosocial intervention is an additional concern as, given what is known regarding psychosocial interventions for this population in addressing other substance use disorders (Cleary et al., 2009; Cleary et al., 2007), individuals with a severe mental illness are likely to require long-term support beyond the life of most eight to twelve week tobacco cessation programs. This could influence not only the level of professional interest in providing treatment to this particular cohort, but could in fact exceed most program mandates and resources. A study examining smoking outcomes for individuals with schizophrenia and non-psychotic psychiatric disorders found a session 'dose' effect where the number of sessions that a participant attended, increased proportionally the odds of quitting (Selby, Voci, Zawertailo, George & Brands, 2010). The actual dose and duration of treatment may in fact be relevant for all smoking cohorts, as indicated in a recent meta-analysis of RCT's of behavioural interventions for smoking cessation in the general population that demonstrated increased abstinence with more intensive individual, group, and telephone counselling (Mottillo et al., 2009).

The use of psychoactive drugs such as varenicline and bupropion has been established as an effective intervention to treat nicotine dependence both in the general population (Cahill, Stead & Lancaster, 2011; Hughes, Stead & Lancaster, 2000), and in individuals with mental illness (Evans et al., 2014;Tsoi, Porwal & Webster, 2013; Tsoi, Porwal & Webstar, 2010; Stapleton et al., 2008; Evins et al., 2004). However, monitoring for any emerging neuropsychiatric side effects when prescribing buprorion or varenicline in the psychiatric population is recommended (Els, Kunyk & Sidhu, 2011). In particular, Tsoi et al. (2013) found in a systematic review of two smoking cessation intervention trials for individuals with schizophrenia that, while varenicline was effective, adverse psychiatric side

effects could not be ruled out. Another study that undertook a meta-analysis of 17 RCT's and compared experienced side effects in patients with and without psychiatric disorders, concluded that varenicline is not associated with increased neuropsychiatric events (Gibbons & Mann, 2013). It has also been reported that any other adverse side effects that are experienced could be well managed and mitigated by providing enhanced supports to individuals receiving this treatment (Stapleton et al., 2008). A systematic review of the efficacy and safety of buproprion treatment for nicotine dependence in individuals with schizophrenia found significantly higher abstinence rates without jeopardizing the mental state of study participants (Tsoi, Porwal & Webstar, 2010).

With regard to overall efficacy of smoking cessation interventions, a review of 24 studies assessing the effectiveness of smoking cessation for individuals with mental illness found that at the long term 12 month follow-up, quit rates were only marginally lower as compared to the general population, leading the author to suggest that commonly held beliefs that may question if individuals with mental illness want or are able to quit, need to be challenged (el-Guebably, Cathcart, Currie, Brown & Gloster, 2002). A systematic review of smoking cessation behavioural interventions in disadvantaged groups of smokers found evidence that, on long-term follow-up, the behavioural support interventions showed a significant effect. There was caution expressed in this interpretation though, given the wide range of behavioural support interventions and target populations included in the review (Bryant, Bonevski1, Paul, Mcelduff & Attia, 2011). The 10 studies included three studies that targeted smokers with schizophrenia or schizo-affective disorder, two that targeted smokers with a variety of psychotic disorders, four studies included individuals with depression, and one targeted smokers with PTSD. A systematic review of eight RCT's of

both pharmacological and psychosocial smoking cessation interventions for individuals with severe mental illness concluded that treatment was effective for this population and did not impact negatively on psychiatric conditions (Banham & Gilbody, 2010).

Other research has demonstrated the efficacy of a range of smoking cessation interventions with this population including NRT plus motivational interviewing with psychiatric in-patients (Prochaska, Hall, Delucchi & Hall, 2014), NRT plus psychosocial interventions with clients with psychotic disorder (Baker et al., 2006), combinations of NRT plus psychosocial interventions and bupropion with clients with Schizophrenia spectrum disorders (Ferron, Alteram, McHugo, Brunette & Drake, 2009), intensive psychosocial interventions with smokers with schizophrenia and schizoaffective disorder (Williams, Steinberg, Zimmermann, Gandhi, Stipelman, Budsock & Ziedonic, 2010), and an individualized treatment approach with individuals with schizophrenia and non-psychotic psychiatric disorders (Selby et al., 2010). Other approaches describe the potential benefits of smoking reduction strategies as an initial treatment goal with smokers with schizophrenia (McChargue, Gulliver & Hitsman, 2002), and delivering interventions that are integrated within routine mental health treatment settings for smokers with a range of mental health disorders including schizophrenia and mood disorders (Hitsman, Moss, Montoya & George, 2009). More creative approaches have been proposed such as the utilization of an electronic 'decision support system' to motivate individuals with severe mental illness to access evidence based smoking cessation treatment options (Brunette, Ferron, McHugo, Davis, Devitt, Wilkness & Drake, 2011). Still other research has reported how the provision of even a brief intervention by psychiatrists, with attention to stage of change transitions, can

have an impact on smoking behaviour of individuals with severe mental illness (DiClemente, Delahanty, Kofelldt, Dixon, Goldberg & Lucksted, 2011).

Theoretical and/or Conceptual Framework

Research Paradigms to Examine Smoking Cessation Interventions for Individuals with a Severe Mental Illness

In positioning this research, the objectivist/positivist perspective of neurosciences and cognitive-behaviour research paradigms are part of what helps to conceptualize our understanding of why individuals with mental illness smoke and may be resistant to more mainstream cessation interventions. However, there is also recognition that tobacco dependence and mental illness are not individual-specific 'medical diagnoses' or 'behaviours' requiring modification, but that they are also strongly influenced by the more subjectivist socio-environmental factors that are indications of deep social inequities and poverty (Drake, O'Neal, Erica, Wallach & Michael, 2008; Mueser & Brunette, 2010). Few subgroups of the population are more vulnerable to the effects of such deprivation than those with severe mental illness, and research has highlighted the need to address the determinants of health and social functioning in order to satisfactorily resolve problematic behavioural outcomes such as increased psychological distress, co-occurring substance use disorders and poor mental health treatment compliance (Drake, Wallach, Alverson & Mueser, 2002; Wilton, 2004; Wilton, 2003; Orpana, Lemyre & Gravel, 2009; Hudson, 2005; Mayer, Stein, Grimsrud, Soraya & Williams, 2008). In particular, Drake and Wallach (2008) emphasize a recovery community model stating that "we do not gainsay the importance of biological and psychological approaches, but the most promising evidence suggests that we should direct considerably more research attention to socio-environmental arenas" (p. 192).

In describing a structural approach to mental health promotion, Denis Raphael presents a model by Brunner & Marmot, the 'Social Determinants of Health and the Psychological Pathway to Health' that links social structure to health status' via material, psychosocial and behavioural pathways, acknowledging the contributing role of early life experiences and genetics (Raphael, 2009).

Models such as this help to illustrate that the attainment or designation of a particular health status involves a complex journey, and while individual choice definitely plays a role along the way, the circumstances or social structures one is exposed to will continuously influence, if not prescribe, the route. It is apparent that poor quality social determinants of health, such as traumatic early life experiences, lack of education, food insecurity, inadequate housing, low income, unemployment, and social exclusion, can lead to poverty, deprivation, hunger, inequality, and low income, thereby adversely affecting mental health through addictions, workplace stress, anxiety, depression, hopelessness and blunted coping skills (Raphael, 2009). This structural approach to understanding mental health status is necessary for the purposes of this study in order to understand the complicated multi-dimensional factors that shape tobacco use patterns for this particular client group.

Smoking Cessation as a Population Health Intervention

David Kindig (2007) defines population health simply as “health outcomes and their distribution in a population” (p.141) where he is careful to note the importance of examining which determinants and/or interactions may have produced these outcomes and how this ultimately shapes health inequities. Typically, population health interventions aim to address health inequities by identifying the underlying ‘ingredients’ (such as physical environment, gender, or economic status) that factor in the determination of one’s health,

and to then improve the health status of the entire population through the provision of 'upstream' policy and program development. Tobacco use is an excellent example of a behaviour that requires a population health intervention since "in the context of tobacco control, there is widespread agreement that effective action requires a comprehensive, ecological approach that targets multiple systems and employs multiple strategies" (Richard et al., 2004, p. 410).

In Canada, measures to address tobacco have evolved over time and reflect this socio-ecological approach. Richard, Potvin, Denis & Kishchuk (2002) describe three 'generations' of approaches to address tobacco use, identifying first generation interventions as those that focused on smoking cessation by targeting individual behaviour, while the evolution to second generation interventions moved into the community realm by focusing on prevention and the overall population as well as the high risk 'smokers' group. Building upon these original strategies, the third generation of interventions placed a greater emphasis on public policy issues and public health practice. These 'macro' interventions include demand reduction strategies such as legislation that guides taxation and price control, label warnings and marketing restrictions, supply reduction legislative strategies such as prohibiting the sale of tobacco to minors and addressing the issues related to the illegal tobacco trade, and legislative measures that protect against exposure to second hand smoke in public places, workplaces and even in private places such as vehicles transporting children (von Tigerstrom, 2008).

This described evolution of distinct generations or transition points of interventions plots the trajectory of how tobacco control has 'taken hold' and become embedded in Canadian public health culture. As a population health intervention, the taxation of tobacco

has demonstrated, for example, that by altering the 'dose' of the intervention or amount of taxation, smoking prevalence patterns can be modified (Stephens, Pederson, Koval & Macnab, 2001), and that the reach of this intervention is particularly effective in discouraging the purchase of tobacco products, including within specific youth cohorts (Carpenter & Cook 2008; Auld, 2005). While this multi-system comprehensive approach has produced impressive outcomes and, as previously discussed, resulted in a dramatic modification of smoking behaviour (CTUMS, 2012; Reid et al., 2014), one of the challenges of a population health approach is that particular subpopulations may remain marginalized from the intervention, thereby increasing or exacerbating health inequities. For example, the tobacco tax disincentive has been found to have less effect on individuals who are poor, and who are heavy smokers. The availability of contraband tobacco products also undermines the effectiveness of taxing tobacco, ultimately impacting on taxation revenue through reduced demand and eroding potential health benefits accrued as a result of tobacco taxation (Luk, Cohen & Ferrence, 2007). It becomes imperative then to incorporate a critical population health approach that includes an examination of how "specific social structures, economic relationships and ideological assumptions serve to create and reinforce conditions that perpetuate and legitimize conditions that undermine the health of specific populations" (Labonte, Polanyi, Muhajarine, McIntosh & Williams, 2005, p.10).

Population Health and the 'Vulnerable' Population

Frohlich & Potvin (2008) note in discussing Jeffery Rose's population-based approach, that population health interventions are based on the notion that the population shares an average level of risk exposure, and by applying an intervention to the population as a whole, everyone's risk level shifts. The logic and success of this population-based

approach is certainly evident in the tobacco use interventions discussed previously. However, Frohlich & Potvin (2008) contend that certainly not everyone in a population has the same risk exposure and they define these vulnerable populations "as groups who, because of their position in the social strata, are commonly exposed to contextual conditions that distinguish them from the rest of the population" (p. 218) and "who concentrate numerous risk factors throughout their life course because of shared fundamental causes associated with their position in the social structure" (p. 219). Certainly this concept of the 'vulnerable population' contributes to the understanding of how individuals with severe mental illness have remained marginalized by population health interventions related to tobacco use. This has aptly been described as part of an 'inequity paradox' where "the objective of improving population health may not necessarily be compatible with the objective of reducing health disparities" (Frolich & Potvin, 2008, p. 219). Pat Martens suggests that in planning complex population health interventions "we need to focus on shifting the entire population to improved health while 'squishing' the distribution--in other words, giving targeted interventions to the least healthy so they will 'catch up' to attain the health status of the most healthy" (Martens et al., 2010, p. 183).

Application of eco-social theory further helps to develop different understandings as to how an individual with mental illness becomes a smoker, and how smoking itself may have different health consequences. Nancy Krieger presents eco-social theory as one of many evolving multi-level system frameworks that "more than simply adding 'biology' to 'social' analysis, the eco-social framework begins to envision a more systematic integrated approach capable of generating new hypotheses" (Kreiger, 2001, p. 673). Krieger identifies the four (minimal) constructs in eco-social theory as embodiment, the pathways of

embodiment, the cumulative interplay between exposure, susceptibility and resistance, and accountability and agency (Kreiger, 2001, p. 672). In order to explain and understand disease distribution, and perhaps most importantly, health inequities, "it is necessary to consider causal pathways operating at multiple levels and spatio-temporal scales, in historical context and as shaped by the societal power relations, material conditions, and social and biological processes inherent in the political economy and ecology of the population being analyzed. The embodied consequences of societal and ecological contexts are what manifest as population distributions of and inequities in health, disease, and well-being" (Kreiger, 2008, p. 224). This conceptualization provides a clear framework for understanding how the inequitable distribution of disease related to tobacco use for individuals with severe mental illness has become, what Kreiger (2001) would suggest is, the 'embodied' biological representation of discrimination and injustice.

Additional theoretical perspectives that would contribute to understanding and conceptualizing the incidence of smoking by individuals with severe mental illness through more of an equity lens, are intersectionality and the incorporation of a life course perspective. Intersectionality contributes to the understanding of the complex ways that different categories of social identity (such as gender, disability and race) intersect and impact on one another by "moving beyond the assumption that health outcomes may be caused by a number of contributing causes by asserting that numerous factors are always at play" (Hankivsky& Christoffersen, 2008, p. 275). A life course approach emphasizes the cumulative effects of lifetime exposure and experience in understanding health outcomes (Hertzman & Power, 2003), and cognitive-behavioural, social change and community

change theories lend understanding as to why and how groups and individuals engage in behavioural change (Brunner, Rees, Ward & Thorogood, 2007).

Study Objectives and Methods for Each Paper

The study objectives for this research were specific to each of the two papers and are discussed separately in relation to each particular paper. The methods for each paper are discussed here briefly and presented more completely within the full text of each paper. Ethics approval for both papers was received from the University of Ottawa's Research Ethics Board. As a Health Service Provider (HSP) that operates under a Multi-Sectoral Accountability Agreement (M-SAA) with the Champlain Local Health Integration Network under the Ontario Government's Ministry of Health and Long Term Care, the agency where this reserach was conducted is both contractually and legislatively obliged as a "health information custodian" to comply with a number of pieces of legislation (Personal Health Information Protection Act, 2004). All clients of the agency are informed verbally and in writing of this obligation and the legislation that protects their personal health information.

Paper # 1

Study objectives. The smoking related behaviours and specific characteristics of this population have not been well described in the literature (Baggett & Rigotti, 2010). The objective of this paper was to provide a robust description of the smoking prevalence and smoking-related behaviours of a specific cohort of individuals with severe mental illness who are homeless or vulnerably housed, receiving integrated mental health treatment from a community mental health agency in a large urban setting. A survey had been conducted within the agency for the purposes of service planning and establishing the rationale for

developing smoking cessation interventions for this clientele. The survey data were analyzed to address the following research questions:

1) What is the smoking prevalence within a population of clients with serious mental illness receiving services from a community mental health agency who are homeless or vulnerably housed?
2) What are the smoking behaviours identified by this client group and the identified motivation to reduce or discontinue tobacco use?
3) What clinical and demographic characteristics are associated with the smoking-related variables?

Study method. The individuals who voluntarily participated in the survey were clients of the Ottawa Branch of the Canadian Mental Health Association (CMHA) in Ottawa, Ontario, Canada. CMHA Ottawa is a large community mental health agency and is an accredited health care provider under Accreditation Canada. The agency has an operating budget of over 15 million dollars annually and 85% of all funding is received from the Ontario Government's Ministry of Health and Long Term Care (MoHLTC). With a growing understanding of the extreme and exacerbated health consequences experienced by clients with high levels of tobacco use, CMHA Ottawa became committed to exploring the extent of tobacco use within the population served and any expressed desire by clients to reduce or eliminate tobacco use. The data would then inform the agency as to next steps, including the need to potentially develop clinical interventions focused on addressing tobacco addiction.

During a one week period in November, 2010, an attempt was made to contact all active clients of the agency to inquire if they smoked tobacco. Of the 743 individuals who

were registered as active clients that week, contact was made with 639 clients or 86% of all registered CMHA clients. Clients were surveyed by their primary mental health case manager as part of the overall ongoing data collection undertaken by the agency to ensure service quality and to identify client service needs. All current smokers were then asked to complete the Fagerström Test for Nicotine Dependence (FTND) in order to determine client level of nicotine dependence, and 331 of 456 smokers agreed to complete the FTND in the November survey (73% of the smoking sample). Additional information regarding client smoking behaviours and motivation to quit or reduce tobacco use was collected. In addition, the Ministry of Health and Long Term Care (MoHLTC) requires that the agency collect and report on a set of demographic and clinical data called the Common Data Set (CDS). This provides data for all direct service clients of the agency in a number of key life domain areas and was used to provide a description of demographic and clinical characteristics of this population. Descriptive statistics were examined to describe smoking prevalence rates, smoking behaviours, and level of motivation to address tobacco use. T-tests, Chi-square analyses, and bivariate correlational analyses were used to assess the relationship between clinical and demographic characteristics and smoking-related variables.

The complete description of the study methods, analyses, study outcomes, and conclusions can be found in Paper #1.

Paper #2

Study objectives. Clearly, tobacco use is endemic in this population, with all of the predictable serious health and social consequences. There is an urgent need in both community and hospital settings to better understand the level and intensity of the smoking cessation intervention necessary to meaningfully engage this population in treatment. The

objective of the second paper was to conduct a pilot trial to evaluate if individuals with severe mental illness who have a tobacco dependency are able to reduce or eliminate tobacco, following the administration of specific smoking cessation interventions to clients randomly assigned to one of two groups. Clients randomly assigned to the routine Smoking Cessation group (SC-R) received up to 24 weeks of no cost Nicotine Replacement Therapy (NRT), and clients assigned to the Smoking Cessation Plus group (SC+) received up to 24 weeks of no cost Nicotine Replacement Therapy (NRT) plus two initial individual sessions of motivational interviewing and weekly psychosocial group interventions for up to 24 weeks. As previously discussed, limited research had been conducted on how to assist this particular client group with smoking cessation or reduction, in particular, interventions that include the upward titration of NRT doses for all clients receiving treatment. In addition to testing the feasibility of conducting smoking cessation research with the population, the pilot trial is intended to address the following research questions:

1) Do participants who receive the SC+ treatment have better smoking outcomes than participants who receive the SC-R treatment?
2) Are there differences between the two groups in other monitored and reported participant outcomes such as quality of life, use of psychiatric medication, weight and patterns of other substance use?
3) Do participants who receive the SC+ treatment and participants who receive the SC-R treatment have better smoking outcomes than individuals receiving standard care (i.e. no specific smoking cessation intervention)?
4) Is there a relationship between the amount of the nursing contact and NRT intervention received among participants in the two groups and client outcomes?

Study methods. This study utilized qualitative and quantitative methods to determine the effectiveness of the smoking cessation intervention treatment programs using a random selection of participants to the two groups. The outcomes of the qualitative inquiry have been reported elsewhere (Rae, Pettey, Aubry & Stol, 2015). Sixty-two clients who were eligible to receive the smoking cessation treatment were recruited and randomly assigned to either the SC+ or SC-R group. One participant was removed from the study after suddenly leaving the province and before any treatment had been initiated. The number of participants in this study had been limited by the availability of cost free NRT and the extensive labour requirement to operationalize the intensive support component of treatment. As such, it was considered a pilot trial. Study participants were compared on smoking-related outcomes and level of nicotine dependence to a matched sample comparison group receiving standard care drawn from the cohort described in Study #1, in order to provide a comparison group of individuals who did not receive the smoking cessation treatment in this program.

Treatment outcomes were monitored at three months and at six months. The primary treatment outcomes related to tobacco use were i) 7-day point prevalence abstinence verified by CO levels of 5 *ppm* or less at the 3-month and 6-month time-points, and ii) reported numbers of cigarettes smoked. These outcomes were evaluated on an intent-to-treat (ITT) basis in that any client who withdrew from the study or whose tobacco use could not be verified was considered to be smoking. Client tobacco use was monitored through self-report during weekly meetings with the nursing staff and through regular breath monitoring of carbon monoxide (CO) levels. The secondary client outcomes monitored included

changes in drug and alcohol use, quality of life, financial status, physical health status, mental health status, and housing status.

Descriptive statistics were calculated to describe demographic characteristics, smoking behaviour and clinical characteristics of participants. Categorical variables were summarized by frequencies and percentages and continuous variables were summarized by means and standard deviation (*SD*). T-tests and Chi-square analyses were conducted to determine if there were differences between the groups on measures at baseline. Repeated measures ANOVA's were used to assess differences between groups, changes over time and the interaction of group and time on the continuous variables. McNemar test was used to evaluate differences in each group over time on dichotomous variables. Chi-square analyses were used to examine differences between groups at each follow-up time point on dichotomous variables. Bivariate correlation analyses were used to assess the relationship between clinical and demographic characteristics and smoking-related variables. Additionally, logistic regression and standard multiple regressions were utilized to analyze if number of treatment sessions attended predicted treatment outcome of quitting or reducing tobacco. All analyses were performed using SPSS, version 20.

The complete description of the study methods, analysis, study outcomes and conclusions can be found in Paper #2.

Paper #1

Tobacco Use and Smoking Behaviours in a Sample of Individuals with Severe Mental Illness who are Homeless or Vulnerably Housed

Abstract

Aim: The purpose of this study was to determine the prevalence of tobacco use, the level of nicotine dependence, the intention to quit tobacco and the overall smoking behaviours within a sample of individuals with severe mental illness who were homeless or vulnerably housed receiving services from a community mental health agency. *Methods:* Active clients of the agency (N=639) were asked if they smoked tobacco and all current smokers were then asked to complete the Fagerström Test for Nicotine Dependence (FTND). Additional information regarding client smoking behaviours and motivation to quit or reduce tobacco use was collected. *Results:* Tobacco use prevalence was 72%, and 62% of smokers had high or very high levels of nicotine dependence; however almost half of respondents (47%) were interested in quitting or reducing tobacco within the next 6 months. Respondents identified smoking behaviours such as smoking cigarettes remade from discarded cigarette butts (25%), or smoking contraband cigarettes (47%); smokers were found to be over nine times more likely to have a co-occurring substance use disorder. *Conclusions:* Collecting vital tobacco prevalence and dependency information is a straightforward and important task for community mental health agencies. Individuals with mental illness want to quit or reduce their use of tobacco, and practitioners need to be aware of alternative smoking practices that may contribute to understanding tobacco use patterns and dependence in this population. Other factors such as co-morbid substance use disorder and level of community functioning may influence smoking status and, consequently, how treatment is provided.

Keywords: severe mental illness, smoking prevalence, smoking behaviours, health inequity, concurrent disorders, homelessness

Word Count: 261

Introduction

The Impact of Tobacco Use on Individuals with a Mental Illness

Tobacco use is the worldwide leading cause of preventable death and illness (World Health Organization, 2013), and it is projected that globally, deaths attributable to tobacco will increase from 6.4 million people to 8.3 million people by 2030 (Mathers & Loncar, 2006). Tobacco use is associated with numerous cancers as well as cardiovascular and respiratory diseases, contributing to the significant burden of substance-related death and disability (Patra, Taylor, Rehm, Baliunas & Popova, 2007). In Canada, over 16% of all deaths are attributable to tobacco use, with over half of these deaths due to lung cancer and chronic obstructive pulmonary disease (COPD) (Baliunas et al., 2007). In the United States, smoking-attributable deaths accounted for 25% of all deaths for those between the ages of 35 and 69, with smokers living 10 years less overall than individuals who had never smoked (Jha et al., 2013). Despite these the enduring negative consequences of tobacco use, significant public health interventions have been made in Canada, resulting in reduction of tobacco use and the attendant health consequences. Not only has overall smoking prevalence decreased substantially from 50% of the population in 1965 to just over 16.1% in 2012, but other measures that predict severity of tobacco-related harm, such as number of cigarettes consumed by smokers and levels of nicotine dependence, have also declined (Canadian Tobacco Use Monitoring Survey (CTUMS) 2012; Reid, Hammond, Rynard & Burkhalter, 2014) .

While the population level of tobacco use has impressively decreased, it is estimated that up to 85% of individuals with a serious mental illness continue to use tobacco products (Harris, Parle & Gagne, 2007), and 40% smoke more than 40 cigarettes a day (Horsfall,

Cleary, Hunt & Walter, 2009). In the U.S., individuals with a mental illness comprise over 44% of the tobacco market (Lasser et al., 2000), accounting for 39 billion dollars in annual sales (Hall & Prochaska, 2009). This high tobacco use prevalence has contributed to early mortality within this population and an inequitable distribution of negative health outcomes (Kilbourne et al., 2009; Parks, Svendsen, Singer & Foti, 2006). An analysis of standardized mortality rates of public mental health patients in eight U.S. states revealed that individuals died on average, between 49 to 60 years of age, depending upon the state and year studied (Colton & Manderscheid, 2006). Overall, individuals with severe mental illness were found to die an estimated 25 years earlier than the general population, with 60% of these deaths due to cardiovascular, pulmonary and infectious disease (Parks et al., 2006). For individuals with schizophrenia, coronary heart disease is now the primary cause of premature death (Hennekens, 2007; Curkendall, Mo, Glasser, Stang & Jones, 2004; Hennekens, Hennekens, Hollar & Casey, 2005). Individuals with bipolar disorder also have an elevated risk of death from cardiovascular disease (Callaghan & Khizar, 2010). An resent study examining causes of mortality in populations of individuals with severe mental illness determined that tobacco accounted for 53% of deaths in individuals with schizophrenia, 50% of all deaths for those diagnosed with a depressive disorder, and 48% of all deaths for those with a diagnosis of bipolar disorder (Callaghan et al., 2014).

Individuals with severe mental illness also struggle with the high co-occurrence of chronic disease (Phutane et al., 2011; Holt & Peveler, 2010; Fagiolini & Goracci, 2009; Saha, Chant & McGrath, 2007; Brown et al., 2010; McEvoy et al., 2005) and co-morbid alcohol and drug use disorders (Canadian Center on Substance Abuse, 2009; Rush et al., 2008; Rush & Koegl, 2008; Drake et al., 2001; Regier et al., 1990; Cleary, Hunt, Matheson,

Siegfried & Walter, 2007; Cleary, Hunt, Matheson & Walter, 2009). The combination of these many conditions can impact on overall levels of functioning, often leading to homeless or incarceration, with poor social connections, living in poverty and without access to appropriate health interventions to address the range of serious physical health conditions to which they are vulnerable. With higher smoking prevalence and overall tobacco-related health disparities, individuals with a mental illness are part of the social gradient for smoking that exists, along with many concurrently diagnosed marginalized populations (Bonevski, Baker, Tywman, Paul & Bryant, 2012; Guydish et al., 2011; Baggett & Rigotti, 2010; Hwang, Wilkens, Tjepkema, O'Campo & Dunn, 2009; Chesterman, Judge, Bauld & Ferguson, 2005; Murray, Bauld; Hackshaw & McNeill, 2009; Elton-Marshall, Leathersdale & Burkhalter, 2011; Moolcha et al., 2007).

A recent study of mortality causes in homeless adults living in Boston, Massachusetts, found the leading cause of death in 45 to 64 year olds to be cancer and heart disease, representing a two and three fold higher mortality rate for these diseases than in the general population (Baggett et al., 2013a). A Canadian study that examined mortality rates among the homeless and marginally housed concluded the probability of survival to age 75 for those living in the marginal housing environments was 32% for men and 60% for women, compared with 51% and 72% respectively for those in even the lowest income percentile of the general population. Some of the largest differences in the mortality rates from the general population were for smoking-related heart and respiratory diseases (Hwang et al., 2009). There is also abundant evidence of specific target marketing of marginalized populations by the tobacco industry that is well documented and has been explored in the

literature (Prochaska, Hal & Bero, 2008; Bero, 2005; Bero, 2003; Vagg & Chapman, 2005; Apollonia & Malone, 2005).

Individuals with severe mental illness form part of this heterogeneous "smoking poor" population that is difficult to definitively describe, given the various combinations of social, mental and physical health conditions that often resign individuals to lives of poverty and, seemingly, lives of tobacco use. Part of the difficulty in capturing accurate data on tobacco use is that this information is not routinely collected by community mental health agencies. In the province of Ontario, all mental health agencies receiving funding from the Provincial Ministry of Health and Long Term Care must annually submit a mandatory set of data called the "Common Data Set" (CDS) that describes client characteristics, including diagnostic information on mental and physical health conditions and utilization of the health and social service system. The CDS does not contain any specific questions related to tobacco use. Additionally, the province has developed a general assessment of client needs to be conducted and updated every six months. The "OCAN" or Common Assessment of Need contains one question to indicate tobacco use under a section labelled 'other addictions'. Not only does this make it difficult to monitor level of nicotine dependence and develop a rationale for establishing appropriate clinical interventions, it also reinforces the notion that monitoring tobacco use is neither a responsibility of the mental health system nor a concern. Moreover, given that most community mental health practitioners are currently not even required to assess the level of tobacco dependency of their clients, it would not be unreasonable for them to conclude that monitoring and addressing tobacco use is not part of their role. This is quite alarming, given the impact that tobacco use actually has on the health status and ultimately the mortality, of this particular population.

Addressing Tobacco Use within the Mental Health System

Clinical guidelines for smoking cessation for individuals with mental illness have been produced by the Department of Health and Human Services in the United States (Fiore, Jaén, Baker et al., 2008) and in Canada by the Canadian Action Network for the Advancement, Dissemination and Adoption of Practice-informed Tobacco Treatment (CAN-ADAPTT, 2011). Slow uptake and implementation of these guidelines in treating individuals with mental health and/or substance use disorders has been reported (Hall & Prochaska, 2009). One complication in widespread uptake of relevant clinical guidelines is the divergence between the community of practitioners who have developed these evidenced-based clinical guidelines for use of medications such as NRT, and the government entities that ultimately control labelling and the use of medications. Specific recommendations have been proposed to the FDA to enable pharmaceutical companies to alter existing NRT labelling, bringing it into line with current recommended practice guidelines (Fucito et al., 2014), and changes to legislation are anticipated. In the interim however, a gap exists between practice guidelines and medication packaging directives. This lack of consensus as to the implementation of an evidenced-based treatment approach has been reinforced by a limited research agenda to investigate interventions specific to the population of individuals with severe mental illness (van der Meer, Willemsen, Smit & Cuijper, 2013; Tsoi, Porwal & Webster, 2010; Tsoi, Porwal & Webster, 2013) as well as the assessed low methodological quality of much existing work (Molina-Linde, 2011).

This is further complicated by the historic health system ‘silos’ of the mental health, addiction, and primary health care treatment worlds when an individual requires support and treatment for concurrent mental health, substance abuse, and physical health concerns. In

both in-patient and community settings, individuals with serious mental illness are less likely to even be offered information or support to address their tobacco use (Johnson et al., 2009). Psychiatrists have been found to provide cessation counseling during only12% of visits with their patients as opposed to general health physicians where the rate is 38% of visits (Ziedonis, et al., 2008; Himelhoch & Daumit, 2003).

A range of enduring beliefs and practices at work within the mental health system have been identified as contributors to the ambivalent attitude toward tobacco use. These include the primacy of addressing medication and mental health treatment, inadequate education and understanding by mental health practitioners of the actual negative health impacts of smoking, and a pervasive belief that clients are either uninterested or incapable of addressing their nicotine addiction (Schroeder & Morris, 2010; Hall & Prochaska, 2009). A U.S. survey of health care professionals providing primary health care to homeless individuals found that just over 15% of staff identified that they had given tobacco to patients as a form of incentive to engage in service or to gain compliance with treatment but 26% knew of colleagues who had engaged in this practice (Baggett et al., 2012).

A Canadian study that examined the attitudes and practices of community mental health practitioners revealed higher levels of smoking among these practitioners than in the general population and that the staff who smoked were less likely to engage in conversation with clients about tobacco use (Johnson et al., 2009). Workers were also less likely to address tobacco use with their clients if they did not perceive that dealing with tobacco was part of their role or if they believed that individuals with mental illness were not interested in quitting (Johnson et al., 2009). This aspect of assumed motivation is also at the core of a health system that systematically neglects to offer treatment with the assumption that

individuals with mental illness are not interested in, or capable of, quitting. These persistent beliefs are at odds with the research that has demonstrated that smokers with psychiatric disorders have similar levels of expressed desire as the general population to quit or reduce smoking (Siru, Hulse & Tait, 2009; Hall & Prochaska, 2009; Moeller-Saxon, 2008; Khara and Okoli, 2010; Selby et al., 2010).

Treatment itself is cost prohibitive for anyone living in poverty, as interventions such as Nicotine Replacement Therapy (NRT) are not routinely paid for as part of the Ontario government provincial drug plan for individuals receiving either the Ontario Disability Support Plan (ODSP) or Ontario Works (OW). An initiative that provides free NRT treatment in Ontario, the Smoking Treatment for Ontario Patients (STOP) program, has been developed for enrolled patients of Family Health Teams and Community Health Centres, with a more recent addition to include clients of addiction treatment programs (Center for Addiction and Mental Health, 2014). Community mental health programs are currently not eligible to participate in the program, although clients of these services, who are also patients of any of the eligible program, could access NRT in this way.

Although high smoking prevalence is a well-documented issue for many vulnerable populations, little specific research has been undertaken to determine the smoking patterns of individuals with severe mental illness and how, or if, an understanding of these behaviors could influence the development of appropriate treatment.

Research Objectives

The current study had 2 objectives:

1. To determine the prevalence of tobacco use, the level of nicotine dependence, the intention to quit tobacco, and to capture an understanding of the overall smoking behaviours

within a sample of individuals with severe mental illness who are homeless or vulnerably housed and receiving services from a community mental health agency.

2. To examine the clinical and demographic characteristics that are associated with the smoking-related variables, with the intention of identifying relevant factors to consider while developing clinical interventions that target smoking cessation.

Method

Setting and Participants

The individuals who voluntarily participated in the survey were clients of the Ottawa Branch of the Canadian Mental Health Association (CMHA) in Ottawa, Ontario, Canada. CMHA Ottawa is a large community mental health agency and is an accredited health care provider under Accreditation Canada. The agency has an operating budget of over 15 million dollars annually and 85% of all funding is received from the Ontario Government's Ministry of Health and Long Term Care (MoHLTC). With a growing understanding of the extreme and exacerbated health consequences experienced by clients with high levels of tobacco use, CMHA Ottawa became committed to exploring the extent of tobacco use within the population served and any expressed desire by clients to reduce or eliminate tobacco use. The data would then inform the agency as to next steps, including the need to potentially develop clinical interventions focused on addressing tobacco addiction.

The agency has a mandate to serve adult individuals with severe mental illness who are homeless or vulnerably housed at point of referral. Consequently, most clients are initially referred from area homeless shelters, the court and criminal justice system services and psychiatric hospital in-patient units. Severe mental illness is defined utilizing the common guidelines of diagnosis, level of disability and duration of illness provided by the

Ontario Ministry of Health and Long Term Care (Government of Ontario, 1999). Typically this includes people who have a diagnosis of schizophrenia or mood disorder, a global level of impairment in more than two life domain areas as a result of their diagnosis, and the illness has lasted, or is likely to last, more than 1 year. Clients are provided with intensive case management support services, integrated individual and group treatment for co-occurring substance use disorders, access to psychiatric nursing care and primary health care through nurse practitioner support, psychiatric consultation, after hours and weekend on-call mental health support, and access to rent supplements (when available) to secure permanent affordable housing. Services at the agency are offered in accordance with the values and principles of intensive case management services that include a low client to worker ratio and a strengths-based approach that is oriented toward a client-directed practice (Government of Ontario, 2005). In 2010 the agency served a total of 1,100 unique clients during the year. Schizophrenia (42%) and mood disorders (31%) accounted for the majority of the diagnoses of clients and 60% of clients were male. Ages ranged from 16 to 84 years (M=41) and 70% of clients were between 25 and 54 years of age.

Procedure

During a one week period in November, 2010, an attempt was made to contact all active clients of the agency to inquire if they smoked tobacco. Of the 743 individuals who were rostered as active clients that week, contact was made with 639 clients or 86% of all registered CMHA clients. Clients were surveyed by their primary mental health case manager as part of the overall ongoing data collection undertaken by the agency to ensure service quality and to identify client service needs. At the time of the survey, close to 80% of clients who were surveyed had been working with CMHA and receiving case

management services for more than six months. Case managers meet weekly with their clients in the community, often for extended periods of time, and were therefore readily able to validate the smoking status as reported by their clients. Surveys were conducted during regular hours of operation between 9:00 AM - 8:00 PM Monday-Friday and 9:00 AM-5:00 PM on Saturday and Sunday. Workers reported that it took less than 15 minutes to administer the questionnaire to each client.

Measures

Fagerström Test for Nicotine Dependence. All current smokers among surveyed clients were asked to complete the Fagerström Test for Nicotine Dependence (FTND), which consists of a 6-item measure (Heatherton, Kozlowski, Frecker & Fagerström, 1991) designed to determine client level of nicotine dependence. Smokers are rated on a scale of 0 (very low nicotine dependence) to 10 (very high nicotine dependence). The FTND is the most widely used scale to measure levels of nicotine dependence and has produced varying reliability scores for internal consistency in non-psychiatric populations (α=.56 , Payne, Smith, McCracken, McSherry, & Antony, 1994; α=.64, Pomerleau, Carton, Lutzke, Flessland & Pomerleau, 1994; α=.61, Heatherton et al., 1991), and in a population of individuals with schizophrenia (α=.74, Weinberger et al., 2007). The FTND has been found to have high test-re-test reliabilities in non-psychiatric populations (r=.88; Pomerleau et al., 1991) and with specific investigations with individuals with schizophrenia (r=.65, Weinberger et al., 2007; r=.78, Yang, McEvoy, Wilson, Levin & Rose, 2003). However, other studies have questioned the sensitivity of the FTND to detect the severity of nicotine dependence for individuals with schizophrenia (α=.46; Steinberg,William, Steinberg, Krejci, & Ziedonis, 2005), with the potential for producing scores that underestimate

dependency levels (Prochaska, Leek, Hall & Hall, 2007). Crobach's alpha for the FTND in this study was somewhat marginal at α=.651.

Prochaska et al (2007) suggest that one of the issues that could compromise the sensitivity of the FTND is that the test does not inquire as to nocturnal smoking which, if practiced, could mediate an immediate morning impulse to smoke. A further complication with this population is that individuals may be living in environments such as hospitals, emergency shelters or supportive housing programs that restrict when and where they are allowed to smoke first thing in the morning and throughout the day (Steinberg et al., 2005). To determine if clients in this survey faced environmental restrictions, they were asked "*Do you currently live someplace that restricts when and where you are allowed to smoke?"*

Smoking behaviors. Estimating amount of cigarettes smoked may also be difficult for individuals who engage in such smoking behaviours as sharing cigarettes and smoking discarded cigarette butts. The FTND in its current state does not take these behaviours into account, so scores may be an underestimate of actual levels of nicotine dependence. In order to identify if clients engaged in alternative smoking behaviours, they were asked: "*Do you share cigarettes? Do you smoke cigarettes remade from discarded cigarette butts and filters? Do you smoke discarded cigarette butts?"* These questions were modified from a nursing assessment originally undertaken with homeless adults in Los Angeles that was investigating smoking behaviours that contributed to disease transmission (Aloot, Vredevoe, & Brecht, 1993). Additionally, we inquired: "*do you smoke contraband cigarettes (cigarettes not made by tobacco companies)*?" Recent research has found that smokers who smoke contraband cigarettes are heavier smokers and have less successful short term smoking cessation outcomes (Mecredy et al., 2013), making this an important behaviour to

monitor. Given that virtually all participants in the study live below the poverty line on social assistance, it would be reasonable to assume that regularly purchasing cigarettes would be cost prohibitive for this cohort. As of June, 2014, legally purchasing 200 cigarettes in Canada costs between $85.39 in Quebec to $117.86 in the Northwest Territories (Non-Smokers' Rights Association, 2014). However, contraband cigarettes cost between $10.00 - $20.00 for 200 cigarettes so it is important to understand if individuals are engaging in this purchasing behaviour. Since 200 contraband cigarettes are typically packaged loosely in a Ziploc plastic bag, this can also contribute to having an inaccurate sense of how many cigarettes are being consumed on a daily basis.

Desire to quit or reduce smoking. Finally, clients were given four statements and asked to choose the statement that best described their situation in regard to their interest and motivation in quitting or reducing their use of tobacco. These questions are related to the transtheoretical stages of change model developed by Prochaska and Diclemente (1984) that conceptualizes change in human behaviour as a staged process that begins even before one is thinking about change (pre-contemplation), progresses to contemplating what it would take to make changes (contemplation), explores the actions necessary to facilitate behaviour change (preparation), practices the new behaviour (action), and ultimately resolves to undertake the ongoing activities necessary to maintain the behaviour change (maintenance). These questions are intended to identify the potential stage of change or level of readiness that a smoker may be feeling in relation to quitting smoking: *I am seriously considering quitting in the next 6 months, but not in the next 30 days* (contemplation)*; I am interested in drastically reducing the number of cigarettes I currently smoke (reduce by half or more), but am not interested in quitting totally* (preparation)*; I am interested in quitting*

smoking/tobacco use in the next month, and I would be interested in any assistance I could get (preparation); *I currently smoke/use tobacco and I do not want to quit in the next 6 month* (pre-contemplation). Understanding the stage of change of a population of smokers not only identifies if there is interest in addressing tobacco use, but also can provide direction in regard to appropriate intervention. (Health Canada, 2015).

Level of disability and community functioning. This study was also interested in identifying possible relationships between smoking behaviours and the level of disability that each client may have been experiencing. Although the agency is mandated to serve individuals with a severe mental illness, beyond psychiatric diagnosis, a variety of factors can contribute to how well an individual is able to function in the community. Research has linked functional impairment in activities of daily living (ADL's) to risk of all-cause early mortality for this population (Hayes et al., 2012).

Multnomah Community Ability Scale. The level of community functioning was measured using the Multnomah Community Ability Scale (MCAS), which has 17 items and uses a 5-point scale to measure the four areas of health, adaptation, social skills and behaviour to provide a global assessment of functioning of individuals with severe mental illness living in the community (Barker, Baron, McFarland & Bigelow, 1994a; Barker, Baron, McFarland, Bigelow & Carnahan, 1994b). Example questions used on the MCAS include: *How impaired is the client's thought processes? How frequently is the client involved in meaningful activities that are satisfying to him or her? How impaired is the client by inappropriate and/or dysfunctional responses to stress and anxiety?* Barker et al. (1994a) found the inter-rater reliability of the total score to be .85 and the test-retest reliability to be .83, and a large state wide study in Oregon validated that MCAS scores were

predictive of how well individuals with severe mental illness were able to function in the community (Zani, McFarland, Wachal, Barker & Barron, 1999). Scores range from 17 to 85, and clients with low or no disability would have a 'high' rating of 63-85, clients with a 'medium' rating of 48-62 would be assessed as having some disability, and clients with a 'low' rating of 17-47 would be assessed as having more severe levels of disability. The scale was designed not only to provide an overall measure of current community functioning of an individual client, but to enable agencies to better describe the potential range of clients receiving service and, ultimately, the differing levels of support they may require. A recent randomized control trial testing Housing First approaches for individuals with severe mental illness developed an operational definition for a 'high needs' client that included a MCAS score of 62 or below, in conjunction with a psychiatric diagnosis of psychosis or mood disorder and concurrent conditions such as substance abuse and housing instability (Goering et al., 2011). The MCAS has been incorporated into regular clinical practice at CMHA Ottawa since 2000 and all clinical staff receive initial standardized training from a registered psychiatric nurse and then periodic refreshers on using the tool. Clients at CMHA Ottawa are assessed upon intake into the agency, annually and at closure by their primary mental health worker. MCAS scores of the participants in the study were collected from their clinical files. At the time of the survey, 574 of the 639 participants had MCAS scores available for analysis (90%).

Demographic and clinical characteristics. As previously described, the Common Data Set (CDS) data collected by the agency for the MoHLTC provides data on all direct service clients of the agency in a number of key life domains and was used to provide a description of demographic and clinical characteristics of this population. These data are

collected by the mental health case manager at the point of referral to the agency to ensure that the client meets the entry criteria for service, and information is supplemented over time as the client begins to receive treatment and support. The case manager enters all data and case note files into the Client Record Management System (CRMS), which is the agency's computerized administration data base. Collected information includes psychiatric diagnosis, housing type, source of financial support, any outstanding legal issues such as probation or pending criminal charges, history of substance use and any outstanding physical health care issues such as diabetes, with a detailed accounting of all service contacts by staff of the agency. Information is collected from the referral source, directly from the client, from family members and, over time, through professional interaction with other practitioners working with the client such as the psychiatrist, primary health care practitioner, Ontario Disability Support Program (ODSP) case manager and landlord.

Data Analysis

Descriptive statistics were calculated to describe smoking prevalence rates, smoking behaviours and level of motivation to address tobacco use. Categorical variables were summarized by frequencies and percentages and continuous variables were summarized by means (*M*) and standard deviation (*SD*). T-tests, Chi square analyses, and bivariate correlational analyses were used to assess the relationship between clinical and demographic characteristics and smoking-related variables. All analyses were performed using SPSS, version 20.

Ethics approval for research based on secondary use of data was received from the University of Ottawa's Research Ethics Board. As a Health Service Provider (HSP) that operates under a Multi-Sectoral Accountability Agreement (M-SAA) with the Champlain

Local Health Integration Network under the Ontario Government's Ministry of Health and Long Term Care, the agency is both contractually and legislatively obliged as a "health information custodian" to comply with a number of pieces of legislation (Personal Health Information Protection Act, 2004). All clients of the agency are informed verbally and in writing of this obligation and the legislation that protects their personal health information.

Results

Sample Characteristics

Table 1 provides a description of the sample who were surveyed. Of the 639 individuals surveyed, 457 (71.5%) reported that they used tobacco. Participants were predominantly male (60%), with a mean age of 41.8 (*SD* = 12.29) years. Half of the participants had a diagnosis of schizophrenia (49.5%), just over 60 % had a co-occurring substance use disorder and 44% had not completed high school. The mean Multonomah Community Ability Scale (MCAS) score was 56.97 (*SD* = 9.3) with scores ranging from 31 to 84. The overall breakdown between designated levels of disability revealed that 28% of clients scored in the high disability category with scores of 31-47; 58% of the clients scored in the moderate disability range with scores of 48-62; and 14% of clients scored in the low disability range with scores of 63-81. These scores, in conjunction with diagnostic information, indicate that the majority of clients were assessed as demonstrating a need for a high level of service in order to support community living. Given that the agency has a mandate to serve individuals who are homeless or vulnerably housed at point of referral, as expected, the majority of participants were unemployed (89%), in receipt of social assistance or disability and pension support (95%) and at the time of the survey, 22% were living in a rooming house, emergency shelter, hospital, correctional facility or had no fixed address.

Table 1

Demographic and Clinical Characteristics of the Survey Sample

Variable	Total Survey N=639	Smokers N=457 (71.5%)	Non Smokers N=182 (28.5%)	Smokers vs non-Smokers (χ^2)	Test of Comparison
Gender [3] (Male)	384 (60.3%)	291 (63.8%)	93 (51.4%)	*p*=.004 χ^2 (1) =8.37	OR=1.68 95% *CI* [1.19,2.37]
(Female)	253 (39.7%)	165 (36.2%)	88(48.6%)		
Do you have a co-occurring substance use disorder? (Yes)	387 (60.6%)	343 (75%)	44 (24.2%)	*p* <.0001 χ^2 (1) =141.1	OR=9.44 95% *CI* [6.33,14.08]
Do you have co-occurring chronic physical disease? (Yes)	299 (46.8%)	217 (47.5%)	82 (45.1%)	ns	
Do you have co-occurring developmental disability? (Yes)	51 (8%)	26 (5.7%)	25(13.7%)	*p* =.001 χ^2 (1) =11.48	OR=2.64 95% *CI* [1.48,4.70]
Do you have a diagnosis of Schizophrenia? (Yes)	316(49.5%)	217 (47.5%)	99 (54.4%)	ns	
Do you have a diagnosis of mood disorder? (Yes)	188(29.4%)	144 (31.5%)	44 (24.2%)	ns	
Variable		Smokers Mean (SD)	Non Smokers Mean(SD)	Significance of Test Statistic (t)	Cohen's d
Age at time of survey	41.83 (12.29)	41.5 (11.96)	42.7 (13.07)	ns	
Multnomah Community Ability Scale [4] N=574	56.97 (9.3)	56.23 (9.26)	58.84 (9.20)	p =.002 t(572)=-3.04	d= .28 95% CI [.74,.48]

[3] (N=637) Individuals who identified as transgendered were excluded in this calculation (n=1 non-smokes & n=1 smokers)

[4] MCAS scores are assessed yearly and 574 of 639 scores were available for analysis at the time of the survey (90%)

Comparison of Smokers and Non Smokers

As shown in Table 1, there are differences in the smoking and non-smoking groups. Smokers were more likely to be male, were over 9 times more likely to have a co-occurring substance use disorder and were close to 3 times less likely to have a co-occurring developmental disability. There was no evidence of significant associations between smokers and non-smokers in relation to age or to having a diagnosis of either schizophrenia or mood disorder. Similarly, smoking status was not associated with reported chronic physical health conditions. Analysis of the MCAS scores suggests that smoking was associated with having a lower MCAS score, although the effect size was small (*d*=.28, 95%*CI*[.74,.48]) .

Characteristics of Smokers

Overall, 331 of 457 smokers or 72.4% of the smoking sample agreed to complete the full FTND and the smoking behavior questions. An analysis was undertaken to determine if there were any significant differences in the clinical and demographic characteristics of the 331 smokers who completed the survey and the 126 smokers who did not participate in the survey. This analysis revealed that there were no significant differences in any diagnostic or demographic category, with the exception of their MCAS scores. Smokers who did not complete the questionnaire had a mean on the MCAS (*M* = 54.39, *SD*=10.37) that was lower than the mean score of smokers who did complete the survey (M = 56.91, *SD*=8.74) (*t* [168.5]=2.27, *p* = .02). This difference was calculated as involving a small effect size (*d*=.27, 95% *CI* [.09,.57]).

Table 2 provides a summary of frequencies of nicotine dependencies and participant responses to questions regarding their smoking behaviours.

Table 2

Levels of Nicotine Dependence and Smoking Behaviours in the Sub-sample of Smokers

Variable	Total Survey Smokers N=331 (%)	Mean (*SD*) N=331(*SD*)
Fagerström Test for Nicotine Dependence		6.0
Range of FTND Scores (Skewness=3.4)		(*SD*=2.29)
0-2 Very Low Dependence	27 (8.0 %)	
3-4 Low Dependence	50 (15.1 %)	
5 Medium Dependence	50 (15.1 %)	
6-7 High Dependence	119 (36.0 %)	
8-10 Very High Dependence	85 (25.7 %)	
Currently living someplace that limits when and where I smoke? Yes	114 (35.3 %)	
Smoking Behaviours		
I share cigarettes: Yes	168 (50.8%)	
I smoke cigarettes remade from discarded cigarette butts and filters: Yes	83 (25.1%)	
I smoke contraband cigarettes: Yes	155 (46.8%)	
I smoke discarded cigarette butts: Yes	72 (21.8%)	
I block filter vents or tear off filters: Yes	31 (9.4%)	
Intention to quit or reduce smoking		
I currently smoke/use tobacco and do not want to quit in the next 6 months: Yes	180 (54.4%)	
I am seriously considering quitting in the next 6 months, but not in the next 30 days: Yes	76 (23.0%)	
I am interested in drastically reducing the number of cigarettes I currently smoke but am not interested in quitting totally: Yes	53 (16.0%)	
I am interested in quitting smoking/tobacco use in the next month and I would be interested in any assistance I could get: Yes	27 (8.2 %)	

The mean score of the 331 smokers who agreed to complete the Fagerström Test for Nicotine Dependency (FTND) was 6.0 (*SD*=2.29), with 61.7% of the sample assessed as having scores over 6 reflecting 'high' or 'very high' levels of nicotine dependence. The time lapse from waking to first cigarette is an indicator of level of nicotine dependence and 52.6% of this sample reported smoking within 5 minutes of waking in the morning. Even these high levels of dependency may be an underestimate, given that 34.4% of participants identified that they are currently living in supportive or supervised environments that restrict when and where they are allowed to smoke.

Respondents identified that they engaged in a variety of smoking behaviours such as sharing cigarettes (51%), smoking cigarettes remade from discarded cigarette butts and filters (25%), smoking discarded cigarette butts (22%) and smoking contraband cigarettes (47%).

Even though respondents in this survey had high levels of nicotine dependence, almost half of them (47%) were interested in quitting or reducing their use of tobacco within the next six months. Within this group, 8% of respondents indicated that they were interested in starting a tobacco cessation or reduction program within the next thirty days.

Sex and age. Chi-square tests for association were conducted between sex and the various smoking behaviours. There was no statistically significant association between sex and any of the smoking behaviours. With regard to expressed interest in quitting tobacco, participants who reported that they had no interest in quitting smoking in the next 6 months were more likely to be men (χ^2 (1) =4.31, *p*=.038, *OR*= 1.61, 95% *CI* [1.03,2.54]) while participants who stated that they were seriously considering quitting in the next 6 months but not in the next 30 days were twice as likely to be women (χ^2 (1) = 7.18, *p*=.007, *OR*= 2.03,

95% *CI* [1.20,3.41]). The age of participants showed no association with any of the intent to quit variables, but age of participants was associated with two of the smoking behaviours. In particular, participants who shared cigarettes were younger (*M* = 39.95, *SD*=12.05) than participants who did not share cigarettes (*M* = 44.1, *SD*=11.45) (*t*[329]= -3.18, *p* = .002). This difference represented a small effect size (*d*= .35, 95% *CI* [-.08,.58]) . Participants who reported smoking contraband cigarettes were older (*M*=43.65, *SD*=11.85) than those who reported that they did not smoke contraband cigarettes (*M*=40.49, *SD*=11.82) (*t*[329]=2.43, *p*=.02) and this represented a small effect size (*d*=.27, 95% *CI* [-.59,.60]).

Diagnosis of schizophrenia or mood disorder. There was no association between a diagnosis of mood disorder or schizophrenia and any of the smoking behaviours or intention to quit questions with the exception that individuals who identified that they had no interest in quitting smoking in the next 6 months were more likely to have a diagnosis of schizophrenia (χ^2 (1) = 5.99, *p*=.014, *OR*= 1.72, 95% *CI* [1.11,2.67]).

Level of nicotine dependence. There was no association found between level of nicotine dependence as reflected in the Fagerström score and whether or not an individual had a diagnosis of schizophrenia or mood disorder. Similarly, there were no associations found between Fagerström scores and any of the co-occurring conditions of substance use disorder, chronic physical health disease or developmental disability. Level of nicotine dependence was associated with whether or not an individual identified an intent to quit or reduce smoking. Individuals with higher levels of dependency (*M*=6.27, *SD*=2.34) were less likely than individuals with lower levels of dependency (*M*=5.68, *SD*=2.19) to say that they were interested in quitting smoking within the next 6 months (*t*[329]=2.38, *p*=.02), representing a small effect size (*d*=0.26 , 95% *CI*[.01,1.08]). Consistent with this finding,

individuals with lower levels of dependency (*M*=4.96, *SD* = 2.14) were more likely than individuals with higher levels of dependency (*M*=6.09, *SD*=2.28) to say that they were interested in quitting smoking within the next 30 days (t[329]= -2.47, *p*=.01), representing a medium effect size (*d*=.50, 95% *CI* [-2.02,-.23]).

Higher level of nicotine dependence were associated with a number of smoking behaviours. Individuals with higher levels of nicotine dependence (*M*=6.80, *SD*=1.75) were more likely than individuals with lower FTND scores (*M*=5.73, *SD*=2.39) to report smoking cigarettes remade from discarded cigarette butts and filters (*t*[190.95]=4.35, *p*=.001). Higher FTND scores were also significantly associated with smoking contraband cigarettes (t[329]=4.64, *p*=.001) and smoking discarded cigarette butts (*t*[143.11]=2.85, *p*=.005).

Co-occurrence of substance use disorders. There was no statistically significant association found between a participant having a co-occurring substance use disorder and any of the variables related to an intention to quit or reduce smoking; however, this group showed a tendency to engage in several of the identified smoking behaviours. Specifically, smokers with a co-occurring substance use disorder were more likely to smoke cigarettes remade from discarded cigarette butts and filters (χ^2 (1) = 27.45, *p*=.0005, *OR*= 10.30, 95% *CI*=[3.65,29.09]), to smoke contraband cigarettes (χ^2 (1) = 7.04, *p*=.008, *OR*= 1.97, 95% *CI* [1.19,3.25]), to smoke discarded cigarette butts (χ^2 (1) = 11.65, *p*=.001, *OR*= 3.64, 95% *CI* [1.67,7.95]), and to share cigarettes (χ^2 (1) = 6.36, *p*=.012, *OR*= 1.88, 95% *CI* [1.15,3.09]) than the smokers without a co-occurring substance use disorder.

Co-occurrence of developmental disability or chronic physical health condition. Having either a developmental disability or a chronic physical health condition was not associated with any of the smoking related or intent to quit smoking variables, with the

exception of smokers with a co-occurring physical health condition being more likely to report smoking contraband cigarettes (χ^2 (1) = 5.96, *p*=.015, *OR*= 1.72, 95% *CI* [1.11,2.66]) than the smokers without a co-occurring physical health condition.

Level of disability and community functioning. Overall level of disability and community functioning as measured by the MCAS was found to be associated with several of the smoking behaviours. A lower MCAS was associated with a greater likelihood of engaging in smoking behaviours such as smoking cigarettes remade from discarded cigarette butts and filters (*t*[300]=3.2, *p*=.001), (*d*=.42, 95% *CI* [.12,.68]), smoking discarded cigarette butts (*t*[300]=3.7, *p*=.0005), (*d*= .52, 95% *CI* [0.11,0.72]), smoking contraband cigarettes (*t*[296.75]=2.86, *p*=.004), (*d*=.33, 95% *CI* [0.09,0.59]) and blocking vents or cutting off the filters of cigarettes (t[300]=2.24, *p*=.026), (*d*=.44, 95% *CI* [0.16,1.00]). A lower MCAS was also associated with individuals who identified that they did not want to quit smoking in the next 6 months (*t*[299]=2.6, *p*=.010), (*d*=.30, 95% *CI* [0.09,0.59]) while individuals who indicated that they were interested in quitting in the next six months but not in the next 30 days had higher scores (*t*[299]=2.88, *p*=004), (*d*=.39, 95% *CI* [0.11,0.69]).

Table 3 presents the intercorrelational analyses between the clinical and demographic characteristics that are associated with the smoking-related variables.

Discussion

The findings of this study provide a number of insights into understanding tobacco use and smoking behaviours within a highly marginalized population of smokers. To the author's knowledge, this is the first time that specific smoking behaviours such as smoking discarded cigarette butts and smoking contraband cigarettes have been analysed in relation to clinical characteristics such as the co-occurrence of substance use disorders and the level of

Table 3

Intercorrelational Associations Between Smoking Behaviours, Intention to Quit, and Clinical/Demographic Characteristics

Clinical/Demographic Characteristics:	**FTND**[5] *n*=331	**CD**[6] *n*=387	**MCAS**[7] *n*=574	**Phys.**[8] *n*=299	**Age** *n*=639	**Schiz.**[9] *n*=316	**Sex**[10] *n*=637
Smoker-yes (*n*=457)	NA	**-.47*****	**.13****	-.02	.05	.06	**-.12**(F)**
FTND (*n*=331)	NA	.07	-.10	.08	**.17****	.01	-.08
Smoking Behaviours:							
I smoke cigarettes remade from discarded cigarette butts and filters-yes (*n*=168)	**-.21*****	**-.29****	**.18****	-.07	.02	-.06	-.09
I smoke contraband cigarettes-yes(*n*=155)	**-.25**	**-.15*****	**.16*****	**-.13***	**-.13***	.10	.02
I smoke discarded cigarette butts-yes (*n*=72)	**-.14**	**-.19*****	**.21*****	-.02	.003	.-05	.06
I share cigarettes-yes (*n*=168)	-.001	**-.14***	.06	-.05	**.17**	-.05	-.08
I block filter vents or tear off filters-yes (*n*=31)	.01	-.03	**.13***	.02	.03	-.05	-.07
Intention to quit or reduce smoking:							
I currently smoke/use tobacco and do not want to quit in the next 6 months-yes (*n*=180)	**-.13***	.05	**.15****	.06	-.07	**-.14***	**-.11*(M)**
I am seriously considering quitting in the next 6 months, but not in the next 30 days-yes (*n*=76)	.04	-.02	**-.16****	-.09	-.001	.09	**.15**(F)**
I am interested in quitting smoking/ tobacco use in the next month and I would be interested in any assistance I could get-yes (*n*=27)	**.14***	.02	-.01	.05	.03	.04	.10

* p < .05; ** p < .001; *** p < .000

[5] FTND=Fagerström Test for Nicotine Dependence
[6] CD=Concurrent Disorders -yes(co-occurring mental health and substance use disorder)
[7] MCAS=Multnomah Community Ability Scale
[8] Phys.=Co-occurring chronic physical health condition-yes
[9] Schiz.=Diagnosis of schizophrenia-yes
[10] M=Male-yes & F= Female-yes

disability and community functioning. These finding have implications for understanding and interpreting level of nicotine dependence and in the development of appropriate interventions to address tobacco use in similar groups of smokers. The client population in this study is typical of a community mental health program that is mandated to support individuals with a serious mental illness. Unlike the patient population in outpatient psychiatric programs that are typically designed to treat individuals according to their primary diagnosis, community mental health programs tend to serve individuals with a variety and mix of diagnoses. Overall, respondents in this study could best be described as a diagnostically heterogeneous population with significant co-occurrence of substance use disorder, chronic physical health conditions, and, given the pervasive poverty that is endemic with this population, housing vulnerability and homelessness.

The overall smoking prevalence in this study was reported as 72% which, while alarming, is consistent with the high prevalence of smoking reported among individuals with a mental illness (Harris, Parle & Gagne, 2007; Grant, Hasin, Chou, Stinson & Dawson, 2004; Lasser et al., 2000). Smoking prevalence in large U.S national samples of homeless adults has been reported as being 73% (Baggett & Rigotti, 2010) and 69% (Connor, Cook, Herbert, Neal & Williams, 2002). With regard to diagnosis, this study reported no evidence of significant associations between smokers and non-smokers in relation to having a diagnosis of either schizophrenia or mood disorder. While the literature consistently reports higher prevalence of tobacco use among individuals with a diagnosis of schizophrenia (de Leon, 1996; de Leon & Diaz, 2005; Diaz, Velasquez, Susce & de Leon, 2008), this may have been mediated by the presence of other factors that are associated with elevated tobacco use, such as the high co-occurrence of substance use disorder, housing vulnerability, and the

overall high incidence of poverty that were experienced by all participants in the sample, regardless of any particular diagnosis. Similarly, smoking status was not associated with reported chronic physical health conditions although intuitively one might have anticipated that smokers would have a higher likelihood of suffering from a chronic physical illness. Again, this is a particularly marginalized population where physical health status is poor, regardless of smoking status. This is consistent with research that identifies compromised overall physical health status for individuals with mental illness and those who are homeless or vulnerably housed. (Baggett, Tobey & Rigotti, 2013b; Baggett et al., 2014; Hwang et al., 2011).

There were two particular findings related to diagnosis and level of community functioning between smokers and non-smokers that bear examination. Individuals with a co-occurring substance use disorder were 9 times more likely to be a smoker than clients who did not have a co-occurring substance use disorder. A high co-occurrence of tobacco use and co-occurring mental health and substance use disorders is well documented in the literature (Okoli & Khara, 2011; Khara & Okoli, 2010; Selby et al., 2010; Grant, Hasin, Chou, Stinson, & Dawson, 2004). Given the high prevalence of tobacco use in general among the mentally ill and the fact that community mental health programs serve a high proportion of individuals with concurrent disorders in particular, this speaks to the importance of assessing for tobacco dependence and developing the capacity to provide integrated treatment opportunities.

A similar integration of treatment would be prudent for addiction treatment programs, given the high co-occurrence of mental health disorders in individuals with an identified substance use disorder (Rush et al., 2008; Rush & Koegl, 2008). This could be

particularly vital in this population, as a meta-analysis of 19 studies of tobacco cessation within addiction treatment programs concluded that addressing tobacco cessation appears to enhance the capacity to maintain long term sobriety gains from other substances (Prochaska, Delucchi & Hall, 2004). A recent survey of community mental health and addiction treatment programs in the province of Ontario reported that, while 71% of programs stated that they served individuals with a concurrent disorder, less than a quarter of the programs included 'tobacco' as part of their definition of 'concurrent disorder' (Addictions and Mental Health Ontario & Canadian Mental Health Association, Ontario Division, 2013). Clearly, this is a practice that needs to change if community mental health and addiction programs are to respond to what is an urgent need for treatment within the populations that they are serving.

With regard to level of disability and community functioning, an analysis of the MCAS revealed that smokers had lower scores than non-smokers. Lower scores on the MCAS suggests potential difficulty in areas of functioning such as health, community adaptation, social skills and behaviour. This could mean that individuals were not stably housed, were not taking medication as prescribed, had poor social connections or were suffering from chronic physical health conditions. The combination of lower scores on the MCAS and significant co-occurrence of substance use disorders among smokers has implications for the development and implementation of treatment to address tobacco use in this population. With the potential for compromised community functioning, it would be important to integrate tobacco treatment within mental health services that are capable of addressing overall community functioning and life domain issues such as housing, family support and psychiatric medication management.

The co-occurrence of alcohol and drug use disorders also suggests the need to integrate tobacco treatment within programs that are addressing these problems and that modifications for more intensive support to meet the needs of a highly disabled population may be warranted (Khara & Okoli, 2010; Okoli & Khara, 2011; Selby et al., 2012;Williams & Ziedonis, 2004). A recent review of the specific harms associated with tobacco use in the homeless population suggests a similar need to integrate tobacco treatment within the sector in order to better respond to client needs (Baggett, Tobey & Rigotti, 2013; Baggett et al., 2014).

Understanding the extent of nicotine dependence in this population is important given that studies have found that individuals with serious mental illness have reported tobacco use as a 'core need' above food (Ziedonis et al., 2008). The level of nicotine dependence in this sample was considerable, with a mean Fagerström score of 6 and over 60% of the sample assessed with a score between 6 and 10 indicating 'high' or 'very high' levels of nicotine dependence. Reported mean Fagerström scores in studies that have targeted similar populations are 4.4 (Butler et al., 2002), 6.3 (Burling, Burling, Latini & Kendall, 2001), 4.1 (Okuyemi et al., 2006), 3.7 (Shelley, Cantrell, Wong & Warn, 2010), and 6.4 (Khara & Okoli, 2010). As previously discussed, while the FTND has good reliability for determining level of nicotine dependence in individuals with a serious mental illness, there are some potential challenges for capturing an accurate assessment of nicotine dependence in marginalized groups of smokers due to specific smoking behaviours, practices, and even potentially, their living environment. In this study, one-third of the sample reported that they lived someplace that controlled when and where they were allowed to smoke cigarettes. Since these types of environments tend to be temporary or transient, it

is possible that these individuals would consume even more cigarettes, given a completely unrestricted living environment.

Approximately half the sample reported either sharing cigarettes or smoking contraband cigarettes. The use of contraband cigarettes on a regular basis by the general population of smokers has been reported as 13% (Mecredy et al., 2013). In this study, those who reported smoking contraband cigarettes tended to be older, have a lower MCAS, have a co-occurring chronic physical health condition and a concurrent substance use disorder, while those who reported sharing cigarettes had a concurrent substance use disorder and a diagnosis of schizophrenia. Additionally, one in four clients reported smoking cigarettes remade from discarded cigarette butts and filters, and one in five reported smoking discarded cigarette butts. Individuals who engaged in these smoking behaviors and practices were more likely to have a concurrent substance use disorder and to have lower community functioning as reflected by their MCAS score. The combination of a lower MCAS score and a concurrent disorder suggests that the sub populations who engage in these behaviours could be experiencing more chaotic life situations that could ultimately present additional challenges for practitioners providing treatment.

Acquiring cigarettes through these means can make it difficult to calculate the exact amount smoked and ultimately determine nicotine dependence levels, which are critical for administering effective treatment and designing intervention programs. A recent examination of smoking cessation outcomes in the general population revealed an association between the use of contraband cigarettes with poorer smoking cessation outcomes and higher levels of nicotine dependence (Mecredy et al., 2013). In this study, respondents with higher FTND scores were more likely to smoke contraband cigarettes,

smoke cigarettes remade from discarded cigarette butts and to smoke discarded cigarettes butts. These behaviours also provide valuable information regarding the 'culture' of ingrained smoking behaviour in this population. A government intervention such as taxation to raise cigarette prices in order to decrease demand has little or no impact when purchasing contraband cigarettes or smoking the discarded cigarette butts of others.

These are all factors that can influence the accurate calculation of level of nicotine dependence, which could account for variations in dependency levels across similar population groups in the literature. It is essential for practitioners to take these behaviours and practices into consideration when assessing for tobacco dependency within marginalized groups. It is important, though, to be sensitive when gathering information on where clients obtain their cigarettes, as many workers reported that their clients expressed shame at engaging in these behaviours. The availability of low cost contraband cigarettes may help to explain continued high levels of smoking in the face of economic hardship, but even at discount rates, smoking continues to impose an inequitable and substantial financial burden on those with restricted incomes (Johnson et al, 2009).

Analyses between the MCAS and Fagerström Scores found no correlation between these two variables. This result could have been impacted by the fact that the smokers who did not participate in the full survey were also smokers with significantly lower MCAS scores. Also, the FTND score is heavily weighted with amount of cigarettes smoked and individuals with lower MCAS scores tended to be more likely to smoke cigarette butts and cigarettes remade from other cigarettes and filters, making it more difficult to estimate number of cigarettes smoked on any given day.

It is interesting to note that a co-occurring developmental disability may be somewhat of a protective factor against smoking, as these individuals were almost three times less likely to be smokers. This could be due to the more protective and restrictive living environments in which individuals with an intellectual handicap have historically been supported. This is an area that would have to be explored further to determine whether or not this is a particularly vulnerable population to start using tobacco as the system shifts and individuals are increasingly integrated into mainstream services, and all too often end up in the emergency shelter system (Mercier & Picard, 2011).

With regard to interest in quitting or reducing tobacco, Connor et al. (2002) found that 37% of clients in nine different homeless shelters reported that they would like to quit within the next six months and that there was no relationship between interest in quitting and level of nicotine dependence. In a review by Hall and Prochaska (2009) of several studies regarding motivation to quit smoking among populations of individuals with a mental illness or a substance use disorder, there were similar expressed desires to quit or reduce smoking as in the general population. In this study, almost half of the respondents (47%) were interested in quitting or reducing their tobacco use within the next six months, and eight per cent of this group wanted to quit within the next thirty days. Individuals who were not interested in quitting in the next six months were more likely to be male, have a higher level of nicotine dependence, have lower functioning as reflected in a lower MCAS and have a diagnosis of schizophrenia. Overall, people who identified an interest in quitting in the next thirty days had a lower level of nicotine dependence and a higher MCAS. These combinations of clinical and social factors could impact on the development of intervention strategies for building motivation and interest in tobacco cessation.

It is evident that, even though this is a complex population to serve with a high prevalence of tobacco use and high level of nicotine dependence, people are interested and want assistance to quit or reduce smoking. Given the potential overwhelming demand for treatment from groups of marginalized smokers, information pertaining to who is more likely to engage in treatment could be useful for the targeting of scant resources. A study that was attempting to explain the social gradient of smoking concluded that there were no differences between various economic groups in regard to quit attempts and interest in engaging in treatment, but suggested that the social gradient in smoking exists due to the differences in who is able to succeed and stay in treatment (Kotz & West, 2009). This could be a key factor in understanding how to address the high smoking prevalence in this population. In this sample, factors such as co-occurring substance use disorders and poor community functioning that suggest instability in a number of life domain areas, could have an impact on whether someone is able to succeed and stay in treatment, and therefore interventions would have to be designed to take these conditions into consideration.

This study has limitations. This was a sample of clients from one agency and the survey was undertaken originally as a needs assessment to determine the need for service development within the agency. While the participation rate was high, there were still clients who did not participate in the survey. These clients were not available to participate for a number of reasons beyond personal choice, including incarceration, hospitalization and other chaotic life events, and as such, their contribution to the survey results were lost. The survey was administered by the client's primary mental health case manager and, while this definitely contributed to the overall high response rate, having several different people administer the survey, even well-trained professionals, could have impacted on the

consistency of how the data were collected. The survey participants represented a wide range of diagnostic profiles; while this may typify the client population served within community mental health services, it is a population with a myriad of complex and co-occurring medical and social conditions. The contribution that tobacco makes to this maelstrom is clearly significant yet, as previously stated, solutions to address poverty and inequity require program and policy responses outside the health care system within the realm of social justice.

Conclusions

As community mental health programs become more concerned with issues of health equity, they are challenged to understand why tobacco use prevalence is so high among individuals with severe mental illness. Clearly many factors have combined to create and sustain the 'perfect storm' of conditions that facilitate continued tobacco use: a highly addictive product, a vulnerable population, an absence of treatment, a heavily invested corporate interest, and, until recently, a complicit mental health care system. In conclusion, it is clear that the prevalence of tobacco use and level of nicotine dependence in this population is exceptionally high and collecting vital tobacco prevalence and dependency information is a straightforward and important task for community mental health agencies. It is also clear that individuals with a mental illness want to quit or reduce their use of tobacco. Practitioners need to be aware of the wide range of smoking practices that may impact on a true understanding of tobacco use patterns and dependence in this population. Other factors such as co-morbid substance use disorder and higher levels of disability may impact on smoking status and, ultimately, how treatment needs to be provided in order to keep individuals engaged in treatment.

Paper #2

Efficacy of Smoking Cessation Treatment Interventions for Individuals with Severe Mental Illness: A Pilot Randomized Controlled Clinical Trial

Abstract

Objectives: To investigate the effectiveness of Nicotine Replacement Therapy (NRT) only versus NRT plus psychosocial group support and individual motivational interviewing (MI) sessions on smoking cessation or smoking reduction in individuals with severe mental illness.

Design, setting & participants: Block pilot randomized controlled trial of clients with severe mental illness who smoked tobacco, conducted in a large accredited community mental health agency in Ottawa, Canada between April 2012 and November 2012. Level of nicotine dependence was assessed using the Fagerström Test for Nicotine Dependency (FTND), monitoring of exhaled carbon monoxide (CO) levels, and self-report of number of cigarettes smoked daily. Participants were 61 adults (62% male; mean age of 44 [*SD*=11] years; mean months homeless in lifetime 31 [*SD*= 47]), with large proportion having a diagnosis of schizophrenia or mood disorder (77%), and a co-occurring substance use disorder (74%), a mean FTND score of 6.2 (*SD*=1.8), mean expired CO level of 24 *ppm* (SD= 13*ppm*) and a mean daily consumption of 25 (*SD*=12) cigarettes at baseline. Participant smoking outcomes from the two RCT groups were also compared with a matched sample group (*n*=61) drawn from an existing data base who had received standard care.

Intervention: Participants were block randomized by FTND score and gender into smoking cessation routine (SC-R) or smoking cessation plus (SC+) treatment groups. All participants were offered combination NRT at titrated doses during weekly individual meetings with a registered nurse. Participants in the SC+ group were also offered a weekly psychosocial support group and two individual sessions of motivational interviewing therapy. Due to

limited resources, the period of treatment offered was for 24 weeks. Participants in the matched standard care group had no specific smoking cessation intervention offered to them.

Main Outcomes: Primary outcomes were verified 7-day point prevalence abstinence and number of cigarettes smoked at the 3-month and 6-month follow-up. Secondary outcomes included change in reported quality of life, physical health and mental health status functioning over the course of the study.

Results: The 7-day point prevalence abstinence rate measured at 3 months was 21.9% (*n*=7) for the SC+ group and 13.8% (*n*=4) for the SC-R group (OR=1.75,95%CI[.45,6.74]). At 6 months, the 7-day point prevalence abstinence rate was 12.5% (*n*=4) for the SC+ group and 6.9% (*n*=2) for the SC-R group (OR=1.93, 95%CI[.33,11.41]). There were no statistically significant differences in the smoking quit or smoking reduction rates between the SC-R treatment group and the SC+ group. At the 3-month time point the overall quit rate for both groups combined was 18% (*n*=11) and at the 6-month time point the quit rate was 10% (*n*=6). Reduction in the number of daily cigarettes smoked was statistically significant over time (F [1.68, 98.90] = 55.13, $p < .001$, $\eta_p^2 = 0.48$) as was the overall reduction of the FTND score (F [2, 94] = 17.98, $p < .001$, $\eta_p^2 = 0.28$) for both groups together. Number of cigarettes smoked at baseline predicted cessation at three months and greater number of nursing contacts and weeks of NRT predicted cessation and reduction of tobacco at six months. The SF-36 Physical Component Scale (PCS) score showed a statistically significant increase in both groups together from a baseline mean of 41.72 (*SD*=12.60) to a six month mean of 45.48 (*SD*=12.40) (F[2,118]=5.21, p=.007, η_p^2=0.08). Individuals in the SC+ group who quit smoking attended more weekly group sessions (t[10.24]=-3.86, p=.003), (d=1.10, 95%*CI*[0.43,2.74]) and individual MI sessions (t[24.0]=-3.36, p=.003),

(*d*=.74,95%*CI*[0.34,2.19]) than SC+ group participants who remained smokers. The natural smoking quit rate in the matched standard care sample was lower (5%; *n*=3) and their FTND scores at 6 month follow-up were significantly higher when compared to the FTND scores of participants in the study (*t*[110]=-3.36, *p*=.001), (*d*=.64,95%*CI*[0.15,0.99]) at six months. Comparison of the FTND scores across time points showed a significant interaction effect between the scores of the combined RCT study groups and the matched standard care sample group with the matched sample group having a higher score (*F*[1,110]=11.65, *p*=.001, η_p^2=0.096).

Conclusions: As a pilot study, this research demonstrates that smoking cessation and smoking reduction treatment can be successfully introduced into a very vulnerable population of individuals with severe mental illness and that the research protocols used in this study were well tolerated by participants. Although not statistically significant, the effect size associated with the between group comparison suggests that a more definitive trial with a sufficiently powered sample is warranted. With such ingrained patterns of nicotine dependence as experienced by individuals with multiple and complex needs, programs need to support reduction of cigarette smoking as an alternative or at least a bridge to complete smoking cessation. Individuals benefit from combination and titrated doses of NRT and the availability of longer treatment periods in order to sustain treatment gains. Physical health status did improve, and mental health status did not decline during the treatment period, and use of other substances did not increase.

Funding: No funding was received to conduct this study.

Words: 771

ISRCTN registry: ID ISRCTN11353250

Introduction

Background and Objectives

Tobacco use and mental illness. Tobacco use killed close to 6 million people worldwide in 2011, and given current smoking trends in low and middle income countries in particular, it is projected that up to 1 billion people could die from tobacco-related illness in the twenty-first century (Eriksen, MacKay & Ross, 2012). In Canada, 16.6% of all deaths are attributable to tobacco use, accounting for over 37,000 deaths annually (Baliunas et al., 2007) and up to half of all smokers will ultimately die of a smoking-related disease (Health Canada, 2014a). Tobacco use is associated with numerous cancers as well as cardiovascular and respiratory diseases contributing to the significant burden of substance-related death and disability (Patra, Taylor, Rehm, Baliunas & Popova, 2007). However, as a result of comprehensive public health care interventions over the past several decades, impressive gains have been made in Canada that has resulted in both reduced overall tobacco use and the reduction of related negative health consequences. Smoking prevalence in the general Canadian population has decreased in all age cohorts to a current rate of 16.1%. (Canadian Tobacco Use Monitoring Survey (CTUMS) 2012; Reid, Hammond, Rynard & Burkhalter, 2014).

By most standards of analysis this reduction of tobacco use is a population health intervention success story. However, the shortcomings in current practice are revealed when considering who is represented within the populations of remaining smoking cohorts. While the term 'vulnerable population' can be considered ambiguous, Borelli (2010) has proposed that vulnerable populations of smokers can be defined by the following four criteria. As compared to the general population they experience a greater than 10% higher smoking

prevalence rate, a disproportionate number of tobacco-related health consequences, barriers in accessing treatment, and finally, there is a lack of research on how to effectively address smoking cessation for the specific group (Borrelli, 2010). Clearly, individuals with severe mental illness fulfil these criteria. Depending upon the particular diagnostic grouping, up to 85% of individuals with a mental illness continue to use tobacco products (Harris, Parle & Gagne, 2007) contributing to the established 25 year early mortality of this population (Colton & Manderscheid, 2006;Kilbounre et al., 2009; Parks et al., 2006).

Early mortality in schizophrenia is due to many causes, but cigarette smoking is specifically associated with an almost fivefold increased risk of death (Dickerson et al., 2013) and accounts for 53% of all deaths (Callaghan et al., 2014). Individuals with bipolar disorder also have an elevated risk of death from cardiovascular disease (Callaghan & Khizar, 2010) and tobacco use accounts for 50% of all deaths for those diagnosed with a depressive disorder and 48% of all deaths for those with a diagnosis of bipolar disorder (Callaghan et al., 2014).

Other vulnerable populations of smokers, such as people who are homeless and individuals with substance use disorders suffer from similar tobacco-related health disparities (Baggett et al., 2014; Baggett et al., 2013a; Baggett, Tobey & Rigotti, 2013b;Bonevski, Baker, Tywman, Paul & Bryant, 2012; Guydish et al., 2011; Baggett & Rigotti, 2010; Hwang, Wilkens, Tjepkema, O'Campo & Dunn, 2009; Chesterman, Judge, Bauld & Ferguson, 2005; Murray, Bauld; Hackshaw & McNeill, 2009; Elton-Marshall, Leathersdale & Burkhalter, 2011; Moolcha et al., 2007). The distinct role of targeted marketing strategies by the tobacco industry of specific vulnerable populations has been well documented in the literature as a contributing factor in the continued high smoking

prevalence rates within these populations (Prochaska, Hal & Bero, 2008; Bero, 2005; Bero, 2003; Vagg & Chapman, 2005; Apollonia & Malone, 2005). As evidence of this marketing success, it has been determined that individuals with mental illness comprise over forty-four percent of the U.S. tobacco market (Lasser et al., 2000), accounting for 39 billion dollars in annual sales (Hall & Prochaska, 2009).

Individuals with severe mental illness often present with complex clinical needs such as chronic disease (Phutane et al., 2011; Holt & Peveler, 2010; Fagiolini & Goracci, 2009; Saha, Chant & McGrath, 2007; Brown et al., 2010; McEvoy et al., 2005) and co-morbid alcohol and drug use disorders in the population (Canadian Center on Substance Abuse, 2009; Rush et al., 2008; Rush & Koegl, 2008; Drake et al., 2001; Regier et al., 1990; Cleary, Hunt, Matheson, Siegfried & Walter, 2007; Cleary, Hunt, Matheson & Walter, 2009). Various social determinants of health, such as access to appropriate housing, financial support, social support, and health care services can also be compromised for this population, contributing to their overall vulnerability (Raphael, 2009).

Developing tobacco use and other substance abuse treatment services to address the health care needs of this population has been challenging, given the historic lack of consensus as to an evidenced-based treatment approach, reinforced by an almost absent research agenda to investigate interventions specific to the population. The development of treatment is further complicated by the need to often integrate treatment plans across the enduring health system 'silos' of the mental health, addiction and primary health care treatment worlds. Tobacco use not only affects the mentally ill with particularly deadly consequences, but the record of investment in treatment and intervention by the health system targeting the problem in this population group is demonstrably inadequate.

Smoking cessation interventions for individuals with severe mental illness. In general, smoking cessation intervention programs recommend a combination therapy of pharmacological intervention, including nicotine replacement therapy (NRT), which comes in the form of patches, inhalers, lozenges, nasal spray and gum, psychotropic medications such as varenacline and buproprion, and psychosocial interventions (CAN-ADAPT, 2011). Psychosocial interventions include individual and group counseling typically utilizing motivational interviewing (MI) and cognitive behavioural therapy (CBT) approaches that address a broad range of issues related to smoking behaviour, with most programs consisting of eight to twelve weekly sessions.

There are many challenges with this standard approach in meeting the smoking cessation needs of a population with severe mental illness. In considering NRT, there are two main considerations. First and foremost, the therapy itself is cost prohibitive, as NRT is not routinely paid for as part of the Ontario government provincial drug plan[11] for individuals receiving either the Ontario Disability Support Plan (ODSP) or Ontario Works (OW). Free NRT treatment is provided under the Smoking Treatment for Ontario Patients (STOP) Program in the Province of Ontario for enrolled patients of Family Health Teams and Community Health Centres and clients of addiction treatment programs (Center for Addiction and Mental Health, 2014). Community mental health programs are currently not eligible to participate in the program, but clients of community mental health programs would have access if they were also enrolled patients of one for the approved STOP sites.

[11] The government of British Columbia currently provides no cost NRT for up to 12 weeks to any resident. All other provinces and territories, with the exception of Newfoundland and New Brunswick where no subsidization is provided, offer various levels of subsidy for NRT products and other smoking cessation medications. In August 2011 the Ontario Government added 12 weeks of varenicline and bupropion to the Ontario Drug Benefits Plan and currently makes NRT available to patients of specific health funded services under the Smoking Treatment for Ontario Patients (STOP) program.

The second issue with regard to use of NRT is that, while individuals with severe mental illness have high levels of nicotine dependence (Horsfall et al., 2009; Harris et al., 2007; Dixon et al., 2007), current labelling directives for NRT are for populations that do not typically have such extreme levels of dependence. The existing recommended dosage and titration schedules included on the NRT packaging will not necessarily be appropriate for the heavily addicted who may benefit from higher doses of NRT, combination NRT therapies and longer periods of treatment. Work is underway to allow pharmaceutical companies to revise their labelling of NRT packaging (Fucito et al., 2014) but there is also specific urging from the SRNT for further changes that would include allowing for combination NRT dosing, extended treatment times without needing to consult with a healthcare professional and the use of NRT prior to a quit date (Fucito et al., 2014).

In the United States, clinical guidelines for smoking cessation for individuals with mental illness have been produced by the Department of Health and Human Services (Fiore, Jaén, Baker et al., 2008), but there has been a slow uptake and implementation of these guidelines in treating individuals with mental health and/or substance use disorders (Hall & Prochaska, 2009). In Canada, there are widely accepted smoking cessation guidelines for the general population, and the Canadian Action Network for the Advancement, Dissemination and Adoption of Practice-informed Tobacco Treatment (CAN-ADAPTT) has recently produced treatment guidelines for "Specific Populations: Mental Health and/or Other Addiction(s)". The three summary statements recommend screening, offering of counselling and pharmacotherapy at appropriate dosages, and monitoring of mental health status with possible adjustment of psychotropic medications as needed (CAN-ADAPTT, 2011). In 2008, the Ontario Medical Association also produced a position paper that addressed a range

of myths regarding the use of stop-smoking medications in order to guide practice (OMA, 2008).

Intensity of psychosocial intervention is an additional concern, given what is known regarding psychosocial interventions for this population in addressing other substance use disorders (Cleary et al., 2009; Cleary et al., 2007), individuals with a severe mental illness are likely to require long-term support beyond the life of most eight to twelve week tobacco cessation programs. This could influence not only the level of professional interest in providing treatment to this particular cohort, but could, in fact, exceed most program mandates and resources. A study examining smoking outcomes for individuals with schizophrenia and non-psychotic psychiatric disorders found a session 'dose' effect, where the number of sessions that a participant attended increased proportionally the odds of quitting (Selby et al., 2010). Similarly, length of treatment predicted smoking cessation outcomes in a study of individuals with co-occurring mental health and substance use disorders (Okoli & Khara, 2014; Khara & Okoli, 2010; Okoli & Khara, 2011). A meta-analysis of RCT's of behavioural interventions for smoking cessation in the general population also demonstrated increased abstinence with more intensive individual, group, and telephone counselling (Mottillo et al., 2009).

With regard to the incorporation of a MI approach into a smoking cessation intervention, in a recent meta-analysis of 31 RCT's, MI counselling was found to produce a modest overall 2.3% difference in smoking abstinence rates in MI versus comparison groups (Hettema & Hendricks, 2010). It was found to show particular promise in groups with lower levels of tobacco dependence and low motivation to quit, individuals with other physical health problems, in sessions that were less than 1 hour, and when MI was practised with

attention to fidelity to a MI standard of practice (Hettema & Hendricks, 2010). MI is recommended as an integrated practice in working with individuals with severe mental illness (Mueser et al., 2001; Barrowclough et al., 2001), in the treatment of psychological problems (Arkowitz, Westra, Miller & Rollnick, 2008), and as an integrated treatment with CBT in working with individuals with mental illness (Westra & Arkwitz, 2011). In particular, application of the MI 'spirit' denotes a focus on client autonomy, a non-confrontational collaboration approach, and working toward evoking internal intrinsic motivation of the client through a non-confrontational approach (Miller & Rollnick, 2005). This approach is very complimentary to the 'strengths model' (Rapp & Goscha, 2008) that is incorporated within many community mental health programs.

Varenicline and bupropion has been established as an effective treatment for nicotine dependence both in the general population (Cahill, Stead & Lancaster, 2011; Hughes, Stead & Lancaster, 2000), and in individuals with mental illness (Tsoi, Porwal & Webster, 2013; Tsoi, Porwal & Webstar, 2010; Stapleton et al., 2008; Evins et al., 2004). In prescribing buprorion or varenicline however, monitoring for any emerging neuropsychiatric side effects in the psychiatric population is recommended (Els, Kunyk & Sidhu, 2011). In a systematic review of two smoking cessation intervention trials for individuals with schizophrenia, Tsoi et al., (2013) found that, while varenicline was effective, adverse psychiatric side effects could not be ruled out. Other evidence suggests that adverse side effects could be managed effectively and mitigated, by providing enhanced supports to individuals receiving this treatment (Stapleton et al., 2008). A systematic review of the efficacy and safety of buproprion treatment for nicotine dependence in individuals with schizophrenia found

significantly higher abstinence rates and that mental health symptoms were not adversely impacted (Tsoi, Porwal & Webstar, 2010, p. 351).

A review of 24 studies assessing the effectiveness of smoking cessation for this population found that, at the long term one year follow-up, quit rates were only marginally lower as compared to the general population (el-Guebably, Cathcart, Currie, Brown & Gloster, 2002). A more recent systematic review of 10 smoking cessation behavioural interventions in disadvantaged groups of smokers found evidence of significant effect, with expressed caution given that the studies represented wide parameters in behavioural support interventions and the overall studies samples were small (Bryant, Bonevski1, Paul, Mcelduff, & Attia, 2011. p. 1581). The review included three studies that targeted smokers with schizophrenia or schizo-affective disorder, two that targeted smokers with a variety of psychotic disorders, four that included individuals with depression, and one that targeted smokers with PTSD.

There are a number of additional studies that document a range of smoking cessation interventions for this population. This includes studies that utilized NRT plus psychosocial interventions for clients with psychotic disorders (Baker et al., 2006), combinations of NRT plus psychosocial interventions and bupropion for clients with schizophrenia spectrum disorders (Ferron, Alteram, McHugo, Brunette & Drake, 2009), intensive psychosocial interventions for smokers with schizophrenia and schizoaffective disorder (Williams et al., 2010), and an individualized treatment approach for individuals with schizophrenia and non-psychotic psychiatric disorders (Selby et al., 2010). Still other approaches describe the potential benefits of smoking reduction strategies as an initial treatment goal for smokers with schizophrenia (McChargue, Gulliver & Hitsman, 2002) and the advantages of

delivering interventions that are integrated within routine mental health treatment settings (Hitsman, Moss, Montoya & George, 2009). More innovative approaches have also been proposed, such as the utilization of an electronic 'decision support system' to motivate individuals with severe mental illness to access evidence-based smoking cessation treatment options (Brunette et al., 2011). With regard to even brief interventions delivered by a psychiatrist, changes is the smoking behaviour of psychiatric patients can be found after a brief smoking cessation intervention that pays attention to stage of change transitions (DiClemente et al., 2011).

The need to study the use of NRT to assist individuals to reduce or quit cigarette smoking and the use of combination NRT at the higher titrated doses has been identified as a research gap in the provision of smoking cessation care for this client group (CAN-ADDAPT, 2011. p. 11). Systematic reviews have also identified a need for smoking cessation intervention research specific to the populations of individuals with severe mental illnesses. In particular, there has been an identified need for research that investigates the effectiveness of NRT and psychosocial interventions (van der Meer, Willemsen, Smit & Cuijper, 2013; Tsoi, Porwal & Webster, 2010; Tsoi, Porwal & Webster, 2013). Much of the research to date has also been assessed as being of low methodological quality (Molina-Linde, 2011).

Objective of the study. The objective of the study was to evaluate if individuals with severe mental illness who use tobacco are able to reduce or eliminate tobacco use following the administration of two specific and different smoking cessation interventions. Study participants in both conditions, defined in the study as the smoking cessation plus (SC+) group and the smoking cessation routine (SC-R) group, were offered combination

NRT at titrated doses during weekly individual meetings with a registered nurse. In addition, participants in the SC+ group were offered a weekly psychosocial support group and two individuals sessions of motivational interviewing therapy. The period of treatment offered was for 24 weeks. The study was conducted as a pilot RCT.

Research Questions. In addition to examining the feasibility of conducting smoking cessation research with the population, the pilot study was intended to answer the following research questions:

1) Do participants who receive the SC+ treatment have better smoking outcomes than participants who receive the SC-R treatment?
2) Are there differences between the two groups in other monitored and reported participant secondary outcomes such as quality of life, use of psychiatric medication, weight and patterns of other substance use?
3) Do participants who receive the SC+ treatment and participants who receive the SC-R treatment have better smoking outcomes than individuals receiving standard care (i.e. no specific smoking cessation intervention)?
4) Is there a relationship between the amount of the nursing contact and NRT intervention received among participants in the two groups and client outcomes?

Methods

Trial Design

This was a non-blind parallel group study conducted in a large accredited mental health agency in Ottawa, Canada (1 site) between April 2012 and November 2012. Sixty-two participants were block randomized in pairs to one of two smoking cessation interventions based on sex and level of nicotine dependence determined by their Fagerström

Test for Nicotine Dependency (FTND) score of 0-10. Further details regarding the randomization process are provided in a later section of the methods. One participant left the province shortly after the baseline data were collected and before any treatment was initiated, so that participant was removed from the study, leaving 61 participants for the intent-to-treat analysis. Clients randomly assigned to the SC-R group (*n*=29) were offered 24 weeks of no cost NRT and clients assigned to the SC+ group (*n*=32) were offered 24 weeks of no cost NRT plus two initial individual counselling sessions of motivational interviewing and weekly psychosocial group support interventions for 24 weeks.

Treatment as usual group. A previous survey, conducted at the agency in May and November 2010 and reported in Study 1 of this thesis, collected data to determine the overall smoking prevalence and level of nicotine dependence in the agency's client population. Clients in this group were eligible to receive 'standard care' defined as the range of integrated treatment services provided by the agency that includes intensive case management, treatment for substance use disorders, access to housing, and access to primary health care and psychiatric consultation services. In order to draw a comparable group from this survey database, the SPSS case controlled 'fuzzy matching' process was utilized. 'Fuzzy matching' is a case-controlled matching function that takes two datasets and matches the records to the greatest possible fit according to selected variables. The matched sample 'treatment as usual' group (*n*=61) was randomly selected from the client data base created from the initial larger survey dataset, using sex and level of nicotine dependence as the matching variables. Any participants in the study who had also been clients of the agency in 2010 and who participated in the needs assessment, were removed from the data base. The comparison group consisted of 61 exact matches in terms of sex and FTND scores.

Participants

Eligibility criteria for participants. Participants in the study were recruited from the client pool of a community mental health agency with an annual client census of over 1,200 individuals located in a large urban setting. Clients of the agency are adult men and women over 16 years of age with a severe mental illness who, upon referral to the agency, are homeless or vulnerably housed. The agency currently employs an integrated treatment 'Housing First' approach, and has been assessed as showing a high fidelity to the standards identified in the Housing First Fidelity Scale (Stefanic, Tsemberis, Messerib, Drake & Goering, 2013) . As part of the comprehensive integrated treatment approach, clients are provided intensive case management (ICM) support and may access treatment for co-occurring substance use disorders, Dialectical Behavioural Therapy (DBT), primary health care nurse practitioner support, psychiatric nursing and psychiatrist support and consultation, after hours and weekend mental health support and subsidized housing units. The mandate of the agency is to assist individuals in securing the housing and support they require in order to maintain community stability and avoid homelessness, housing instability, hospitalization and incarceration.

Adult men or women with severe mental illness, who use tobacco and have identified an interest to reduce or eliminate tobacco use were eligible for the study. Severe mental illness is defined utilizing the common guidelines provided by Ontario's Ministry of Health and Long Term Care to include people who have an Axis I diagnosis (primarily psychotic and mood disorders), a global level of impairment in more than two life domain areas as a result of their diagnosis, and an illness that has lasted, or is likely to last, more than 1 year (Government of Ontario,1999). The agency considers clients to be homeless or vulnerably

housed at point of referral when they do not have security of tenure, are at imminent risk of losing their housing due to financial, physical property or circumstantial conditions, or have a historical pattern of repeated episodes of homelessness or housing instability.

Use of tobacco was initially defined as daily tobacco use of at least 10 cigarettes a day but was lowered to include 5 or more cigarettes a day when it became apparent that participants had a difficult time in estimating the exact amount they were smoking, given the common practice of smoking contraband cigarettes and smoking discarded cigarette butts and filters. For example, there were 3 participants with self-reported daily smoking of less than 10 cigarettes but their expired carbon monoxide (CO) levels were 15 *ppm* to 25 *ppm*. Validation of non-smoking status in the past 24 hours is typically determined with CO levels of 8 *ppm* to 10 *ppm*. A review of the use of CO monitoring for validation of smoking cessation use suggests, in order to eliminate false positives, to use 3 *ppm* as the cut-off indicator for cigarette smoking (Javors, Hatch & Lamb, 2005). Use of tobacco was defined, then, as tobacco use of a least 5 cigarettes a day. No other inclusion criteria was used.

Recruitment of participants. Clients were informed of the opportunity to participate in the research study by their primary mental health worker at the agency and through flyers that were distributed by workers and that were posted throughout public areas of the agency where clients attend. Flyers featured the question, "do you want to participate in a treatment program designed to help you quit or reduce how much you smoke?", with details on how to attend information sessions that were conducted by the study research personnel and by the registered nurses of the agency. Sessions were offered in either English or French, and individual information sessions were also offered for those unavailable or unable to attend group information sessions. The sessions included information on the types

of treatment offered, demands of participating in the study, risks and benefits of participation, procedures to ensure confidentiality, the right to withdraw from the study, and assurances that their decision regarding participation in the study would not impact on the other services they were receiving from the agency.

Following the information sessions, clients who were interested in participating in the study met individually with the University of Ottawa Research Assistant to sign a consent form that included the written description of all information points addressed in the session (see Appendix A). Information sessions were offered twice a week between February and April 2012 and clients were gradually recruited throughout this time period. As clients consented to participate in the study, baseline data were collected by the researchers and the nurses. Once clients consented to participate in the study, a letter was sent by the agency Nurse Practitioner to the attending treating Physician of each client to notify them of the study and to follow-up if any clinical concerns were noted. Baseline interviews (n=62) were conducted between February and April 2012 (see Appendix B). The interim 3 month follow-up interviews (n=56) were conducted in July and August 2012 and the final 6 month follow-up interviews (n=57) were conducted between September and November 2012. Treatment was gradually initiated at three time points, as participants were recruited over time into the study. Time point A group (n=20) initiated treatment the week of April 2nd 2012, time point B group (n=20) initiated treatment the week of April 9th 2012 and time point C group (n=21) initiated treatment the week of April 30th 2012.

Types of Interventions

All mental health and addiction workers and nursing staff working as part of the smoking cessation study had attended the three-day training course on tobacco cessation

treatment through the Training Enhancement in Applied Cessation Counselling and Health (TEACH) program provided through the Centre for Addiction and Mental Health, and three staff also attended the two-day Tobacco Interventions for Patients with Mental Health and/or Addiction Disorders training offered through the TEACH program. Additionally, staff had attended the two-day "Ottawa Model for Smoking Cessation Workshop" offered through the University of Ottawa Heart Institute. All clinical staff have also been trained in utilizing cognitive restructuring (CR) techniques (Mueser, Rosenberg & Rosenberg, 2009) and in utilizing the MI approaches outlined in Miller and Rollnick (2002). The individual MI sessions were conducted by two staff who have received advanced training in MI and are members of the Motivational Interviewing Network of Trainers (MINT).

Combination NRT. Clients assigned to both the SC-R and the SC+ groups were offered 24 weeks of cost-free combination NRT at upward titration doses as described in the medical directives of the "University of Ottawa Heart Institute Primary Care Smoking Cessation Program Nicotine Replacement Therapy (NRT) Protocol" (See Appendix C). Combination NRT included 7*mg*, 14 *mg* or 21 *mg* patches, the inhaler, lozenges and chewing pieces. All clients were expected to meet weekly with either a registered nurse or nurse practitioner for assessment of their mental and physical health status, CO monitoring, the ongoing provision of education regarding NRT, and to receive their NRT doses for the following week.

Individual MI sessions. Clients assigned to the SC+ group were additionally offered two individual counselling sessions of MI and 24 weeks of weekly group support sessions. Each MI practitioner was assigned 16 clients from the SC+ group and offered up to two individual MI sessions to each client. These sessions did not focus on adherence to

treatment. Session 1 focused on examining each participant's personal target behaviour goal in regards to reducing or quitting smoking, and session 2 focused on developing a specific change plan for achieving the smoking cessation or smoking reduction goal. In keeping with the MI spirit, these sessions were focused on the importance of developing intrinsic motivation to change arising from the personal goals and values of the participants in relation to changing their smoking behaviour. Most sessions occurred at the agency offices, but the clinicians also met with clients in their homes and in the community in order to facilitate access to the sessions. In keeping with indicators associated with better MI outcomes in smoking cessation studies (Hettema & Hendricks, 2010), all sessions were under an hour and clinicians were assessed for adherence to a MI approach. The clinicians rated each other's adherence to an MI approach by sitting in on 2-4 separate client sessions and coding practitioner responses utilizing the 'Motivational Interviewing Treatment Integrity Code' manual (Moyers, Martin, Manuel, Miller & Ernst, 2010). As reported in this manual "these thresholds are based on EXPERT OPINION, and currently lack normative or other validity data to support them" (Moyers et al., 2010., p.26). The authors are in an ongoing process of collecting normative data toward the development of a revised manual and suggest the use of these assessments in conjunction with other data collected in the process of undertaking MI in order to determine overall clinician competency. Table 1 provides a summary of the ratings of each clinician in specific MI skill areas. The overall assessments indicate broad competency in the practice of MI for both practitioners.

Weekly psychosocial support group sessions. Each of the participants in SC+ were assigned to one of three weekly 90-minute support groups. Each group was facilitated

Table 1

Summary of MI Competency of the Clinicians Providing Individual MI Sessions

Clinician Behavior-Count or Summary-Score Thresholds	**Beginning Proficiency**	**Competency**
Global Clinician Ratings (evocation + collaboration + Autonomy/support)	**Average of 3.5**	**Average of 4**
MI Clinician # 1's ratings		5
MI Clinician # 2's ratings		4.5
Reflection to Question Ratio (R-Q)	**1:1**	**2:1**
MI Clinician # 1's ratings	1:1	
MI Clinician # 2's ratings	1:1	
Percent Open Questions (%OQ)	**50%**	**70%**
MI Clinician # 1's ratings		94%
MI Clinician # 2's ratings		60%
Percent Complex Reflections (%CR)	**40%**	**50%**
MI Clinician # 1's ratings		60%
MI Clinician # 2's ratings		58%
Percent MI-Adherent (%MIA)	**90%**	**100%**
MI Clinician # 1's ratings		100%
MI Clinician # 2's ratings		100%

by trained mental health and addiction workers who have received additional advanced training in MI and training in addressing tobacco dependency and who have extensive experience in the facilitation of concurrent disorder treatment groups for this population. A paid peer worker who was an ex-smoker co-facilitated all of the groups. There were 10 participants assigned to Time Point A group, 10 participants assigned to Time Point B group and 12 participants assigned to Time Point C group. Clients who missed their assigned group weekly session were always encouraged to attend another weekly group session during that week if at all possible but in practice that did not occur. Clients were provided bus tickets to attend sessions and their primary mental health support worker also encouraged and supported their clients to attend group sessions.

Content for the groups had been modified from the technical guide "Intervention for tobacco dependence among people with a mental illness" (Baker et al., 2004). Group members established their group operational 'norms', and all groups had the same basic structure of a welcoming mindfulness exercise, an educational topic for the week, a check-in with participants to share how their smoking cessation/reduction goals were progressing, and a concluding 'check-out' with an identification of goals for the week ahead. Groups incorporated both MI (Miller & Rollnick, 2002) and cognitive restructuring approaches (Mueser, Rosenberg & Rosenberg, 2009). Groups were structured with a more prescribed psychoeducational focus for the initial 8 week block of sessions and the remaining 16 weeks of treatment focussed on reinforcing psychoeducational material, building up coping skills and relapse prevention. Groups incorporated guest speakers such as a nurse, pharmacist, dietician and financial advisor to help reinforce the educational content. The team working in this program have collaborated in the development of a standardized manual of materials

that continues to be utilized in facilitating the smoking cessation group sessions at the agency.

Following each group session, the co-facilitators independently rated and described the group content of each session, utilizing a standardized 'group facilitator check-list' in order to determine the overall program fidelity to the outlined content. All group facilitator check-list forms for each session were reviewed and revealed that the recorded group content summary from the session was consistent between the co-facilitators. Table 2 provides a summary of the group content topic summaries for each of the three groups, as described by the co-facilitators. Variation in the content and the timing of content delivery between the groups was due to the scheduling of available guest speakers and the specific demands of a particular group on a given week. As previously identified, the first eight weeks of the groups were more structured, but following that, the educational content could be re-visited, depending upon the needs of the group. For example, the topic of the financial impact of smoking and money management skills really resonated with one of the groups, so that topic continued to be their content focus over a three week period.

Outcomes

Types of comparisons. Client outcomes in the SC-R treatment group were compared with the client outcomes in the SC+ treatment group. The smoking status outcome and levels of nicotine dependence of both groups were compared to the standard care group in order to provide a comparison group of individuals who did not receive the smoking cessation treatment in this program.

Table 2

Summary of Group Session Topics

	Main topic summary for each group session as delivered
Time Point A Group (n=10) Thursday morning group First Group Session: April 5, 2012	**Week 1** On the road to freedom (beginning steps, building motivation); **Week 2** (nurse guest speaker) Wanting to quit (exploring ambivalence, making healthy goals) **Week 3** Strategies to quit (pharmacist guest speaker) NRT facts: smoking and mental illness; **Week 4** Coping with Stress and Negative Emotions (art therapist guest speaker) using relaxation strategies through art therapy **Week 5** The new you! (grief process of giving up cigarettes) **Week 6** Positive Self Talk (dietician guest speaker) Nutrition and impact on smoking **Week 7** Life Beyond Smoking -cognitive restructuring (CR): identifying distortions and dissonance in thoughts about cigarettes and smoking) **Week 8** Celebration of Progress -social event **Week 9** Strategies to cut down/restructuring negative thoughts **Week 10** Building motivation/ restructuring negative thoughts **Week 11** - Testimony of ex-smoker/encouragement to try 24 hour non-smoking period **Week 12** Cognitive restructuring-cutting back/ focus on reframing negative thoughts, feelings and behaviours **Week 13** Preparing for holiday/coping with stress **Week 14** Money Skills (guest speaker focussing on budgeting skills) **Week 15** Financial money management and budgeting continued **Week 16** (modified group) Brief Financial money management and budgeting continued **Week 17** Review of past 16 weeks and revisiting change plan/5 steps of CR **Week 18** Common styles of thinking and coping with emotional distress **Week 19** Breathing Retraining practiced in the group (CR) **Week 20** Coping with difficult emotions **Week 21** Review Toolbox of Skills **Week 22** Harmful effects of cigarettes and tobacco **Week 23** (guest art therapist) Celebration of smoking cessation journey-focus on what you have done not on what you haven't yet achieved **Week 24** Health and metabolism (reducing smoking/going back on NRT) **Week 25** Celebration!
Time Point B Group (n=10) Friday afternoon group First Group Session: April 12, 2012	**Week 1** On the road to freedom (beginning steps, building motivation); **Week 2** Wanting to quit (exploring ambivalence, making healthy goals) **Week 3** Strategies to quit (pharmacist guest speaker) NRT facts: nicotine withdrawal **Week 4** Coping with Stress and Negative Emotions (art therapist guest speaker) using relaxation strategies through art therapy **Week 5** The new you! (grief process of giving up cigarettes) **Week 6** Positive self-Talk (ex-smoker guest speaker) seeing yourself as an ex-smoker **Week 7** Life Beyond Smoking-cognitive restructuring (CR): identifying distortions an dissonance in thoughts about cigarettes and smoking / called smokers Helpline **Week 8** Dietician guest speaker- Nutrition and impact on smoking **Week 9** Celebration of Progress - review of progress to data/reinforcement of information **Week 10** Non-smoking

	Main topic summary for each group session as delivered
	social event **Week 11** Dealing with cravings - strategies to cut down/restructuring negative thoughts (CR) **Week 12** Honesty in the group - revisiting of group norms **Week 13 C**hallenges and supports/strategies to reduce smoking **Week 14** reframing negative thoughts (CR) **Week 15** Money Skills I - financial money management and budgeting (guest speaker focussing on budgeting skills) **Week 16** Celebration of progress to date/review past 16 weeks **Week 17** Connection between thoughts, emotions and behaviour (CR) **Week 18** Non-smoking social event **Week 19** Money Skills II-financial money management and budgeting (guest speaker focussing on budgeting skills) **Week 20**- Life beyond Smoking (art therapist guest speaker)-seeing yourself as a non-smoker **Week 21** Financial literacy-linking smoking with practicing money management skills **Week 22** Building supports that support a non-smoking life **Week 23** Health and self-perception as a smoker and non-smoker **Week 24** Celebration!
Time Point C Group (n=12) Monday afternoon group First group session: April 30, 2012.	**Week 1** On the road to freedom (beginning steps, building motivation); **Week 2** Wanting to quit(nurse guest speaker) exploring ambivalence, making healthy goals **Week 3** Strategies to quit (pharmacist guest speaker) NRT facts: smoking and mental illness; **Week 4** The new you! (dietician guest speaker) Nutrition and impact on smoking **Week 5** Coping with Stress and Negative Emotions (art therapist guest speaker) using relaxation strategies through art therapy **Week 6** Stages of grief & process of giving up cigarettes **Week 7** Life Beyond Smoking - cognitive restructuring (CR): identifying distortions and dissonance in thoughts about cigarettes and smoking) **Week 8** Celebration of Progress -setting goals **Week 9** Emotional Awareness- strategies to cut down/restructuring negative thoughts (CR) **Week 10** Building motivation/restructuring negative thoughts/connecting thoughts, feelings and actions (CR) **Week 11** - Coping with Stress and Negative Emotions (art therapist guest speaker) using relaxation strategies through art therapy **Week 12** Managing stress **Week 13** Money Skills I -Financial money management and budgeting (guest speaker focussing on budgeting skills) **Week 14** Celebration of smoking cessation journey **-** (guest art therapist) **Week 15** - Money Skills II -Financial money management and budgeting (guest speaker focussing on budgeting skills) **Week 16** Next Steps in setting goals **Week 17** Breathing Retraining practiced in the group (CR) **Week 18** - Recognizing strengths and self-affirmation **Week 19** Focus on CR to build motivation & explore change strategies **Week 20** Breathing Retraining practiced in the group / challenging internal negative thoughts (CR) **Week 21** 0 participants **Week 22** Common styles of thinking and coping with emotional distress **Week 23** 0 participants **Week 24** Celebration!

Types of outcomes. Treatment outcomes were monitored at three months and at six months during interviews with the research staff and during weekly monitoring contacts with the nursing staff.

Primary Treatment Outcomes: The primary treatment outcomes related to tobacco use were i) 7-day point prevalence abstinence verified by CO levels of 5 *ppm* or less and ii) the overall reduction of number of cigarettes smoked at three months and six months (or end of the study period). These outcomes were evaluated on an intent-to-treat (ITT) basis, in that any client whose smoking status could not be verified was considered to be smoking. Client tobacco use was measured through self-report of number of cigarettes smoked and through monitoring of expired breath carbon monoxide (CO) levels taken during their weekly meetings with the nursing staff. Clients were considered having quit through self-report of their non-smoking status to the nurse and with a verified expired breath carbon monoxide level of 5 *ppm* or less. Monitoring of number of cigarettes smoked was used to determine any overall reduction of cigarette use.

Secondary Treatment Outcomes: The secondary outcomes monitored included changes to drug and alcohol use, quality of life indicators, hospitalization, housing status, physical health functioning, physical health indicators such as body weight, and mental health status. This were monitored to detect any change over time during the course of the study period.

A variety of data sources and methods of data collection were utilized. Quantitative data was collected utilizing a combination of clinician rating and self-report measures that have been commonly used in community mental health research and that have good psychometric properties.

Fagerström Test for Nicotine Dependence. The Fagerström Test for Nicotine Dependence (FTND) consists of a 6-item measure (Heatherton, Kozlowski, Frecker & Fagerström, 1991) and is designed to determine client level of nicotine dependence. Smokers are rated on a scale of 0 (very low nicotine dependence) to 10 (very high nicotine dependence). The FTND is the most widely used scale to measure levels of nicotine dependence and has produced varying reliability scores for internal consistency in non-psychiatric populations (α=.56 , Payne, Smith, McCracken, McSherry, & Antony, 1994; α=.64, Pomerleau, Carton, Lutzke, Flessland & Pomerleau, 1994; α=.61, Heatherton et al., 1991), and adequate scoring in a population of individuals with schizophrenia (α=.74, Weinberger et al., 2007). The FTND has been found to have high test-re-test reliabilities in non-psychiatric populations (r=.88; Pomerleau et al, 1991) and with specific investigations with individuals with schizophrenia (r=.65; Weinberger et al., 2007; r=.78, Yang, McEvoy, Wilson, Levin & Rose, 2003). However, other studies have questioned the sensitivity of the FTND to detect the severity of nicotine dependence for individuals with schizophrenia (α=.46; Steinberg,William, Steinberg, Krejci, & Ziedonis, 2005), with the potential for producing scores that underestimate dependency levels (Prochaska, Leek, Hall & Hall, 2007). Cronbach's alpha for the FTND in this study were unacceptably low at the three time points, notably α=.22 at baseline, α=.52 at 3 months and α=.56 at 6 months.

Prochaska et al. (2007) suggest that one of the issues that could compromise the sensitivity of the FTND is that the test does not inquire as to nocturnal smoking which, if practiced, could mediate an immediate morning impulse to smoke. A further complication with this population is that individuals may be living in environments such as hospitals, emergency shelters or supportive housing programs that restrict when and where they are

allowed to smoke first thing in the morning and throughout the day (Steinberg et al., 2005). To determine if clients in the study faced environmental restrictions, they were asked if they currently lived someplace that restricted when and where they were allowed to smoke and they were asked how frequently they woke in the night in order to smoke a cigarette. In fact, these occurrences were quite common in our sample, as 26% reported living in an environment that restricted their smoking and 40.9% reported getting up at least one night during the week to smoke, with 13% reporting that they got up every night of the week to smoke. There was a strong positive correlation between number of daily cigarettes smoked at baseline and the baseline FTND score, $r(61) = .59$, $p < .0005$, and a medium positive correlation between baseline CO levels and the baseline FTND score, $r(61) = .38$, $p = .003$.

Smoking behaviors. Estimating amount of cigarettes smoked may also be difficult for individuals who engage in alternative smoking behaviours such as sharing cigarettes and smoking discarded cigarette butts. The FTND in its current state does not take these factors into account, so scores may be an underestimate of actual levels of nicotine dependence. In order to identify if clients engaged in alternative smoking behaviours, they were asked: *Do you share cigarettes? Do you smoke cigarettes remade from discarded cigarette butts and filters? Do you smoke discarded cigarette butts?* These questions were modified from a nursing assessment originally undertaken with homeless adults in Los Angeles that was investigating smoking behaviours that contributed to disease transmission (Aloot, Vredevoe, & Brecht., 1993). Additionally, we inquired: *Do you smoke contraband cigarettes (cigarettes not made by tobacco companies)*? Recent research has found that smokers who smoke contraband cigarettes are heavier smokers and have less successful short term smoking cessation outcomes (Mecredy et al, 2013), making this an important behaviour to

monitor. Given that virtually all participants in the study live below the poverty line on social assistance, it would be reasonable to assume that regularly purchasing cigarettes would be cost prohibitive for this cohort. As of June, 2014, legally purchasing 200 cigarettes in Canada costs between $85.39 in Quebec to $117.86 in the Northwest Territories (Non-Smokers' Rights Association, 2014). However, contraband cigarettes cost between $10.00 - $20.00 for 200 cigarettes so it is important to understand if individuals are engaging in this purchasing behaviour. Since 200 contraband cigarettes are typically packaged loosely in a Ziploc plastic bag, this can also contribute to having an inaccurate sense of how many cigarettes are being consumed on a daily basis.

Level of community functioning. Although all participants in the study had a severe mental illness, beyond psychiatric diagnosis, a variety of factors can contribute to how well an individual is able to function in the community. Research has linked functional impairment in activities of daily living (ADL's) to risk of early mortality for this population (Hayes et al., 2012).

Multnomah Community Ability Scale. The level of community functioning was measured using the Multnomah Community Ability Scale (MCAS) which has 17 items and uses a 5-point scale to measure the four areas of health, adaptation, social skills and behaviour to provide a global assessment of functioning of individuals with severe mental illness living in the community (Barker, Baron, McFarland, & Bigelow, 1994a; Barker, Baron, McFarland, & Bigelow, 1994b). Barker et al. (1994a) found the inter-rater reliability of the total score to be .85 and the test-retest reliability to be .83, and a large state wide study in Oregon validated that MCAS scores were predictive of how well individuals with severe mental illness were able to function in the community (Zani, McFarland, Wachal, Barker &

Barron., 1999). Scores range from 17 to 85, with higher values associated with better functioning. Clients with higher functioning (low level of disability) would have a 'high' rating of 63-85, clients with a 'medium' rating of 48-62 would be assessed as having a moderate level of disability, and clients with a 'low' rating of 17-47 would be assessed as having more severe levels of disability. The scale was designed not only to provide an overall measure of current community functioning of an individual client, but to enable agencies to better describe the potential range of clients receiving service and, ultimately, the differing levels of support they may require. A recent randomized control trial testing Housing First approaches for individuals with severe mental illness developed an operational definition for a 'high needs' client that included a MCAS score of 62 or below, in conjunction with a psychiatric diagnosis of psychosis or mood disorder and concurrent conditions such as substance abuse and housing instability (Goering et al., 2011). The MCAS has been incorporated into regular clinical practice at the agency since 2000, and all clinical staff receive initial standardized training from a registered psychiatric nurse and then periodic refreshers on using the tool. Clients at the agency are assessed upon intake into the agency, annually, and at closure by their primary mental health worker. MCAS total scores of the participants in the study were collected from their clinical file.

Substance use. The recognition that an individual with a mental illness might also have a substance abuse problem or that an individual struggling with addiction might also have a mental illness has taken a long time to emerge (Canada, Parliament, Senate.,2006). Substance use disorder is now acknowledged as a common co-morbid condition found within the population of those living with severe mental illness but, given the heterogeneous nature of the population, lifetime prevalence rates in studies have varied from under 20% to

over 60% (Mueser, Noordsy, Drake, & Fox, 2003). The impact of untreated substance abuse on individuals with severe mental illness is well documented and is typically associated with increased psychiatric relapse and hospitalization, increased housing instability and homelessness, increased suicide risk, increased family/interpersonal conflict, increased financial problems, increased risk of exposure to infectious disease, poor physical health, increased involvement with the criminal justice system, and increased risk of victimization (Buckley, 2006; Drake et al, 2001).

The agency where this research was conducted specifically targets clients who may have a co-occurring substance use disorder and, in 2010, just over 50% of clients served were assessed as having a concurrent disorder. A survey to assess the overall use of tobacco by clients of the agency in 2010 revealed that 90% of the clients with a concurrent disorder used tobacco (Paper number 1). Further analysis revealed that clients with a concurrent disorder were 9 times more likely to be a smoker than the clients without a concurrent disorder. Given that all study participants were drawn from a similar pool of clients, it was anticipated that a significant proportion of participants would have a current or pre-existing concurrent disorder and that it would therefore be important to monitor patterns of substance use, beyond tobacco, during the course of the study.

Global Assessment of Individuals Needs Substance Use Problem Scale. Changes in patterns of substance use by participants was monitored utilizing the short version of the Global Assessment of Individuals Needs Substance Use Problem Scale (GAIN-SPS) that utilizes a DSM-IV-TR framework to identify substance abuse issues (Dennis, Chan & Funk, 2006). The GAINS-SPS is a 16-item measure developed from the longer GAIN (Global Appraisal of Individual Need) assessment tool (Dennis et al., 2006) that includes seven

questions to identify dependence, four to assess for abuse, two questions regarding the impact of substance use on health and three questions to identify behaviours associated with lower levels of severity of use. For the current study, the first five items of the GAIN-SPS that function as the GAIN-Short Screener (GAIN-SS) were utilized to determine how many symptoms of substance use disorder were experienced in each of the past month, past year, and over the course of the person's lifetime. In each particular time frame, scores of 0 would indicate the person did not meet criteria for any diagnosis of a substance use disorder, scores of 1-2 would indicate that the person possibly would meet criteria for diagnosis of a substance use disorder, and scores of 4-5 would indicate a probable diagnosis of a substance use disorder. Other items on the scale (e.g. *"How old were you when you first got drunk?*") were assessed as individual indicators of substance use. While studies to investigate the reliability of this tool for use with the study population have not been undertaken, in two studies of adults and adolescences the GAINS-SS has demonstrated satisfactory reliability in identifying substance use disorders (Dennis et al., 2006; McDonell, Comtois, Voss, Morgan & Ries, 2009). The tool was recently used in a large multi-site evaluation of homeless individuals with severe mental illness to screen for and monitor outcomes concerning substance use (Goering et al., 2011), and it is used as a common screening tool for all mental health and addiction agencies within the Champlain LHIN. Cronbach's alpha for past month GAIN-SS in this study were adequate to good, notably an α=.78 at baseline, α=.86 at 3 months and α=.76 at 6 months.

Physical and mental health functioning. Physical and mental health functioning were measured utilizing the Short Form-36 Health Survey (SF-36) (Ware, Kosinski & Gandek, 2002) and the Colorado Symptom Index (CSI) (Shern et al., 1994).

The Short Form-36 Health Survey (SF-36). The SF-36 measures eight components of overall health in relation to both physical health and mental health. These components include a measure of overall physical and mental health functioning, limitations experienced as a result of physical health or emotional issues, level of physical pain experienced, overall general health perceptions, level of social functioning and feelings of vitality. Components are combined to provide an overall Physical Component Summary (PCS) and a Mental Component Summary (MCS). In the general population in the United States the mean score has been standardized to a *t*-score of 50 (*SD*=10); scores from 40-49 indicate mild disability, scores from 30-39 indicate moderate disability and scores below 30 indicate more severe levels of disability. There is evidence that the SF-36 has good reliability and validity with populations of individuals with severe mental illness (Tunis et al., 1999; Russo et al., 1998; Salyers, Bosworth, Swanson, Lamb-Pagone & Osher, 2000). Cronbach's alpha in this study for the SF-36 PCS were good, with an α=.83 at baseline, α=.81 at 3 months and α= .85 at 6 months and for the SF-36 MCS, the scores were adequate with an α=.70 at baseline, α.= .75 at 3 months and α=.68 at 6 months.

The Colorado Symptom Index (CSI). The Colorado Symptom Index (CSI) is a 14 item self-report tool utilized to assess the severity of experienced psychiatric symptomatology within the past month. Individuals are given a 5-point Likert scale with options ranging from 1- 'Not at All' to 5 - 'At Least Every Day' to respond to each question, with higher scores indicating greater psychiatric distress. Boothroyd and Chen (2008) found the CSI to have excellent internal consistency (α=.92) and test-retest reliability (*r*=0.71) and they also established a cut off score of 30 to indicate the need for further psychiatric assessment. A study of homeless adults who had either mental health and substance use

disorders by Conrad et al. (2002) found the CSI to have excellent internal consistency (α=0.90) and good test-retest reliability(r=0.79). Cronbach's alpha in this study for the CSI were very good with an α=.89 at baseline, α=.90 at 3 months and α=.86 at 6 months.

Quality of Life. The quality of life measures were captured utilizing the Quality of Life Inventory-20 Item (QoLI-20), which is a self-report tool that was specifically developed to assess the quality of life as experienced by individuals with severe and persistent mental illness (Lehman, 1996; Uttaro & Lehman, 1999). Individuals were asked how they felt in response to 20 questions, with options ranging on a 7-point Likert scale from 'Terrible' to 'Delighted'. Questions address overall satisfaction with life, family, finances, leisure time, living situation, feelings of safety and relationships. Internal consistency has been shown to range for 0.79 to 0.88 for the subjective scales (Lehman, 1996), and this internal consistency was maintained in the 20-item version of the scale (Uttaro & Lehman, 1999). Cronbach's alpha in this study for the QoLI-20 were adequate with an α=.76 at baseline, and an α= .70 at 3 months and somewhat marginal with an α= .62 at 6 months.

Sample Size

The number of participants in this study was limited by the availability of cost free NRT and the extensive labour requirements to undertake the intensive intervention. For example, all participants were seen each week by a registered nurse or nurse practitioner for ongoing monitoring of their physical and mental health status and for the distribution of their assessed appropriate NRT dose. All participants assigned to the SC+ intervention could attend one of three weekly support groups co-facilitated by a mental health and substance use worker and peer worker for the 24 week duration of the study. Additionally they had

access to two individual motivational interviewing sessions with trained MI counsellors at the agency.

Though underpowered, as a pilot study, this provided important opportunities for learning about implementing smoking cessation with people with severe mental illness with a history of homelessness. In particular, pilot studies provide the opportunity to demonstrate the ability to recruit clientele for the intervention; test out processes to gain consent and the feasibility of utilizing the data collection instruments; determine if the intervention is acceptable to the participants by examining overall rates of treatment compliance; raise staff clinical and research capacity within the site of the study, and ultimately, will provide the means, through an examination of the effect size achieved by an intervention, to determine an estimate of sample size for a larger study (Lancaster, 2015; Shanyinde, Pickering & Weatherall, 2011;Dolgin, 2013).

Given the trial is intended as a pilot study with 30 individuals assigned to each group, it had insufficient power to detect significant differences between the groups in terms of quit rates. In line with conducting a pilot, the effect size for the between group comparison will be calculated and used to determine the needed sample for conducting a definitive trial.

A power analysis was conducted for outcomes that are continuous variables using G*Power 3.1 with alpha set at .05 and power at .95 for 2 groups of 30 and 3 time point measures (baseline, 3 months and 6 months). An effect size of .31 is required to obtain significance on the within-between interaction using a Repeated Measure ANOVA. A second power analysis was conducted for 2 groups of 61 and 2 time point measures (baseline and 6 months) for the TAU and study participants (SC-R and SC+). An effect size of .21 is

required to obtain significance on the within-between interaction using a Repeated Measure ANOVA.

Randomization

Sequence Generation

As previously described, the study was designed to provide the SC-R treatment to 30 participants and the SC+ treatment to 30 participants. Part of the SC+ intervention included the opportunity for participants to attend a weekly psychosocial support group for the 24 week duration of the study. Since the size of each support group was limited to 10 individuals, the 30 participants in the SC+ group were assigned to 1 of 3 weekly support groups with a lagged entry. Participants were recruited gradually over time into the study, so in order to begin offering treatment to participants as soon as possible, we had designed a staged block randomization process. These staged time points for each group of 20 participants would become Time Point A, Time Point B, and Time Point C. In this way, the initial participants did not have to wait until all 60 participants were enrolled in the study in order to be randomized to their treatment group and to begin their smoking cessation program. This allowed us to not only capitalize on whatever motivation the individual had demonstrated by engaging in a smoking cessation study but it also enabled the clinical staff to gradually adjust to the implementation of a new intervention. All participants were enrolled in the study and randomized between February and April 2012.

Participants were ready for randomization once they had signed consent forms, completed a baseline nursing assessment, and had completed a baseline research interview. The randomization exercise was conducted by the researchers. Our goal was to randomly assign participants in groups of 20 as they were enrolled in the study to either the SC+ or the

SC-R treatment groups. Individuals were also matched in pairs within the groups of 20 for randomization by sex and level of nicotine dependence.

With regard to sex, population studies have found that men and women have different attitudes and experiences with smoking cessation (Reid, Pipe, Riley & Sorensen, 2009) and different smoking cessation outcomes (Perkins & Scott, 2008). In recent smoking cessation studies examining sex differences in populations with mental illness however, no significant differences between men and women in absolute rates of smoking cessation were found in individuals with co-occurring mental health and substance use disorder (Okoli et al., 2011) or in the characteristics and smoking outcomes of smokers with psychosis (Filia et al., 2014). A study of smoking behaviours in the population of smokers at this agency (Paper number 1) did not find any statistically significant association between sex and the smoking behaviours that were examined, but women were more likely to say that they were interested in quitting or reducing their smoking within the next 6 months but not the next 30 days.

Our primary rationale in selecting sex as a grouping for randomization was to ensure that each of the weekly support groups had 3 or more women participants. While all study participants were seen weekly by female nursing staff, all support groups were co-facilitated by male staff. Given that 60% of the clients who smoke at the agency where the study occurred are male, we anticipated that there would be more men than women enrolled in the study and wanted to make sure that women participants did not feel marginalized in a predominantly male support group environment. In the existing concurrent disorder treatment program operated by this agency, clients are given the option of participating in female only, male only, or mixed male and female groups. However, given the resource

limitations of the study, only mixed male and female participant support groups could be offered.

Level of nicotine dependence can be predictive of success in smoking cessation (Hyland, 2006), so it was important that the SC-R and SC+ groups had an equal representation of individuals with similar levels of nicotine dependence. We reviewed the CO levels, the number of reported daily cigarettes smoked and the Fagerström Test for Nicotine Dependency (FTND) scores for all participants to ensure that there was a general consistency between the measures. We selected individual Fagerström scores as a basis of grouping participants to perform a blocked randomization, as the CO levels reflect only a point prevalence level of nicotine use within the last 8 hours while the FTND provides an overall indication of nicotine dependence.

Allocation Concealment

The initial group, that was randomized, consisted of 18 men and 10 women. For this initial block randomization, we separated the men and women into two separate lists. We determined that there were approximately 1/3 the number of women as men. We wanted to maintain this ratio for the group of 20 participants starting the intervention at Time Point A and to do so, we determined that we should have 14 men and 6 women in Time Point A or roughly a 3:1 ratio. We therefore selected 14 of the 18 men, and 6 of the 10 women to be included in the Time Point A intervention. Using a randomization function in Excel, we assigned each of the 18 men with a random number. We identified the 4 highest random numbers, and "demoted" the participants that corresponded to those 4 numbers down to Time Point B. We completed the same process with the 10 women by assigning a random number, and demoting the participants that corresponded to the 4 highest random numbers to

Time Point B. Thus, of the 18 men, we had randomly selected 14 to proceed with the Time point A intervention, and of the 10 women, we had randomly selected 6 to proceed with the Time point B intervention. Those who were not selected for Time Point A were simply moved to another list for Time point B and were randomly assigned to treatment groups at a later date as more participants were enrolled in the study.

With our list of 20 participants to randomize into treatment groups at Time Point A, we listed the men and the women separately. We organized the men into order from lowest to highest Fagerström scores, and did the same for the women. We observed that the distribution of scores was relatively normal. We then “paired” up the men by their Fagerström scores. We selected the participants with the two lowest Fagerström scores, wrote each of their ID numbers down on a card, and put the two cards into two envelopes. We shuffled the envelopes, and then randomly chose one envelope on which to write "SC+", and then wrote “SC-R” on the other envelope. We did the same process for the next two lowest scores on the Fagerström, and so on. We did this process once for men, and once for women. In this way, we had essentially created two treatment groups of 10 participants that consisted of 3 women and 7 men each. As an assurance that we had been accurate in our method of blocking for this initial group, we checked the average Fagerström score of the participants randomly assigned to treatment group SC+ and compared it to the average score of participants randomly assigned to treatment group SC-R, and found that these average scores were exactly the same at 6.4 out of 10, indicating that on average, as expected, participants had a similar high level of nicotine dependence.

As more participants were enrolled in the study, this process was repeated in order to create the SC-R and SC+ treatment groups for Time Point B and the SC-R and SC+

treatment groups for Time Point C. With the creation of the last group at Time Point C, there were a total of 62 participants enrolled in the study, with 30 participants in the SC-R group consisting of 19 men and 11 women and 32 participants in the SC+ group consisting of 20 men and 12 women.

Statistical Analyses

Descriptive statistics were calculated to describe demographic, smoking behaviour and mental and physical health information. Categorical variables were summarized by frequencies and percentages, and continuous variables were summarized by means and standard deviation (*SD*). T-tests and Chi-square analyses were conducted to determine if there were differences between the groups on measures at baseline. The t-test and degrees of freedom for unequal variances were reported at any time when Levene's test was found to be significant. Repeated measures ANOVA's were used to assess differences between groups, changes over time and the interaction of group and time on the continuous variables. The McNemar test was used to evaluate differences in each group over time on dichotomous variables. Chi-square analyses were used to examine differences between groups at each follow-up time point on dichotomous variables. Bivariate correlation analyses were used to assess the relationship between clinical and demographic characteristics and smoking-related variables. In addition, effect sizes were calculated in examining for differences in outcomes between the two groups. All analysis were performed using SPSS, version 20. Additionally, logistic regression and standard multiple regressions were utilized to analyze if number of treatment sessions attended predicted treatment outcome of quitting or reducing tobacco.

For missing data related to a participant's verified smoking status at the 3-month time point (n=4) or the 6-month time point (n=3), these participants were classified as smokers.

Treatment contacts such as number of weeks of NRT, number of nursing contacts, number of group sessions attended and number of motivational interviewing individual sessions attended are reported based on actual participant attendance. Overall, less than 10% of data points were missing. On other smoking outcome variables at the 3 month and 6 month time points, such as the FTND score, exhaled carbon monoxide *ppm*, number of cigarettes smoked per day, and for secondary outcomes analysis of scored instruments such as the SF-26, the CSI, GAINS-SS and Quality of Life Measures, multiple imputation using the expectation-maximization algorithm in SPSS was performed to provide a data point for analysis. For missing data points on all other variables, the exact number of participants (denominator) is noted.

Ethics approval for the research was received from the University of Ottawa's Research Ethics Board. As a Health Service Provider (HSP) that operates under a Multi-Sectoral Accountability Agreement (M-SAA) with the Champlain Local Health Integration Network under the Ontario Government's Ministry of Health and Long Term Care, the agency is both contractually and legislatively obliged as a "health information custodian" to comply with a number of pieces of legislation (Personal Health Information Protection Act, 2004). All clients of the agency are informed verbally and in writing of this obligation and the legislation that protects their personal health information (see appendix A for consent forms).

Results

Participants flow

Figure 1 is a CONSORT diagram that depicts the participant flow into the 'Take a Breath' study. The study was designed to enrol 30 participants into each of the two treatment

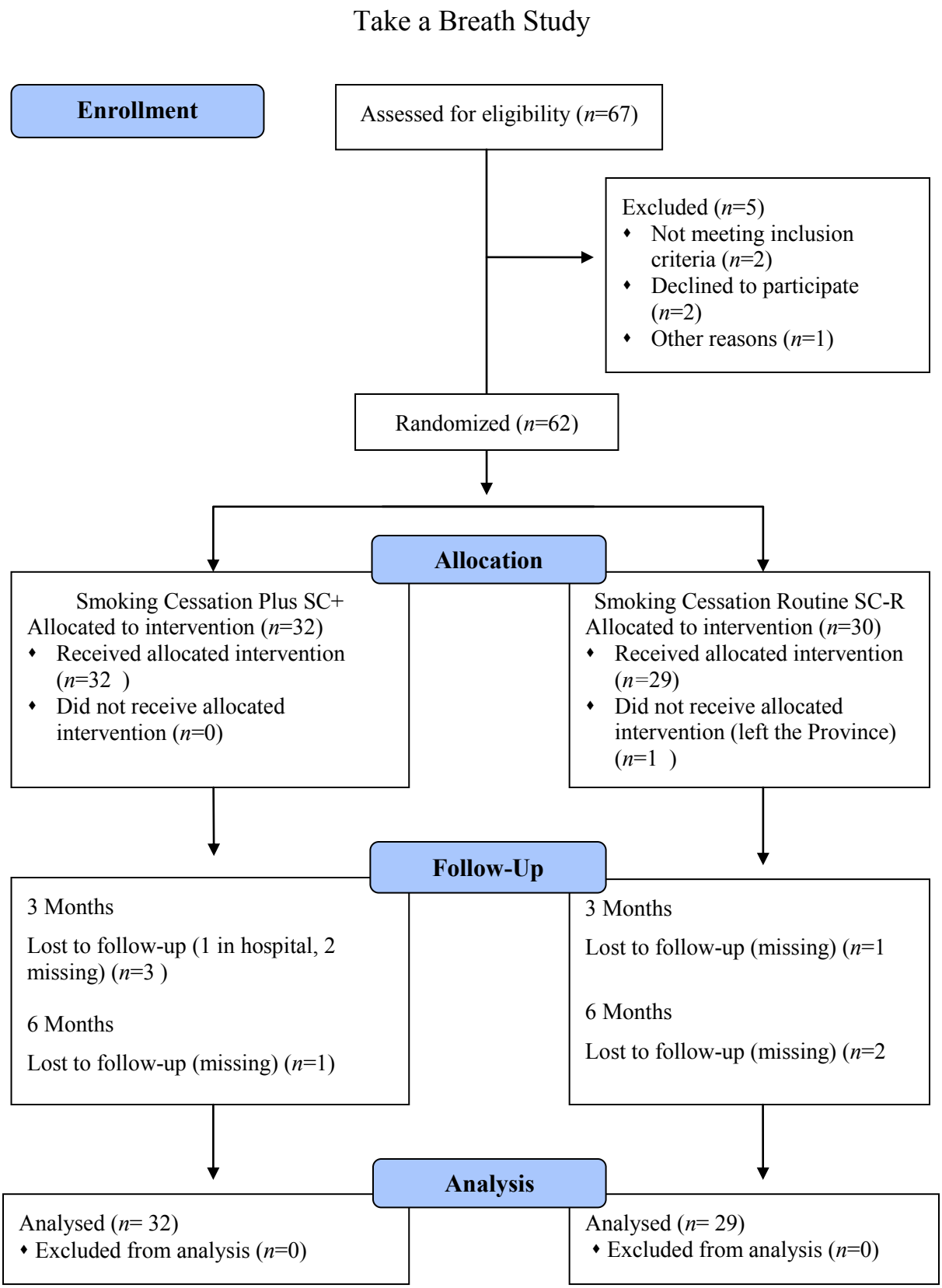


Figure 1: CONSORT participant flow diagram

interventions. Overall, 67 individuals were assessed for eligibility and of those, five were excluded from the study, leaving 62 participants to be randomized into either the SC-R or the SC+ intervention groups. Before treatment could be initiated, one individual in the SC-R group suddenly left the province with no possibility of follow-up, and he was therefore excluded from the study. This left 32 participants in the SC+ group and 29 participants in the SC-R group to receive their allocated interventions. At the 3-month time point, four individuals were lost to follow-up. One person was hospitalized and unavailable to be interviewed and the other three individuals had withdrawn from services of the agency at that point and either refused to be interviewed or could not be located by their workers. At the 6-month time point, three different individuals were unavailable to be interviewed and, similar to circumstances at the 3-month time point, these individuals had withdrawn from services of the agency and either refused to be interviewed or could not be located by their workers. The three participants who could not be located at the 3-month mark had returned to services and were interviewed at the 6-month time point, which provided at least one follow-up interview for all study participants. Participants were given a $20.00 honorarium for completing the final interview. All participants in both the SC+ and the SC-R groups (n=61) were included in the final analyses.

Recruitment

Participants were recruited between January, 2012, and April, 2012. Flyers distributed by the primary mental health worker and posted in public areas of the agency invited clients to attend an information session on the study. Information sessions were offered twice a week between February and April, 2012, during which time clients were

gradually recruited for the study. As clients consented to participate in the study, baseline data were collected by the researchers and the nurses. Baseline interviews (*n*=62) were conducted in February, March, and April, 2012. The interim 3 month follow-up interviews (*n*=56) were conducted in July and August, 2012 and the final 6 month follow-up interviews (*n*=57) were conducted between September and November, 2012.

Treatment was gradually initiated at 3 time points as participants were recruited over time into the study. Time point A group (*n*=20) initiated treatment the week of April 2nd, 2012, time point B group (*n*=20) initiated treatment the week of April 9th, 2012; and time point C group (*n*=21) initiated treatment the week of April 30th, 2012. The trial ended at the end of the 24-week period of intervention for each group.

Based on estimates from data collected for an earlier needs assessment at the same agency where participants were recruited for this study, there would be an estimated 531 active clients who were smokers on an average week. Of those, approximately 24% or 127 smokers would potentially identify as being interested in either reducing the amount of cigarettes they were smoking or being interested in quitting smoking within the next 30 days. For this study, we were able to recruit 67 participants who were interested in quitting or reducing their use of tobacco. Two of these participants withdrew their consent to participant in the study.

Baseline Characteristics of SC+ and SC-R Groups

Table 3 provides a description of the study sample and any differences between the SC+ and SC-R arms of the study. T-tests and Chi Square analyses on baseline variables such as MCAS scores, gender, level of substance use, psychiatric diagnosis, CO level, number of

Table 3

Baseline Demographic, Psychosocial and Tobacco-Related Characteristics of the Sample by Treatment Group

Variables	Total Survey *N*=61	Smoking Cessation Plus (SC+) *n*=32	Smoking Cessation Routine (SC-R) *n*= 29	SC+ vs. SC-R *p* value
Male, *n* (%)	38 (62%)	20 (63%)	18 (62%)	*p*=.97
Age, *M* (*SD*)	44.33 (10.80)	45.2 (11.76)	43.34 (9.74)	*p*=.50
Never Married, *n* (%)	37 (61%)	20 (63%)	17 (59%)	*p* =.54
Years of Education *M (SD)*	11.8 (3.65)	11.78 (4.27)	11.81 (2.89)	*p* =.98
Language *n* (%)				
English	52 (85%)	27 (84%)	25 (86%)	*p* =.58
French	6 (10%)	3 (9%)	3 (10%)	*p* =.93
Race/Ethnicity *n* (%)				
White	49 (80%)	25(78%)	24(83%)	*P*=.65
Had worked continuously > 1 year in the past *n* (%)	48 (79%)	25 (78%)	23(79%)	*p* =.91
Income Support[12]:				
ODSP *n* (%)	51 (87%)	28 (88%)	25 (86%)	*p* =1.0
OW *n* (%)	2 (3%)	1 (3%)	1 (3%)	*p* =1.0
Housing:				
Own apartment	51 (84%)	24 (83%)	27(84%)	*p*=.29
Housing is subsidized	41 (67%)	22 (69%)	19(66%)	*p*=.79
Veteran *n* (%)	4 (7%)	1 (3%)	3 (9%)	*p* =.35
Has ON Health Card *n* (%)	60 (98%)	31(97%)	29(100%)	*p* =.51
Has Family Physician *n* (%)	48 (79%)	25(79%)	23(79%)	*p* =.91

[12] ODSP = Ontario Disability Support Plan and OW = Ontario Works

Variables	Total Survey *N*=61	Smoking Cessation Plus (SC+) *n*=32	Smoking Cessation Routine (SC-R) *n*= 29	SC+ vs. SC-R *p* value
Number of Co-morbid Health Conditions *M (SD)*	5.92 (3.73)	5.2 (3.69)	6.69 (3.68)	*p* =.13
VAS Scale[13] *M (SD)*	58.61(23.23)	63.09(22.71)	53.66(23.17)	*p* =.12
Had a health professional who advised to quit smoking > 1 day in the past year *n*=59 (%)	35 (57%)	18(56%)	17(58%)	*p* =.60
Ever received substance abuse treatment services in lifetime *n* (%)	39 (64%)	22(69%)	17(59%)	*p* =.41
GAIN-SPS[14]				
Past Month *M (SD)*	1.12 (1.48)	1.22(1.58)	1.02(1.39)	*p* =.60
Past Year *M (SD)*	1.88 (1.84)	1.97(1.84)	1.80 (1.87)	*p* =.70
Lifetime *M (SD)*	3.91 (1.50)	3.88(1.50)	3.99 (1.53)	*p* =.77
Age first got drunk *M (SD)*	13.51(3.37)	14.52(2.49)	12.66(3.80)	***p* =.03**
Age first used drugs *M (SD)*	15.71(4.65)	16.46(5.87)	14.96(2.91)	*p* =.23
Diagnosis:				
Schizophrenia *n* (%)	24 (39%)	15(46%)	9 (31%)	*p* =.21
Mood Disorder *n* (%)	23 (38%)	11(34%)	12 (41%)	*p* =.57
Anxiety Disorder *n* (%)	9 (15%)	3(9%)	6(21%)	*p* =.29
Personality Disorder *n* (%)	5 (8%)	3(9%)	2(7%)	*p* =1.0
Concurrent Disorder *n* (%)	45 (74%)	22(69%)	23(79%)	*p* =.35
2 or more Psychiatric hospitalizations in any 1 year in the past 5 years *n* (%)	21 (34%)	12(38%)	9(31%)	*p* =.60

[13] VAS score =Visual Analogue Scale for State of Health

[14] GAIN-SPS=GAIN Substance Problem Scale

Variables	Total Survey *N*=61	Smoking Cessation Plus (SC+) *n*=32	Smoking Cessation Routine (SC-R) *n*= 29	SC+ vs. SC-R *p* value
Psychiatric hospitalization > 6 months in past 5 years *n* (%)	4 (7%)	3(9%)	1(3%)	*p* =.61
Months homeless lifetime *M (SD)*	30.6 (46.83)	33.88(41.34)	27.18(52.81)	*p* =.65
Longest single period of homelessness in months M (SD)	9.51(15.33)	14.09(19.65)	4.25(4.26)	***p*=.03**
Had criminal justice system contact within past 6 months *n* (%)	8 (13%)	6(19%)	2(7%)	*p* =.26
Spent >1 night in hospital, jail, shelter or detox within past 6 months *n* (%)	19 (31%)	9(28%)	10(35%)	*p* =.60
MCAS[15] Score *M (SD)*	62.36(7.73)	62.72(8.77)	61.97(6.52)	*p* =.71
CSI [16] score *M (SD)*	37 (12.25)	34.75(12.29)	39.48(11.92)	*p* =.13
SF-36 Physical Health Score *M (SD)*	41.72(12.60)	41.58(13.33)	41.88(11.92)	*p* =.93
SF-36 Mental Health Score *M (SD)*	36.87(9.57)	37.93(10.74)	35.71(8.12)	*p* =.36
Physical Health Monitoring:				
Weight in kg *M(SD)*n=58	95.04(28.57)	90.55(28.78)	95.13(28.69)	*p* =.55
Men *M (SD)*n=37	97.91 (30.52)	93.91(28.73)	102.62(32.74)	*p* =.39
Women *M(SD)*n=21	83.70(22.69)	83.86(29.18)	83.55(16.23)	*p* =.98
BMI *M(SD)*n=57	30.32(9.12)	28.52(9.27)	32.32(8.69)	*p* =.19
Men n=36	29.87(9.59)	27.46(8.92)	32.88(9.80)	*p* =.09
Women n=21	31.09(8.44)	30.65(10.06)	31.49(7.13)	*p* =.83

[15] MCAS score =Multnomah Community Ability Scale

[16] CSI score=Colorado Symptom Index

Variables	Total Survey *N*=61	Smoking Cessation Plus (SC+) *n*=32	Smoking Cessation Routine (SC-R) *n*= 29	SC+ vs. SC-R *p* value
Waist circumference in cm *M(SD)* n=57	108.47(22.42)	107.93(21.97)	108.1(23.27)	*p* =.87
Men *M (SD)*n=37	108.98(23.64)	107.38(22.31)	110.66(25.50)	*p* =.68
Women *M (SD)*n=20	107.55(20.53)	109.12(22.43)	105.97(19.53)	*p* =.74
Glucose Reading (non-fasting) *M (SD)*	6.58(1.66)	6.39(1.27)	6.78(1.0)	*p* =.92
FTND[17] score *M (SD)*	6.23 (1.76)	6.41(1.78)	6.03(1.76)	*p* =.42
Number of cigarettes/day *M(SD)*	24.80(12.01)	27.25(12.02)	22.10(11.6)	*p* =.10
Exhaled Carbon Monoxide, *ppm M(SD)*	24.43(13.15)	23.09(11.23)	25.90(15.06)	*p* =.41
Started smoking age 10 or under *n*(%)	15 (24.6%)	8 (25%)	7 (24.1%)	*p*= 1.0
Currently lives in housing that restricts where smoking is allowed *n* (%)	16 (26.2%)	8 (25%)	8 (27.6%)	*p*=.82
Shares cigarettes *n* (%)	16(26.2%)	6(18.8%)	10(34.5%)	*p* =.16
Smokes cigarettes remade from discarded cigarette butts/filters *n* (%)	16(26.2%)	9(28.1%)	7(24.1%)	*p* =.72
Smokes contraband cigarettes *n* (%)	36(59.0%)	19(59.4%)	17(58.6%)	*p* =.95
Smokes discarded cigarette butts *n* (%)	16(26.2%)	9(28.1%)	7(24.1%)	*p* =.72
On a scale of 1-10 level of confidence in stopping tobacco use? *M* (*SD*)	7.2(2.28)	7.17(2.44)	7.22(2.12)	*p* =.93
On a scale of 1-10 importance of quitting tobacco *M* (*SD*)	8.80(1.82)	8.8 (1.68)	8.8(2.1)	*p* =.95
Believes that NRT will be helpful in order to quit *n* (%)	57 (97%)	31 (97%)	26(96%)	*p*=.90

[17] FTND=Fagerström Test for Nicotine Dependency

Variables	Total Survey *N*=61	Smoking Cessation Plus (SC+) *n*=32	Smoking Cessation Routine (SC-R) *n*= 29	SC+ vs. SC-R *p* value
Interested in quitting in the next 3 month *n* (%)	50(82%)	27(84%)	23(79%)	*p*=.61
Interested in drastically reducing number of cigarettes but not quitting *n* (%)	8(13%)	3(9%)	5(17%)	*p*=.46
Seriously considering quitting in the next 6 months, but not in the next 30 days *n*(%)	3(5%)	2(6%)	1(3%)	*p* =1.0
Quality of Life Measures:				
Family Life	4.04(1.68)	4.36(1.77)	3.68(1.53)	*p*=.12
Finances	2.85(1.61)	3.08(1.66)	2.60(1.53)	*p*=.25
Leisure Time	4.00(1.11)	4.34(1.07)	3.64(1.07)	*p*=.01 t(59)=-2.55 CI[-1.24,-0.15] *d*=0.66, CI[0.21,1.32]
Living Environment	4.66(2.04)	4.94(1.76)	4.35(2.30)	*p*=.27
Safety of Environment	4.83(1.54)	5.27(1.28)	4.35(1.69)	*p*=.02

daily cigarettes smoked, and FTND score were performed. Due to the large number of comparisons, the *p*-level for significance was set at .01.

Overall, this study cohort was predominately male (62%), white (80%), English speaking (85%), with a mean age of 44 years (*SD*=10.8), almost 12 years (*SD*=3.65) of education on average and 87% were receiving financial support through the Ontario Disability Support Program. Given the target population served by the agency where the study occurred, not surprisingly, 77% had a psychiatric diagnosis of either schizophrenia or bipolar disorder, 74% had a co-occurring substance use disorder and, while the lifetime mean months homeless was just under 31months (*SD*=46.83), 67% of participants were stably housed in subsidized housing. Beyond serious mental illness and co-occurring substance use disorders, this cohort identified having an average of 5.92 (*SD*=3.73) co-morbid chronic physical health conditions that included heart disease (8%), high blood pressure (21%), chronic bronchitis/emphysema (23%), asthma (39%), cancer (8%), arthritis (41%), dental problems (56%), gynecological problems (31% of females), diabetes (18%), thyroid disease (10%), epilepsy (15%), HIV (8%), and Hepatitis C (18%).

The mean body mass index (BMI) calculation for men was 29.87 (*SD*=9.59) and for women was 31.09 (*SD*=8.44), indicating average levels associated with being overweight and having increased health risks (Health Canada, 2014b). The overall average SF-36 PCS score was 41.72 (*SD*=12.60), which indicates mild disability and the overall SF-36 MCS score was 36.87 (*SD*=9.57), which indicates a moderate level of disability. Similarly, the overall MCAS score of 62.36 (*SD*=7.73) indicates a moderate level of disability in terms of overall ability to function in the community. The CSI mean score was 37 (*SD*=12.25) and, with a cut-off score of 30 to signal the need for further psychiatric assessment and higher

scores indicating more symptoms of psychiatric illness, a score of 37 indicates the presence of mental health distress in the study cohort. The Quality of Life tool measures overall satisfaction with life on a 7 point Likert scale where '4' indicates neither satisfaction or dissatisfaction. Not surprisingly, given that all participants live below the poverty line, participant's satisfaction with their financial situation was lowest at 2.85 (*SD*=1.61), indicating being unhappy to mostly dissatisfied. Analysis of the 'leisure' score variable, which measures one component within the Quality of Life tool, revealed that the participants in the SC+ group had higher satisfaction with their leisure time with a mean score of 4.34 (*SD*=1.07) as compared to the participants in the SC-R group who had a mean score of 3.64 (*SD*=1.07) (*t*[59]=-2.55, *p*=.01), for an overall effect size of *d*=0.66, *CI*[.0.21,1.32].

With regard to the questions related to tobacco use, this cohort of smokers had a high level of nicotine dependence at study entry, with a mean FTND score of 6.23 (*SD*=1.76), close to 56% of participants reported smoking within 5 minutes of waking in the morning and 41% reported getting up one or more nights during the week to smoke. The self-report mean daily cigarette consumption was 24.80 (*SD*=12.01), and the exhaled carbon monoxide mean was 24.43 (*SD*=13.15) *ppm*. Participants reported engaging in smoking behaviours such as sharing cigarettes (26%), smoking contraband cigarettes (59%), smoking discarded cigarette butts (26%), and smoking cigarettes remade from discarded cigarette butts and filters (26%). They identified quitting tobacco to be important, rating it 8.80 (*SD*=1.82) out of 10, and their confidence in stopping tobacco was rated at 7.20 (*SD*=2.28).

While this study recruited participants who were interested in either quitting or reducing their use of tobacco, 82% of participants indicated that they were interested in quitting their use of tobacco within the next 30 days, and 97% believed that NRT would help

them achieve this goal. All but one participant had an Ontario Health Card and, although 79% reported having a family physician, for this population, a family physician is typically accessed periodically through walk-in clinics. Other than the 'leisure time' score on the Quality of Life assessment, there were no statistically significant differences between intervention group and any of the other baseline scores, thus confirming that the randomization exercise had succeeded in producing equivalent groups and that both intervention groups had similar demographic, clinical, psychosocial, and tobacco-related characteristics.

Numbers Analysed

Data collection points were at baseline, 3 months and 6 months. The SC+ group consisted of 32 participants and the SC-R group consisted of 29 participants. Analysis of the primary smoking outcomes at the different time points was conducted on the number of participants originally assigned to each group. If a participant declined to be interviewed at any time point (n=4 at the 3-month time point and n=3 at the 6-month time point), participants were assumed to still be smoking. For other smoking outcome variables at the 3-month and 6-month time points, such as the FTND score, exhaled carbon monoxide *ppm*, number of cigarettes smoked per day, and for secondary outcomes analysis of scored instruments such as the MCAS, the SF-36, the CSI, GAINS-SS and Quality of Life Measures, multiple imputation, using the expectation maximization algorithm in SPSS, was performed to provide a data point for analysis. For missing data points on other variables the exact number of participants (denominator) is noted.

Outcomes and Estimation of Effect Size

Primary outcomes. Table 4 provides a comparison of the primary smoking related outcomes of each of the two groups in the study. Non-smoking status was determined at three and at six months by self-report 7-day point prevalence abstinence and validated with exhaled carbon monoxide level of 5 *ppm*[18] or less. Both groups achieved positive smoking cessation and smoking reduction outcomes but there was no statistically significant difference in the comparison of the smoking status outcomes between each group. At 3 months, 7 of 32 participants (22%) in the SC+ group and 4 of 29 participants (14%) in the SC-R group had quit smoking (*OR*=1.75,95%CI[.455,6.74]) and at 6 months, 4 of the 32 participants (13%) in the SC+ group and 2 of the 29 participants (7%) in the SC-R group had quit smoking (*OR*=1.95,95%CI[.33,11.41]).

There were no statistically significant differences in the smoking behaviors between the two groups, with the exception that the participants in the SC+ group at the 6 month time point had a lower prevalence of smoking contraband cigarettes, with 10 of 27 (37%) participants reporting this behaviour compared to 16 of 24 (67%) participants in the SC-R group, (χ^2 (1) = 4.46, *p*=.035, *OR*= 3.40, 95% *CI* [1.07,10.78]). McNemar tests performed on the smoking behaviour variables indicated that there were no statistically significant changes in each group over time on any of these variables.

Repeated measures ANOVA's found no statistically significant differences between the two treatment groups on overall FTND scores or the number of cigarettes smoked per

[18] At the 3 month time point one non-smoking participant with a CO level of 9 *ppm* due to continued cannabis use was included as a non-smoker as the no smoking status had been verified by the nurse working in the program. Another participant in the SC-R group who self-reported as a non-smoker at 6 months and who had a CO level of 9 *ppm* was not included as a non-smoker as this status could not be verified and the participant did not use cannabis.

Table 4

Comparison of Smoking-Related Outcomes for SC+ and SC-R at 3 Months and at 6 Months

Variable	Total Survey *N*=61	Smoking Cessation + *n*=32	Smoking Cessation-R *n*=29	SC+ vs. SC-R (χ^2)	Effect Size
Do you smoke? (Yes)					
3 mths *n*=61	50 (82.0 %)	25 (78.1%)	25 (86.2%)	*p*=.41	OR= 1.75 95%CI[.46,6.74]
6 mths *n*=61	55 (90.2%)	28 (87.5%)	27 (93.0 %)	*p*=.46	OR= 1.93 95%CI[.33,11.41]
Smoking Behaviours:					
Shares cigarettes (Yes)					
Baseline *n*=61	16(26.2%)	6 (18.8%)	10(34.5%)	*p*=.16	
3 mth *n*=46(+=22/R=24)	11 (23.9%)	3 (13.6%)	8 (33.3%)	*p*=.12	
6mth *n*=51(+=27/R=24)	14 (27.5%)	8 (29.6%)	6 (25.0%)	*p*=.71	
Smokes discarded cigarette butts (Yes)					
Baseline *n*=61	16(26.2%)	9(28.1%)	7(24.1%)	*p*=.72	
3 mths *n*=46(+=22/R=24)	8 (17.4%)	5 (22.7%)	3 (12.5%)	*p*=.36	
6 mths *n*=51(+=27/R=24)	7 (13.7%)	5 (18.5%)	2 (8.3%)	*p*=.29	
Smokes cigarettes remade from discarded butts/filters (Yes)					
Baseline *n*=61	16(26.2%)	9(28.1)	7(24.1%)	*p*=.72	
3 mths *n*=46(+=22/R=24)	9 (19.6%)	4 (18.2%)	5(20.8%)	*p*=.82	
6 mths *n*=51(+=27/R=24)	9 (17.6%)	6 (22.2%)	3 (12.5%)	*p*=.36	
Smokes Contraband (Yes)					
Baseline *n*=61	36(59.0%)	19(59.4%)	17(58.6%)	*p*=.95	
3 mths *n*=46 (+=22/R=24)	29 (63.0%)	12 (54.5%)	17 (70.8%)	*p*=.25	
6 mths *n*=51 (+=27/R=24)	26 (51.0%)	10 (37.0%)	16 (66.7%)	*p*=.04 χ^2 (1)=4.46	OR=3.40 95%CI[1.07,10.78]

Variable		Mean (*SD*)	Mean(*SD*)	Significance of Test Statistic (*t*)
FTND				
Baseline *n*=61	6.23(1.76)	6.41(1.78)	6.03(1.76)	*p*=.42
3 mths *n*=50	4.95(2.17)	5.0 (2.35)	4.91 (2.01)	*p*=.88
6 mths *n*=54	4.94(2.21)	5.13 (2.32)	4.74 (2.11)	*p*=.52
Exhaled Carbon Monoxide, *ppm*				
Baseline	24.43(13.15)	23.09(11.23)	25.90(15.06)	*p*=.41
3 mth *n*=61	20.85(14.33)	21.63 (16.61)	19.99 (11.53)	*p*=.66
6 mth *n*=61	23.50 (14.22)	23.29(13.28)	23.73(15.42)	*p*=.91
# of cigarettes/day				
Baseline	24.80(12.01)	27.25(12.02)	22.10(11.60)	*p*=.10
3 mths *n*=61	11.90(13.43)	12.53(15.25)	11.20(11.30)	*p*=.70
6 mths *n*=61	12.46(10.48)	13.06(10.37)	11.79(10.74)	*p*=.64

day over the three time points. However, Figure 2 and Figure 3 highlight that there was a significant decrease over time for both groups together on the FTND scores and the number of cigarettes smoked per day from baseline to the 3 month follow-up, with this decrease sustained at the 6 month follow-up. The interaction of group and time was not significant for the two variables. Participants smoked a mean of 24.80 (*SD*=12.01) cigarettes a day at the beginning of the study, 11.90 (*SD*=13.43) cigarettes at 3 months and 12.45 (*SD*=10.48) cigarettes at 6 months (F[1.68,98.90]=55.13,p<0.001, η_p^2=0.48). Although the number of cigarettes smoked was a self-report measure, it was collected by the nurses on a weekly basis in order to properly titrate NRT dosing. To further support the validity of this self-report measure, there was a strong positive correlation between number of reported cigarettes smoked and level of nicotine dependence as indicated by the FTND score at baseline (r[61]=.59, p=.0001), at the 3 month time point (r[50]=.67, p=.0001), and at the 6 month time point (r[55]=.57, p=.0001).

Related to the amount of cigarettes smoked is the overall estimation of nicotine dependence captured by the FTND score. While there were no differences between the SC+ and SC-R groups at any time point, Figure 3 highlights that there were some significant time effects between baseline and 3 months for both the SC+ and the SC-R groups (F [2, 94] = 17.98, p < .001, η_p^2 = 0.28). The level of carbon monoxide measured as expired breath CO *ppm*, did not statistically significantly change either between groups or over time. It did decrease from a baseline mean score of 24.43 (*SD*=13.15) to a mean of 20.85 (*SD*=20.85) at 3 months but at 6 months it had increased to 23.53 (*SD*=14.22). Measures of confidence in quitting tobacco and of the importance of addressing tobacco dependency did both decrease

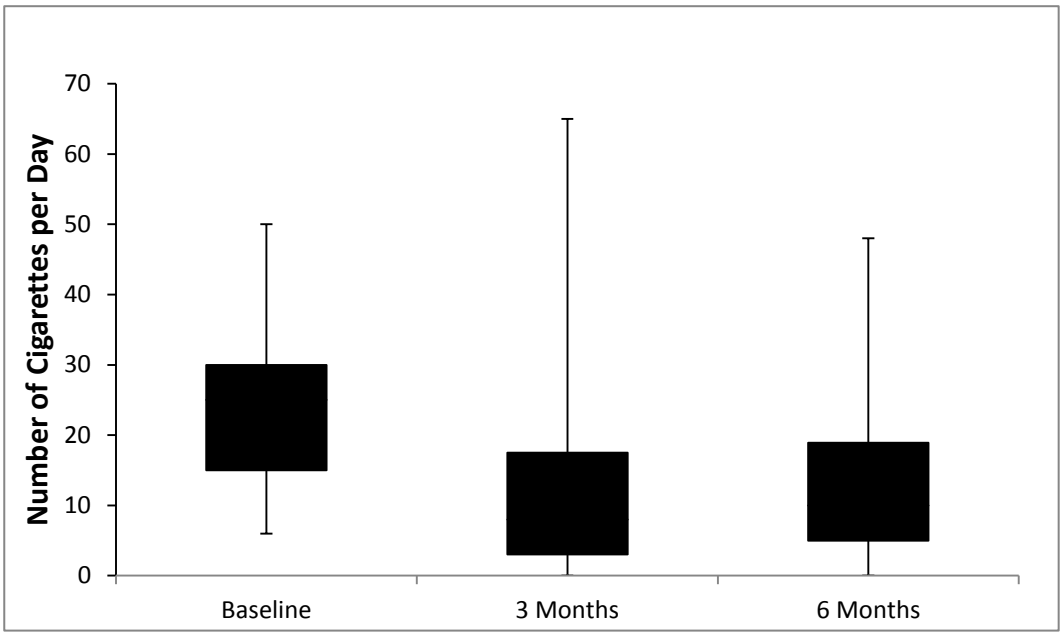


*Figure 2:*Significant Time Effect, Baseline Versus 3 Months and 6 Months For Number of Cigarettes Smoked Daily

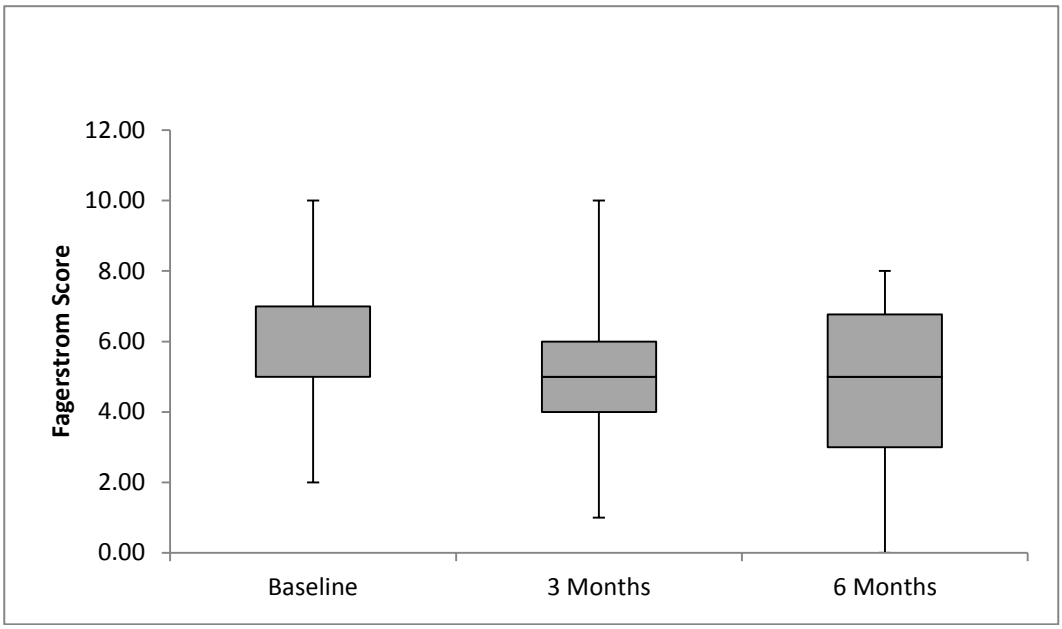


*Figure 3:*Significant Time Effect, Baseline versus 3 months and 6 months for Overall FTND Scores

between the initial baseline and the 6 month time point but the change was not statistically significant either between groups or over time.

Secondary outcomes. Table 5 provides data on secondary outcomes for the two treatment groups over the course of the study. As with the smoking related outcomes, there were no statistically significant differences at either the 3 month or the 6 month time point between the SC+ and the SC-R groups on the physical health outcomes or mental health care outcomes.

***Physical and mental health outcomes*.** Comparison of level of physical and mental health functioning across time points do reveal some effect over time and in between treatment groups as well. For the SF-36 PCS, there was no significant difference between the scores of the two treatment groups but Figure 4 highlights that there was a statistically significant increase in scores in both groups between the baseline mean of 41.72 (*SD*=12.60) and the 6 month mean of 45.48 (*SD*=12.40) ($F[2,118]=5.21$, $p=.007$, $\eta_p^2=0.08$). While the SF-36 MCS did decrease slightly over time in both groups from a combined mean score of 36.87 (*SD*=9.57) at baseline to 35.67 (*SD*=9.85) at the 6 month time point, it was not a statistically significant change.

For the CSI, which monitors severity of mental health symptoms, Figure 5 highlights the significant interaction effect of how the drop in score for the SC-R group between the baseline mean score of 39.48 (*SD*=11.92) to 35.88 (*SD*=9.74) was significantly different compared to the increase in score for the SC+ group from 34.75 (*SD*=12.29) at baseline to 36.90 (*SD*=14.70) at 3months ($F[2,118]=3.41$, $p=.036$, $h_p^2=0.06$). However, there were no differences between the groups at 3 months or 6 months on this measure.

Table 5

Comparison of Secondary Outcomes (Physical and Mental Health) for SC+ and SC-R at 3 Months and at 6 Months

	Total Survey	Smoking Cessation +	Smoking Cessation-R
	N=61	n=32	n=29
Variable		Mean (*SD*)	Mean(*SD*)
Weight(kg)-Men			
Baseline n=37	97.91(30.52)	93.91(28.73)	102.62(32.74)
3 mths n=31	98.15(29.20)	99.77(32.14)	96.42 (26.72)
6 mths n=31	98.85(30.77)	96.47(30.82)	101.61(32.02)
BMI-Men			
Baseline n=36	29.87(9.59)	27.46(8.92)	32.88(9.80)
3 mths n=30	30.37(8.78)	30.21(9.8)	30.56(7.81)
6 mths n=31	30.47(9.30)	29.47(9.16)	31.69(9.66)
Waist (cm)-Men			
Baseline n=37	108.98(23.64)	107.38(22.31)	110.66(25.50)
3 mths n=28	106.23(19.94)	109.81(24.73)	102.09(12.10)
6 mths n=23	107.18(18.80)	103.92(19.44)	110.72(18.31)
Weight(kg)-Women			
Baseline n=21	83.70(22.69)	83.86(29.18)	83.55(16.23)
3 mths n=21	82.34(25.33)	82.18(29.58)	82.89(22.27)
6 mths n=20	82.05(24.71)	80.62(28.24)	83.33(21.20)
BMI-Women			
Baseline n=21	31.09(8.44)	30.65(10.06)	31.49(7.13)
3 mths n=19	31.02(9.59)	30.72(10.23)	31.36(9.43)
6 mths n=20	30.86(9.57)	29.51(9.92)	32.50(9.42)
CSI			
Baseline	37 (12.25)	34.75(12.29)	39.38(11.92)
3 mths	36.41(12.50)	36.90(14.70)	35.88(9.74)
6 mths	35.08(11.56)	35.23(12.82)	34.91(10.22)

	Total Survey N=61	Smoking Cessation + n=32	Smoking Cessation-R n=29
Variable		Mean (*SD*)	Mean(*SD*)
GAINS			
Past Month			
Baseline	1.12(1.48)	1.22(1.58)	1.02(1.39)
3 mth	1.69(1.87)	1.95(2.04)	1.40(1.65)
6 mth	1.36(1.49)	1.34(1.47)	1.38(1.53)
Past Year			
Baseline	1.88(1.84)	1.97(1.84)	1.80(1.87)
3 mth	2.12(1.97)	2.46(2.14)	1.76(1.72)
6 mth	1.80(1.70)	1.76(1.72)	1.85(1.70)
Lifetime			
Baseline	3.91(1.50)	3.88(1.50)	3.99(1.53)
3 mth	3.91(1.43)	4.06(1.43)	3.74(1.42)
6 mth	3.97(1.49)	3.96(1.56)	3.97(1.43)
SF-12 PCS			
Baseline	41.72(12.60)	41.58(13.33)	41.88(11.92)
3mths	43.90(11.79)	43.48(13.04)	44.36(10.46)
6 mths	45.48(12.40)	46.82(13.27)	44.00(11.40)
SF-12 MCS			
Baseline	36.87(9.57)	37.93(10.74)	35.71(8.12)
3mths	37.99(9.69)	38.53(10.26)	37.39(9.16)
6 mths	35.67(9.85)	35.94(10.23)	35.38(9.58)
Quality of Life Measures			
Family Life			
Baseline	4.04(1.68)	4.36(1.77)	3.68(1.53)
3 mths	4.22(1.54)	4.38(1.74)	4.04(1.30)
6 mths	4.21(1.71)	4.49(1.76)	3.90(1.63)
Finances			
Baseline	2.85(1.61)	3.08(1.66)	2.60(1.53)

	Total Survey N=61	Smoking Cessation + n=32	Smoking Cessation-R n=29
Variable		Mean (*SD*)	Mean(*SD*)
3 mths	3.35(1.70)	3.50(1.67)	3.20(1.75)
6 mths	3.25(1.72)	3.45(1.86)	3.031.55)
Leisure Time			
Baseline	4.00(1.11)	4.34(1.07)	3.64(1.07)
3 mths	4.29(1.23)	4.47(1.15)	4.09(1.30)
6 mths	4.05(1.26)	4.27(1.19)	3.80(1.30)
Living Environment			
Baseline	4.66(2.04)	4.94(1.76)	4.35(2.30)
3 mths	5.01(2.03)	5.16(2.18)	4.85(1.87)
6 mths	5.09(2.14)	5.26(1.87)	4.90(2.42)
Safely of Environment			
Baseline	4.83(1.54)	5.27(1.28)	4.35(1.69)
3 mths	5.01(1.33)	5.10(1.39)	4.92(1.28)
6 mths	5.30(1.30)	5.37(1.37)	5.22(1.23)

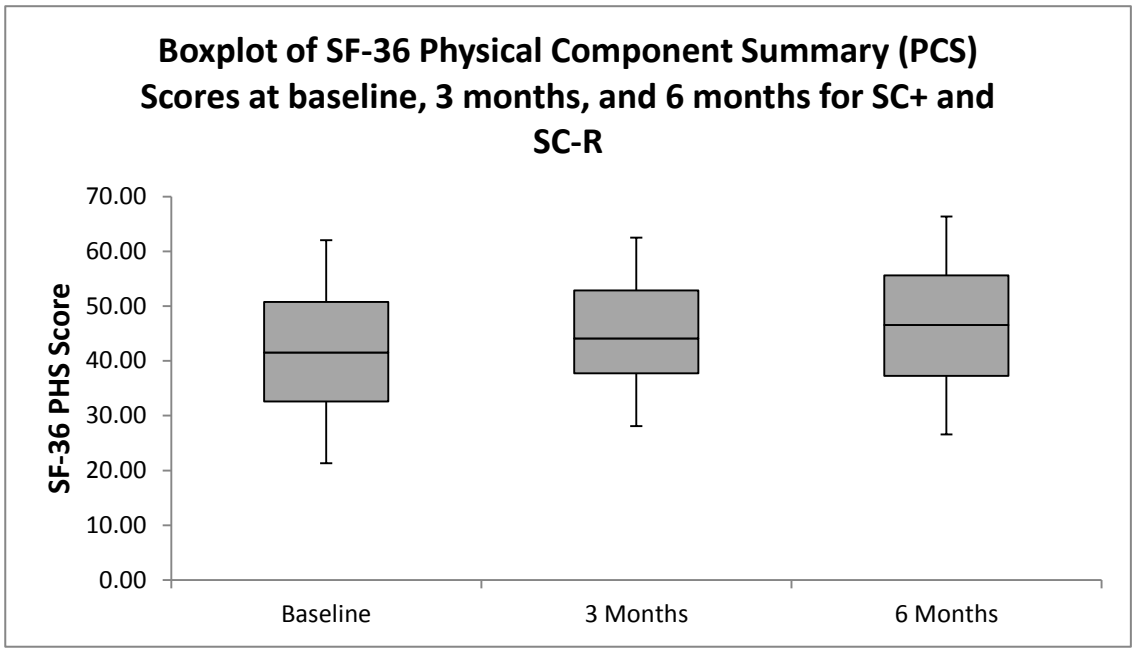


Figure 4: SF=36 PCS Score Comparisons Over Time For Both SC+ and SC-R Groups

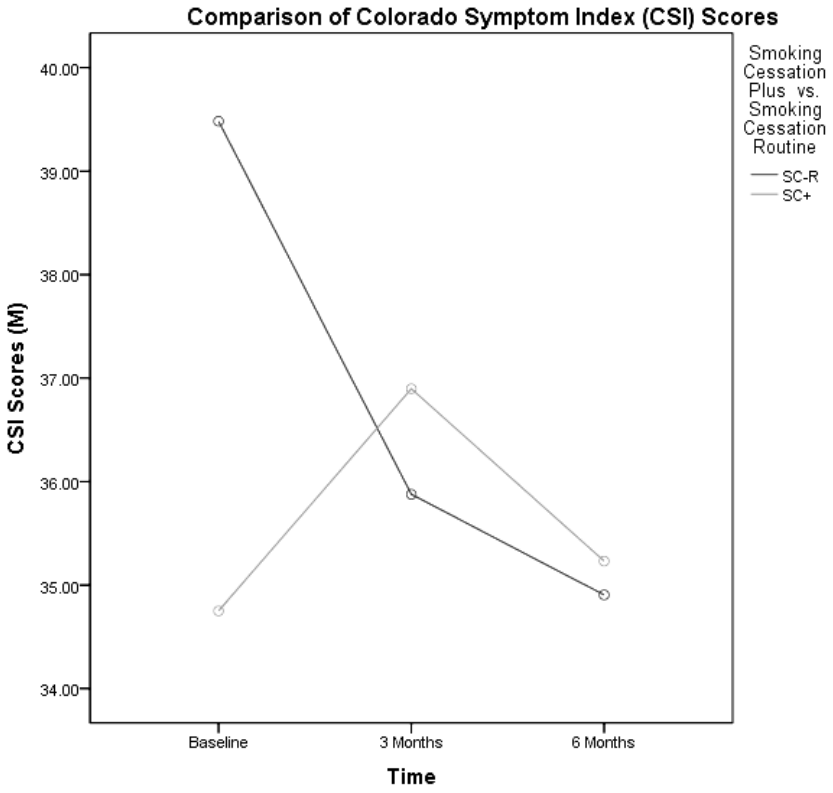


Figure 5: Colorado Symptom Index (CSI) Score Comparison For SC+ and SC-R Groups

Additional monitored physical health indicators such as weight and BMI showed no significant changes over time from baseline to 6 months although both measures did increase slightly over time. Monitoring of substance use also found no indication of significant change in past month use of substances from baseline to the 3 months and 6 month time points.

Quality of Life. Quality of life was evaluated in the life domain areas of finances, family life, living situation, leisure and safety. In the areas of quality of family life and of living situation, both areas showed increased scores over time, but the change was not significant. There was a significant time effect for improvement in safety from the baseline to the 6 month time point (F[1.82,118]=3.56, p=.036, η_p^2=0.06) and also a significant time effect for improvement in finances between the baseline and the 3 month time point (F[2,118]=3.03, p=.05, η_p^2=0.05), with a small non-significant decline in scores at the 6 month mark in financial satisfaction. Overall, all scores for level of satisfaction with finances remained well below 4, indicating persistent dissatisfaction.

Comparison of treatment contacts between SC+ and SC-R groups. Table 6 highlights the differences in the number of treatment contacts for SC+ and SC-R at 3 months and at 6 months. All participants in both groups were offered the opportunity to meet weekly with a registered nurse or nurse practitioner and to receive weekly doses of NRT at the appropriate dosage to respond to their level of nicotine dependence. Only participants randomized to the SC+ group were offered additional support opportunities in the form of a weekly psychosocial support group and two individual MI counselling sessions. Therefore, data related to group attendance and MI counselling session attendance are only reported

Table 6

Comparison of Treatment Contacts for SC+ and SC-R at 3 Months and at 6 Months

Variable	Total Survey	Smoking Cessation +	Smoking Cessation-R	
	N=61	n=32	n=29	*p* value
	Mean (*SD*)	Mean(*SD*)	Mean(*SD*)	
# Nursing contacts In first 3 mths	10.36(4.41)	10.59 (4.41)	10.10 (4.5)	*p*=.67
# of nursing contacts total at 6 mths	18.85(9.03)	20.03(9.69)	17.55(8.22)	*p*=.29
Weeks of NRT In first 3 mths	7.16(3.76)	6.88(3.72)	7.48(3.84)	*p*=.53
Total weeks of NRT at 6 mths	11.49(7.36)	11.47(8.24)	11.72(7.95)	*p*=.61
# of Group sessions 3 mths (*n*=32)		6.22(3.30)	NA	
Total group sessions at 6 mths (*n*=32)		10.28(6.80)	NA	
# of MI sessions attended *N*=32 (max. 2 sessions)		1.63(0.66)	NA	

here for participants in the SC+ group. Participation in these sessions, as with the weekly meetings with the nurses, was encouraged, but attendance was ultimately optional.

One of the initial concerns among the health care practitioners with not providing weekly support groups to the SC-R group was a belief that participants not able to access group support would put additional demands on the nurses through additional weekly contacts. Conversely, there was also concern that without a group support connection to bring participants into the office, participants may become more easily disconnected with the treatment and not come into the office to meet with the nurses.

Analysis of the data revealed that regardless of the treatment, participants had a similar number of nursing contacts and weeks of NRT treatment, with no statistically significant difference between the two treatment groups. By examining the group attendance numbers within the SC+ group, the median number of groups attended was 11 out of 24, sessions and the mean number of sessions was 10.28 (*SD*=6.80), but 4 of 32 participants did not attend even one group session. In reviewing attendance of the MI sessions, 23 of 32 participants (71.9%) attended both of their MI sessions.

Overall treatment non-compliance of the SC+ vs. the SC-R groups revealed no difference in the use of NRT between the groups (see Appendix D for summary of NRT dosing). By the end of the study, the SC+ group had been allocated on average, 2,805 *mg* of NRT per participant and the SC-R group had been allocated on average, 2,858 *mg* of NRT per participant. Overall, there was no differential loss to treatment between the SC+ and SC-R groups when considering weeks of NRT received. At the three month mark, treatment compliance for participants who had received six or more weeks of NRT was 65.5% for the SC-R group and 62.5 % for the SC+ group, for an overall compliance rate of 64%. At the

six month mark, treatment compliance for participants who had received 12 or more weeks of NRT was 48% for the SC-R group and 41% for the SC+ group, for an overall compliance rate of 44%. At the three month mark, the treatment compliance for participants in the SC+ group attending six or more group sessions was 62%, and at the six month mark for those attending 12 or more group sessions, the treatment compliance rate was 46%. The treatment compliance for SC+ participants attending two MI sessions was 72%.

Comparison of NRT and Nursing Contacts for Smokers and Quitters. An analyses of number of nursing contacts and number of weeks of NRT received did reveal some differences between participants who were smokers and non-smokers. Table 7 highlights that participants who became non-smokers had seen the nurse more frequently than those who remained smokers at both the 3-month and 6-month time points. These differences were statistically significant. In regard to number of weeks of NRT received, at the 3-month mark there was not a statistically significantly difference between the amount of NRT received by smokers and those who quit smoking, but by the 6-month mark, those who had quit smoking received a statistically significant higher number of weeks of NRT.

Comparison of group treatment and MI session contacts in SC+ group between smokers and quitters. A further examination of the treatment contacts for the Smoking Cessation Plus group from the perspective of smokers versus quitters did reveal some differences as well in treatment contacts, although the samples under consideration are very small. Table 8 provides a summary of the group session attendance and MI session attendance contacts of the SC+ group participants from the perspective of those who had quit smoking at the 3-month time point (n=7) and at the 6 month time point (n=4). Individuals who had quit smoking at the 3-month time point in SC+ (n=7) had attended all of their MI

Table 7

Comparison of Nursing and NRT Treatment Contacts Between Smokers and Quitters

	Quitters	Smokers		
3 month time point	*n*=11	*n*=50		
Variable	Mean (*SD*)	Mean(*SD)*	Significance of Test Statistic (t)	Cohen`s *d*
#Nursing Contacts	12.45(2.42)	9.90(4.62)	t=(28.66)=-2.60, *p*=.014 CI[-4.56,-.549]	*d*=0.59 CI[0.27,1.71]
#Weeks of NRT	8.73(3.26)	6.82(3.81)	ns	
6 month time point	*n*=6	*n*=55		
# Nursing Contacts	26.50(7.56)	18.02(8.84)	t(59)=-2.26,*p*=.028 CI[-16.0,-.96]	*d*=0.97 CI[0.34,2.21]
# Weeks of NRT	17.87(6.86)	10.82(7.15)	t(59)=-2.24,*p*=.029 CI[-12.98,-.72]	*d*=0.99 CI[0.34,2.21]

Table 8

Comparison of Treatment Contacts for SC+ group Smokers and Quitters

Variable	Smoking Cessation + Quitter	Smoking Cessation+ Smoker		
	Mean (*SD*)	Mean(*SD)*	Significance of Test Statistic (t)	Cohen`s *d*
3 month time points	*n*=7	*n*=25		
# of Group sessions	7.00(2.38)	6.00(3.44)	ns	
# of MI sessions attended	2.00(0.00)	1.53(0.71)	*p*=.003 t(24.0)=-3.36 CI[-.78,-.19]	*d*=0.74 CI[0.34,2.19]
6 month time point	*n*=4	*n*=28		
# of Group sessions	16.50(2.64)	9.39(6.77)	*p*=.003 t(10.24)=-3.86 CI[-11.19,-3.02]	*d*=1.10 CI[0.43,2.74]

sessions as compared to the smokers (*n*=25) who had attended an average of 1.5 sessions, and by the 6-month mark, the non-smokers in SC+ (*n*=4) had attended an average of 16.5 out of 24 group sessions, compared to the 9.4 sessions attended on average by the smokers in the group (*n*=28). Both of these differences were statistically significant.

Comparison of confidence in quitting between smokers and quitters. An examination of how quitters and non-quitters rated their confidence in succeeding at quitting tobacco revealed that there were some differences between these groups. Participants who had quit smoking at the 6-month time point (*n*=6), had rated their confidence in quitting smoking at the 3-month time point as 9.8 out of 10 (*SD*=0.41), as compared to those who remained smokers (*n*=51) who had rated their confidence as 6.1 out of ten (*SD*=3.1). This difference was statistically significant (*t*[53.98]=-8.09, *p*=.0001), (*d*=-3.49, 95%*CI*[-4.99,-2.40]). Similarly, these quitters rated their confidence in succeeding at quitting at the 6 month time point as 9.0 out of 10 (*SD*=1.10), as compared to those who remained smokers by the end of the study who had rated their confidence as 6.13 out of 10 (*SD*=2.79). This difference was also statistically significant (*t*[14.5] =-4.85, *p*=.0001), (*d*=-3.49,95% *CI*[-4.78,-2.19]). At baseline, there was no significant difference in how these groups rated their confidence in succeeding at quitting smoking, with those who would become non-smokers at six months rating their confidence as 7.17(*SD*=3.31) and those who remained smokers rating their confidence as 7.2(*SD*=2.18). This suggests the importance of reaching out to smokers who may be experiencing a drop in confidence but also suggests how the experience of actually quitting can provide a huge boost to confidence.

Comparison of smoking status and FTND scores between study participants and the treatment as usual (TAU) group across time points. Table 9 provides a summary of the comparison of smoking status outcomes and change in level of nicotine dependence between the study participants and the treatment as usual (TAU) group. The treatment as usual group was matched for sex and FTND scores at baseline with study participants and as analyses of comparisons of these specific outcomes between the SC+ and SC-R groups were not significant, the study participants (n=61) were compared as one group to the TAU group (n=61). While more participants quit smoking at the 6-month time point in the study group (n=6) than in the TAU group (n=3), the difference was not statistically significant. The effect size for these differences was OR=2.0,95%CI[.48,8.4]. It is possible that with a larger sample the intervention could have a significant effect on overall quit rates as compared to a group where no treatment was offered.

With regard to the FTND scores, the baseline scores were identical as the groups were matched on these scores, but after six months, the mean score of the smoking participants in the study had dropped to 4.94 (SD=2.21) while the mean score for the TAU group of smoking participants had increased slightly to 6.31 (SD=2.10), (t[110]=-3.36, p=.001). The FTND scores at six months included the remaining 58 smokers in the TAU group and the 55 smokers in the study group. This difference in the two scores at six months was calculated as having a moderate to large effect size (d=0.64, 95%CI[0.15,0.99]).

Comparison of the FTND scores across time points does reveal differences in changes over time for the two group as well. Figure 6 highlights the significant interaction effect with the statistically significant difference between the FTND scores of the two

Table 9

Comparison of Smoking-Related Outcomes for Study Participants (SC+ and SC-R) and Treatment as Usual (TAU) Participants at 6 Months

Variable	Smoking Cessation (SC+ & R) *n*=61	TAU *n*= 61	SC+ & SC-R Vs. TAU (χ^2)	Effect Size
Do you smoke? (Yes) 6 mths	55 (90.2%)	58 (95.1 %)	ns	OR= 2.0 95%CI[.48,8.4]
Variable	Mean (*SD*)	Mean(*SD*)	Significance of Test Statistic (*t*)	Cohen's *d*
FTND				
Baseline *n*=61	6.23(1.76)	6.23(1.76)	ns	
6 mths *n*=54	4.94(2.21)	6.31(2.10)	*p*=.001 *t*(110)=-3.36	*d*=0.64 95%CI [0.15,0.99]

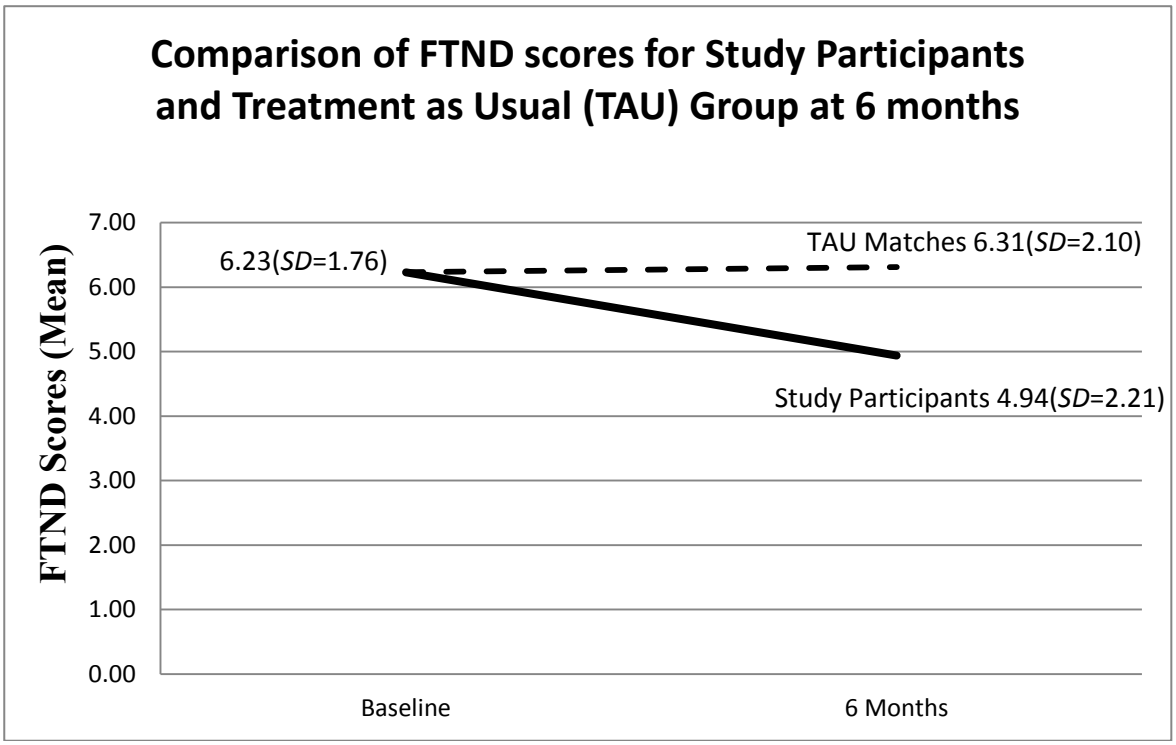


Figure 6: Significant Interaction Effect Between the TAU Group and SC+ and SC-R Group

treatment groups over time and at the 6-month time point (F[1,110]=11.65, p=.001, η_p^2 =0.096).

Comparison of smoking status and FTND scores between study participants and the 'as treated' group across time points. An 'as treated' analysis was undertaken to determine if the individuals, who had received a specified 'dose' of treatment, experienced different smoking outcomes as compared to the intent-to-treat analysis cohort. 'As treated' was defined, at the 3-month time point as participants in both the SC-R and the SC-+ groups who had received six or more weeks of NRT, thereby having had received six or more nursing contacts as well. Additionally, for the SC-+ group participants who had received six or more weeks of NRT, participants also had to have attended both MI sessions, and, six or more psychosocial group support sessions. Table 10 highlights that, for participants in the SC+ who received the prescribed 'as treated' dose, combined group quit rates were higher at both the 3-month time point (27%) and the 6-month (18%) time point. These differences were not statistically significant when compared to the 'intent-to-treat' outcomes at these time points. Chi-square analyses of the 'as treated' group (n=33), comparing the SC+ group (n=14) and the SC-R group (n=19), found a trend towards significance in the quit smoking outcomes at three months (χ^2 (1) =2.97, p=.08, OR= 4.0, 95% CI [.79,20.22]) in the direction of a higher proportion of the SC+ quitting. There were no statistical differences in quit rates between the two groups at six months (χ^2 (1) =1.76, p=.18, OR= 3.4, 95% CI [.53,22.0]). Similarly, t-tests performed on the 'as treated' group failed to detect differences in number of cigarettes smoked or FTND scores at the baseline, 3- month, and 6-month data collection time points, with no statistically significant difference between the SC-+ and SC-R groups.

Table 10

Quit Smoking Outcomes Utilizing 'As Randomized' and 'As Treated' Analyses

	Number of subjects for analysis		
	Total	SC+	SC-R
As Randomized	N=61	n=32	n=29
at 3 months	n=11 quitters 18%	n=7 21.9%	n=4 13.8%
at 6 months	n= 6 quitters 9.8%	n=4 12.5%	n=2 6.9%
As Treated	N=33	n=14	n=19
at 3 months	n=9 quitters 27%	n=6 42.8%	n=3 15.8%
at 6 months	n=6 quitters 18%	n=4 28.6%	n=2 10.5%

Predictors of smoking status at 3 month and 6 month time points for both SC+ and SC-R groups. A series of logistic regressions were conducted to investigate the individual predictors of quitting at 3-month and 6-month follow-ups. In line with findings previously reported, logistic regression indicated that membership in either the SC+ or SC-R group did not significantly predict smoking status at either 3-months or 6-months. Further logistic regression analyses investigating predictors of smoking versus non-smoking status were conducted with both SC+ and SC-R groups together (n=61) and can be found in Table 11 and Table 12. Logistic regression indicated that the number of cigarettes smoked at baseline entered as an individual variable predicted quit status at 3 months, χ^2 (1)=7.47, p=006. Quitters had smoked a mean of 16.81 (SD=7.51) cigarettes a day at baselines whereas those who remained smokers after three months had smoked a mean of 26.56 (SD=12.14) cigarettes at baseline. Neither the number of weeks of NRT received nor the number of nursing contacts were a significant predictor of smoking status when entered as individual variables in logistic regressions.

As reported earlier, participants who were quitters at three months had seen the nurse statistically significantly more times than those who remained smokers but differences in number of weeks of NRT received between smokers and quitters remained non-significant at this point. Nursing contacts and weeks of NRT treatment were closely correlated at the 3-month time point (r [61]= .759 , p=.0001), as participants could not receive their weekly NRT without having contact with the nurse. Other smoking related variables such as the baseline FTND score, expired breath CO *ppm* baseline levels, importance of quitting and confidence in quitting scores were not significant predictors of quitting status at three months.

Table 11

Results of Logistic Regressions Predicting Likelihood of Quit Status at 3 months For Participants in Both SC+ and SC-R Treatment Groups

Predictor Variable	*B*	S.E.	Wald	*Df*	*p*-value	AOR	95% C.I.	
Treatment Group - ns	.560	.688	.662	1	.416	1.75	.455	6.74
# of cigarettes smoked at baseline-sig	**-.100**	**.044**	**5.26**	**1**	**.022**	**.905**	**.831**	**.986**
# of weeks of NRT - ns	.149	.100	2.238	1	.135	1.17	.955	1.410
# of weeks of nursing contacts - ns	.150	.088	2.92	1	.088	1.16	.978	1.38
FTND BL-ns	-.231	.189	1.50	1	.221	.794	.548	1.15

B=unstandardized regression coefficient

Table 12

Results of Logistic Regressions Predicting Likelihood of Quit Status at 6 Months For Participants in Both SC+ and SC-R Treatment Groups

Predictor Variable	*B*	S.E.	Wald	*Df*	*p*-value	AOR	95% C.I.	
Treatment Group - ns	.657	.907	.524	1	.469	1.93	.326	11.41
# of cigarettes smoked at baseline-ns	.092	.055	2.80	1	.094	.912	.819	1.02
# of weeks of NRT - sig	**.140**	**.071**	**3.90**	**1**	**.048**	**1.150**	**1.00**	**1.32**
# of weeks of nursing contacts - sig	**.110**	**.053**	**4.24**	**1**	**.040**	**1.12**	**1.00**	**1.24**
FTND BL-ns	.038	.248	.023	1	.878	1.04	.638	1.69

B=unstandardized regression coefficient

At the 6-month end of treatment time point, logistic regression indicated that weeks of NRT received, entered as an individual variable, predicted quit status, χ^2 (1)= 4.86, p=0.027. As well, a separate logistic regression of nursing contacts entered as an individual variable predicted quit status at 6 months, χ^2 (1)=4.86, p=0.027. The individuals who were not smoking by six months had received a mean total of 17.67 (*SD*=6.86) weeks of NRT treatment as compared to the mean of 10.82 (*SD*=7.15) weeks of NRT received by those who remained smokers (*t*[59]=-.2.24, *p*=.029). Quitters had a mean total of 26.5(SD7.56) nursing contacts compared to the mean of 18.02 (*SD*=8.84) nursing contacts for the remaining smokers (*t*[59]=-.2.26, *p*=.028). Neither the number of cigarettes smoked at baseline nor the number of cigarettes smoked by the 3-month time-point were significant predictors of non-smoking status at the 6-month time-point. Similar to the relationship identified at three months, the number of nursing contacts and weeks of NRT received remained highly correlated at the 6-month time point (*r*[61]=.84, *p*=.0001).

Predictors of Reduction of Tobacco Use at 3 Months and at 6 Month. This study was concerned with determining not only if the intensity of the intervention predicted quitting smoking but also if it predicted overall reduction of tobacco use. To that end, standard multiple regressions were performed to examine the relationship between amount of NRT and number of nursing contacts as predictors of cigarettes smoked at either 3 months or at 6 months, after controlling for number of cigarettes smoked at baseline. Findings of the multiple regressions that were conducted can be found in Table 13.

A multiple regression was conducted to predict number of cigarettes smoked at three months from number of nursing contacts after controlling for number of cigarettes smoked at baseline. Baseline cigarettes and nursing contacts (*F*[2,58]=17.59, *p*=.0001, adj. R^2=.36)

Table 13

Summary of Sequential Multiple Regression Analysis Predicting Likelihood of Reduction of Tobacco Use at 3 Months in Both SC+ and SC-R Treatment Groups

	End of 3 month treatment			End of 6 month treatment		
	B	SE_B	B	B	SE_B	B
Predictor Variable						
Step 1						
Intercept	9.69	3.97		7.18	2.80	
Baseline Cigarettes/day	.544	.109	.487*	.478	.084	.548*
Step 2						
Weeks of NRT Tx	-.1.58	.348	-.442*	-.573	.137	-.403*
Step 1						
Intercept	8.15	4.40		8.17	3.11	
Baseline Cigarettes/day	.599	.116	.536*	.500	.086	.573*
Step 2						
Nursing Contacts	-1.07	.317	-.352*	-.431	.114	-.371*

*p<.05; B=unstandardized regression coefficient ; SE_B = Standard error of the coefficient; β=standardized coefficient

significantly predicted number of cigarettes smoked at the 3-month time-point. A separate multiple regression was conducted to predict number of cigarettes smoked at three months from number of weeks of NRT after controlling for number of cigarettes smoked at baseline. Baseline cigarettes and weeks of NRT (F[2,58]=23.66, p=.0001, adj. R^2=.43) also significantly predicted number of cigarettes smoked at three months.

A multiple regression was conducted to predict the number of cigarettes smoked at the 6- month time-point from total weeks of NRT received after controlling for number of cigarettes smoked at baseline. These variables significantly predicted number of cigarettes smoked at six months (F[2,58]=25.15, p=.0001, adj. R^2=.45). A separate multiple regression conducted to predict number of cigarettes smoked at the 6-month time-point from number of nursing contacts, after controlling for number of cigarettes at baseline, also predicted cigarettes smoked at six months (F[2,58]=22.74,p=.0001, adj. R^2=.42).

Harms

There were no identified harms reported by participants in the study or by the health care professionals delivering the intervention.

Discussion

The purpose of this study was to provide two different interventions to assist individuals with severe mental illness to quit or reduce their use of tobacco and to determine if there were differences between these two groups in the primary smoking related outcomes. Secondary outcomes, such as changes in substance use or mental health status, were monitored over time. All participants in the study received combination NRT at titrated doses for up to 24 weeks and individuals in the SC+ group also were offered up to two individual sessions of MI counselling and 24 weeks of psychosocial group support. The

primary smoking outcomes were validated 7-day point prevalence smoking abstinence rate and the reduction of cigarettes smoked at the three and six month marks.

While the study was underpowered due to an inability to provide treatment to any more than 60 individuals during this period, it has served as a pilot study, examining the feasibility of conducting a clinical trial and evaluating the outcomes of smoking cessation interventions with the population. Given the grave consequences of the high smoking prevalence for this population and the reluctance of the mental health system to engage in a comprehensive strategy to address tobacco use, it is important to demonstrate that this is a population interested and motivated to quit or reduce their use of tobacco and to provide opportunities for mental health practitioners to gain important clinical practice skills in addressing nicotine dependence.

For this study we were able to recruit, gain consent from, and randomly assign a sample of clients with severe mental illness to two different tobacco reduction and smoking cessation treatments. This was a cohort with high levels of nicotine dependence and concurrent physical health and substance use issues, many of whom engaged in smoking behaviours such as smoking contraband cigarettes and smoking discarded cigarette butts. The agency where the study was situated was also able to gain valuable clinical experience in the dispensing and monitoring of combination NRT at titrated doses, and the development and implementation of group interventions to address tobacco use in this population. The data collection questionnaires utilized at the baseline, 3-month, and 6-month time point, also appeared to be well tolerated by participants given the low interview attrition rates (6.6% at three months and 4.9% at six months).

The overall quit rates reported in this study, 18% at three months (*n*=11) and 10% at six months (*n*=6), are comparable with quit rates reported in the literature (Gallagher, Penn, Schindler & Layne, 2007; Okuyemi et al., 2013). One study with a comparable cohort of individuals with schizophrenia and other severe mental illnesses that utilized NRT in one of the treatment arms, reported quit rates between 0% to 16% at week 20 and 3% to 7% at week 36 (Gallagher, Penn, Schindler & Layne, 2007). A RCT of 430 homeless smokers that offered NRT for 8 weeks and MI sessions as an added treatment enhancement to one of the treatment groups, reported no significant differences in the smoking cessation outcomes between the groups at 26 weeks (9% vs. 5.6%) (Okuyemi et al., 2013).

The study found no statistically significant difference in the smoking cessation or smoking reduction outcomes between the SC-R and the SC+ groups. However, more participants did quit smoking in the SC+ group than in the SC-R group at both the 3-month time point (21.8% versus 13.8%) and at the 6-month time point (12.5% versus 6.9%). The effect size (*OR*=1.75 at 3 months and *OR*= 1.93 at 6 months) suggests that with a larger sample it is possible that the SC+ intervention could have a significant effect on overall quit rates as compared to a group where no supplemental group support was offered.

The 'as treated' analysis also found a trend toward significance in the quit smoking outcomes in the direction of a higher proportion of participants in the SC+ group quitting with larger effect size (*OR*=4.0 at 3 months and *OR*=3.4 at 6 months). This trend was the same for the TAU versus the combined SC+ and SC-R study participants with a higher proportion of the study participants quitting at six months (*OR*=2.0), as compared to those who had not received any specific smoking cessation intervention.

While this study is not sufficiently powered to determine significance in the primary smoking outcomes, the literature has suggested that, with smoking cessation and smoking reduction, small effect sizes may indeed justify the application of intensive interventions due to the devastating impact of tobacco use and the enormous health gains that are acquired through cessation or reduction of smoking (West, 2007).

Treatment compliance was highest for the MI intervention where over 70% of the SC+ group attended both sessions. Gauging the specific contribution of group session attendance is difficult, given that 4 of 32 participants did not attend even one session and only 46% of the sample attended 12 or more sessions by the end of the study. However, the differences in overall smoking cessation outcomes for the SC+ group suggest a promising trend. Given that even small effect sizes in smoking cessation studies can be justified (West, 2009), the addition of psychosocial group and MI sessions may be justified, in particular given the relatively small cost in providing this intervention (i.e., estimated at under $1,000 per client) or, at least, offering this to potential clients as an adjunct to the NRT treatment.

Given what is known regarding the devastating relationship of tobacco to health consequences that are experienced by individuals with severe mental illness, being able to produce even a few more quitters with the addition of the SC+ intervention could provide enormous benefits to this population. This cohort was also relatively young, with a mean age of 44, leaving many years of potential health benefits to accumulate. A concurrent qualitative inquiry that was conducted with the study participants found that individuals who did attend group sessions identified benefits such as the non-judgemental approach of staff and the ability to talk about and receive support to address pressing life events beyond 'smoking' (Rae et al., 2015). There was also clear feedback in this qualitative study that

group attendance was not for everyone and should be an option, not a requirement, for participation in a smoking cessation program.

Challenges with treatment compliance were not unanticipated for this client group, but ultimately, it is part of the challenge of conducting 'real world' research within a community mental health practice, where, ultimately, the decision to participate in treatment is voluntary. Other smoking cessation studies have made access to medication contingent upon group attendance (Khara & Okoli, 2011), but this design was not considered for this study as a mandatory treatment approach would be at odds with the clinical operating principles of the agency where the study was conducted. The overall agency practice where the agency was conducted is guided by the principle of the 'strengths model' (Rapp & Goscha. 2008) which champions clients autonomy and the application of a coercive intervention (for example, only having access to NRT if a group session was attended) would not be an accepted practice.

Treatment non-compliance is acknowledged in the literature as a complex challenge for psychosocial interventions. An initial meta-analysis (Wierzbicki & Pekarik, 1993) estimated an overall treatment dropout rate of 46.86%, but a more recent meta-analysis (Swift & Green, 20012) reported a weighted dropout rate of 19.7%, with rates ranging from 0% to74.3%. They described a variety of treatment, client, and study design moderators that impacted on these numbers. Examples of moderators associated with higher drop-out rates were combination group/individual interventions, trainee clinicians, undetermined treatment timelines, and client characteristics such as more severe diagnoses and lower income levels (Swift & Greenberg, 2012). Swift & Callahan (2011) have also found that participations who receive the treatment that they prefer are less likely to discontinue

treatment. The treatment dropout rate for the 'as treated' participants in this study was on the higher end of the continuum but not outside of what has been reported in the literature (Swift & Green, 2012).

It is important to note however, that there was no differential loss to treatment between SC+ and SC-R groups in the utilization of NRT treatment. While the treatment non-compliance rates were at the upper end of treatment non-compliance rates as assessed in the literature (Swift & Greenberg, 2012), this study had elements that are predictive of higher rates of treatment discontinuation. This would include recruiting participants with more serious psychiatric diagnoses, providing a combined group and individual treatment intervention, and the fact that, given participants were randomly assigned to the intervention, not all clients necessarily received their preferred treatment option (Swift & Callahan, 2011).

Another way to consider the potential benefit of the SC+ intervention, is by comparing smokers and non-smokers within the SC+ group. While at three months there was no difference in number of group sessions attended, there was a statistically significant association between the number of group sessions attended and smoking outcome at six months. By the end of the study at the 6-month time point, the quitters in SC+ had attended a total of 17 sessions, whereas those who remained smokers had attended only 9 sessions overall. The effect size of this difference was large (d=1.10). Within the 'as treated' analysis, the SC+ group subjects (n=14) who had completed the prescribed minimum 'dose' of treatment, had a quit rate of 43% at the 3 month time point (n=6) and a quit rate of 29% (n=4) at the 6 month time point. This is in comparison to the 'as treated' SC-R group (n=19) who had a quit rate of 15% at the 3 month time point (n=3) and a quit rate of 11% at the 6 month time point (n=2). In comparing the 'as treated' participants in SC+ versus those in

SC-R, the OR was 4.00 at 3 months and 3.4 0 at 6 months. Although these samples are very small, this does support the potential value of investigating the added benefit of group interventions as part of a smoking cessation intervention for this population. It also suggests that it is over longer term periods of interventions that one begins to see differences in sustained uptake of treatment. However, in looking at the differences between treatment uptake of quitters and those who remained smokers, one must legitimately consider a bi-directional relationship, and consider if participants who attended more sessions were quitters because they attended more sessions, or due to possible positive praise and feedback received for quitting, they attended more sessions, or due to both relationships.

Interestingly, the only other significant difference between the SC+ and SC-R groups was at the 6-month mark where participants in the SC+ group were 3.4 less likely to smoke contraband cigarettes than those in the SC-R group. Decreasing use of contraband cigarettes could be an important factor in overall smoking cessation, as it is associated with heavier smoking and less successful short-term smoking cessation outcomes (Mecredy et al., 2013). This speaks to a potential benefit within the SC+ group, in which the peer co-facilitator group worker specifically addressed the use of contraband cigarettes. There were no statistically significant differences at the 3-month or the 6-month time points between the SC+ and the SC-R groups in their assessed physical and mental health outcomes.

While the quit rates reported in this study are comparable with quit rates reported in the literature, it is difficult to have exact comparisons of quit rates across studies as many studies are focused on a specific diagnosis and are investigating a variety of clinical interventions, or combination of clinical interventions, beyond NRT and psychosocial support. Additionally, studies often have different criteria for determining 'abstinence' and

'reduction' of tobacco use, different time frames for the interventions, they recruit study subjects from different treatment settings, and the sample sizes can be small (Banham & Gilbody, 2010). Other factors, such as access to, or use of, contraband or illegally packaged tobacco and smoking of discarded cigarette butts, are not typically reported in studies. These challenges in smoking cessation studies are not exclusive to inquiries involving individuals with mental illness and this has led to recommendations for standard practice in reporting of smoking cessation trials (West, Hajek, Stead & Stapleton, 2005).

All participants in this study had access to weekly sessions with a registered nurse and to NRT. While there were no differences in the number of nursing contacts or weeks of NRT that participants received between the groups, both groups experienced significant reduction of tobacco use between the baseline time point where the mean number of cigarettes smoked was 25, the 3-month time point where daily cigarette consumption had been reduced to 12, and the 6- month time point when daily cigarette smoking was reported as just over 12 cigarettes. This constitutes more than a 52% reduction of cigarettes from baseline to three months and a 50% reduction from baseline to six months. While number of cigarettes smoked was a self-report measure, this was information collected by the nurses on a weekly basis, not only to monitor progress, but also to titrate individual NRT treatment doses for clients.

There was also a statistically significant reduction from the Fagerström baseline score of 6.2 to 4.9 at both the 3-month and at the 6-month time points for individuals who continued smoking throughout the study. This suggests that reduction of cigarette smoking was sustained over this time period, and while 5 of the 11 people who had quit smoking at the 3 month time point had started smoking again by the end of the study, the amount

smoked in the overall cohort remained at a consistently low level. This overall reduction is a very positive outcome, as reduction of smoking has been found to increase the probability of future smoking cessation in the general population (Hughes & Carpenter, 2006), and has been suggested as a specific strategy to engage individuals with mental health and substance use disorders who may not be ready or interested in committing to a program goal of tobacco abstinence (Baker, Callister, Kelly & Kypros, 2012).

The other positive change over time for participants in the two treatment conditions was the statistically significant increase in physical health functioning. The mean of the PCS scores increased from 42 at baseline to 46 at the 6-month follow-up. These mean scores are still below the U.S. population norm mean score of 50, reflecting the problematic physical health concerns of this cohort. However, seeing the possibility in increasing physical health functioning for this population is noteworthy, given the mortality and morbidity rates associated with severe mental illness. This improvement in physical health is in line with decreasing amount of cigarettes smoked over time, highlighting the potential health benefits of overall reduction of smoking as well as outright cessation. Other intervention studies working with a similar cohort but that did not provide the targeted health behaviour intervention of smoking cessation, did not report changes in physical health functioning over time (Cherner, Aubry & Sylvestre, 2014). Future research needs to investigate the specific significance of targeted smoking cessation and reduction programs on the overall health status of this population and the potential to make significant gains in this area. These outcomes must be interpreted with caution though as the SF-36 is a self-report measure and no reported increase of health status has been corroborated with distinct physical health status indicators, such as a reduction in blood pressure. Study participants could be

reporting an overall increase in physical health functioning due to increased attention and focus on their personal health situation as well as demand characteristics associated with participation in the study.

Other measures of mental health and substance use did not significantly change over time. The purpose in monitoring these indicators was to determine if involvement in the study, and possible cessation or reduction of tobacco, would have an adverse impact on these measures. These areas either remained unchanged or only slightly declined between baseline and end of study measures at six 6 months. Often there is concern that addressing tobacco will compromise sobriety or mental health status and for this cohort, that did not occur. A recent smoking cessation study of in-patient psychiatric patients reported a decrease in psychiatric re-hospitalizations in the group of patients randomized to receive the smoking cessation intervention (Prochaska et al., 2014), suggesting other possible benefits to the health care system. Investigating the relationship between these factors in overall smoking reduction or quit rates are important avenues to explore in future research.

Analyses were undertaken with the entire study cohort to examine if there were variables that helped to either predict quit status or the reduction of overall tobacco use. At the 3-month time point this analysis revealed that the number of cigarettes smoked at baseline predicted quit behaviour in the direction of lower number of cigarettes smoked at baseline being associated with quitting. By the 6-month mark, the number of cigarettes smoked at baseline was no longer a predictor of smoking status. The predictors of a quit status at six months were related to the number of weeks of NRT treatment that an individual had received and the number of nursing contacts that they had accumulated, with quitters

having more nursing contacts and more weeks of NRT. There was no differential loss in nursing contacts and NRT treatment uptake between SC+ and SC-R groups.

After controlling for number of cigarettes smoked at baseline, both increased amounts of NRT treatment and accumulated nursing contacts predicted reduction of cigarette smoking at 3 months and at 6 months. Nursing contacts and amount of NRT utilized by participants were closely correlated as study participants had to see the nurse in order to receive their weekly NRT dose. Therefore, it is not possible to determine which of these two variable or if the two variable together are critical ingredients to reducing smoking. While they could see the nurse without taking any NRT, ongoing contact with the nursing staff likely helped to sustain the connection to treatment and long term commitment to the utilization of the NRT.

With NRT as a key component to predict reduction or elimination of tobacco, it may be important to consider the elements of an intervention that help to sustain uptake of NRT within this vulnerable population. Access to supportive nursing support where symptoms can be monitored and appropriate dosing dispensed is key. In addition, supplemental support through MI sessions and psychosocial group supports may have provided an additional 'boost' to support and inform adherence to an NRT regime. Future research should explore different ways to increase update of NRT, with a cost benefit analysis that considers different staffing models in order to guide treatment interventions.

The program resources required to facilitate this type of nursing support and NRT dosing is substantial. As such, it demonstrates why choosing to address nicotine dependence in this population, without access to cost-free medications and appropriate staffing support, is expensive for most community mental health programs, and beyond the mandate of

current smoking cessation programs. The qualitative study of this cohort (Rae et al., 2015), highlighted the need to have individuals monitored by trained clinicians for any changes in mental health status, given that some individuals identified struggling with managing their symptoms of mental illness due to a variety of individual factors during the course of the study.

While certainly there was an association between amount of NRT and nursing contacts with smoking status, and the reduction of cigarette use in particular, other factors could be at play in shaping the smoking outcomes for this participants in the study. For example, confidence in quitting tobacco was the same at the start of the study for those who became quitters and for those who remained smokers. However, at both the 3-month and the 6-month time point, those who had quit smoking were statistically significantly more confident of their ability to quit using tobacco than the individuals who remained smoking. This may also be an opportunity to 'boost' adherence to NRT by reaching out to individuals who experience a decrease in their confidence levels.

The literature also identifies the 'treatment resistant smoker' who may have a varied response and experience less benefit from NRT treatment (Bittoun, 2007). As well, we know that there are many factors that act as 'protectors' for treatment success in addressing tobacco use, such as stable housing, employment, supportive non-smoking family and friends, supportive non-smoking living and working environments, stable mental and health, and the ability and means to manage external life stressors. This was a particularly vulnerable cohort, and many of these 'social determinants of smoking cessation' may have been compromised and could have influenced their ability to participate in treatment and either quit or reduce smoking. In particular, individuals with lower incomes have been

found to experience about half the success of quitting smoking as compared to those in higher income brackets (Kox & West, 2009).

An objective of the pilot study, is to calculate the sample size required for a larger definitive trial. For the ITT analysis, 435 participants would be required in each group or 870 participants in total, to have a 80% chance of detecting, at the .05 level, an increase in the primary outcome of 7-day point prevalence abstinence at six months from 6.9% in the SC-R group to 12.5% in the SC+ group. For the 'as treated' analysis, 144 total participants or 72 individuals in each group, would be required to have a 80% chance of detecting, at the .05 level, an increase in the primary outcome of 7-day point prevalence abstinence from 10.5% in the SC-R group to 28.6% in the SC+ group.

This study provides evidence that smoking cessation and smoking reduction treatment can be successfully introduced into a very vulnerable population of individuals with severe mental illness. With such ingrained patterns of nicotine dependence as experienced by individuals with multiple and complex needs, programs need to support reduction of cigarette smoking as an alternative, or at least a bridge to complete smoking cessation. Individuals benefit from combination and titrated doses of NRT and the availability of longer treatment periods in order to sustain treatment gains. Physical health status did improve, mental health status did not statistically decline during the treatment period, and use of other substances did not increase. Even as an underpowered study, there is evidence of a trend toward supporting the addition of the enriched psychosocial interventions offered to the SC+ group, and while the treatment effect may be small, it may still be justified, given the enormous health benefits with reducing or eliminating tobacco.

Limitations

This study had limitations. The size of the treatment groups were small and while there was a minimum of missing data, with only four participants unavailable to participate at the 3-month data collection point and three participants at the 6-month data collection point, analysis would benefit from a larger study cohort. The participants of this study do typify clients with severe mental illness being served by intensive case management teams and community mental health programs, but as such, they are somewhat diagnostically heterogeneous with multiple co-morbidities, making generalizations related to a specific diagnostic group difficult.

The nurses were not blinded to the randomization of participants and it is possible that they provided additional counselling and support to participants in the SC-R group. However, given their pressured nursing practice and the fact that the nurses continued to treat a variety of clients other than smoking cessation study clients in their usual practice, it is unlikely that they would have had substantial extra time to spend on a consistent basis over a six month period with 29 patients. It is also possible that SC-R participants could have accessed counselling support outside of the agency, but again, given the usual challenges that clients of this agency face in accessing mainstream support services, it is not likely that this occurred to any great extent.

The treatment as usual (TAU) comparison group was drawn from an existing data base of clients served at the same agency, and they were matched with study participants on sex and FTND scores as these had been the two variables utilized to initially randomize the study sample into their two treatment arms. However, the study sample consisted of individuals who were explicitly interested in quitting or reducing their use of tobacco and

this may contribute to the understanding of why the study group experienced a significantly greater reduction in their FTND scores over a six month period as compared to the TAU group.

While the purpose of monitoring secondary outcomes measures related to substance use and physical health conditions was to determine if these changed following the reduction or elimination of tobacco, given the high co-occurrence of substance use disorder in this population, a more substantial monitoring of actual use rates of specific substances would potentially improve the understanding of why some participants did not participate in the treatment. Having a better sense of the potential role that substance abuse plays, in particular the use of cannabis, will be essential going forward to develop and improve smoking cessation interventions for this population.

Conclusions

Given that tobacco accounts for 50% of all deaths for individuals with schizophrenia and mood disorders (Callaghan et al.,2014), it is shocking that the mental health system continues to neglect to develop any sort of comprehensive tobacco strategy for this particular population. While the resources required to begin to undue decades of neglect may seem daunting, it is imperative that community mental health networks continue to demand equal access to treatment opportunities for the vulnerable clients served in this sector. Research such as this study demonstrate that is it possible to make significant gains in the reduction of tobacco use for even the most marginalized individuals and that clients are motivated and interested in addressing their tobacco dependency. This research highlights the need to conduct cost analysis in relation to differing treatment approaches. If even small effect sizes can justify augmented treatment costs, it will be essential to be able to identify these costs

and the potential benefits to clients. Future research needs to continue to explore, using both quantitative and qualitative approaches, specific dosing and support requirements that individuals identify as essential to enable them to sustain a reduction of tobacco use.

This pilot study has demonstrated that individuals with severe mental illness are interested in receiving treatment and that the described research design is possible to apply in a community mental health setting. NRT compliance was key to predicting tobacco reduction and quit behaviour of participants in this study, and going forward, future research should investigate the most efficient interventions to engage and sustain vulnerable clients in treatment.

Overall Discussion

The impact of smoking-related death and disability on individuals with severe mental illness is crushing. We now know that not only do individuals with severe mental illness die much earlier than the general population (Parks, Svendsen, Singer, & Foti, 2006), but that tobacco use specifically accounts for approximately half of the deaths for people with schizophrenia or mood disorders (Callaghan et al., 2014). Under what circumstances would we have an identified attributable cause of death for 50% of a specific population, and yet, no systematic health intervention plan in place to tackle the cause of death? The completed studies described in this paper are intended to contribute to an increased awareness of the consequences of tobacco use among individuals with severe mental illness and to offer recommendations for future directions, in both program development and research.

The lack of appropriate comprehensive planning to address tobacco use for vulnerable populations is undeniable. For example, the final report for the most recent strategic planning initiative for mental health and addiction services in the province of Ontario by the Ministry of Health and Long Term Care, *Navigating the Journey to Wellness: The Comprehensive Mental Health and Addictions Action Plan for Ontarians* (Government of Ontario, 2010), does not mention tobacco use or treatment. A recent survey of community mental health and addiction treatment programs in the province of Ontario reported that while 71% of programs stated that they served individuals with a concurrent disorder, less than a quarter of the programs included 'tobacco' as part of their definition of 'concurrent disorder' (Addictions and Mental Health Ontario & Canadian Mental Health Association, Ontario Division, 2013). The agency where both studies, presented in this thesis, occurred is located in Ontario; however the situation here is far from unique and quite

reflective of the current struggle to address tobacco within community mental health systems and practices across Canada.

This paper has presented the findings of two studies. The purpose of the first study was to determine the prevalence of tobacco use, the level of nicotine dependence, the intention to quit tobacco and the smoking behaviours within a sample of individuals with severe mental illness who were homeless or vulnerably housed receiving services from a community mental health agency. Tobacco use prevalence was 72%, and 62% of smokers had high or very high levels of nicotine dependence; however almost half of respondents (47%) were interested in quitting or reducing tobacco within the next 6 months. Respondents identified smoking behaviours such as smoking cigarettes remade from discarded cigarette butts (25%), or smoking contraband cigarettes (47%), and smokers were found to be over nine times more likely to have a co-occurring substance use disorder.

The objective of the second study was to conduct a pilot study that investigated if there were differences in smoking-related outcomes between participants with severe mental illness assigned to one of two smoking cessation interventions: Nicotine Replacement Therapy (NRT) only (SC-R) versus NRT plus group and individual motivational interviewing (MI) sessions (SC+). Assessed smoking outcomes were chemically verified 7-day point prevalence abstinence rates at the 3-month and at the 6-month mark, and overall recorded number of cigarettes smoked at three and at six months. Using a RCT design, the study found that, there were no statistically significant differences in the smoking quit or smoking reduction rates between the SC-R treatment group (13.7% at the 3-month time-point and 6.9% at the 6-month time-point) and the SC+ group (21.8% at the 3-month time point and 12.5% at the 6-month time-point). However, as a pilot study, the differences in the

quit rate between the two groups reflected an effect size that warrants the conducting of a definitive trial with a sufficient sample size to detect small differences.

The overall quit rate for both groups combined was 18% at the 3-month time-point, and 10% at the 6-month time-point. Reduction in the number of daily cigarettes smoked was statistically significant over time for the two groups together, with a 52% overall reduction at the 3-month time point, and a sustained 50% reduction at the 6-month time point. Number of cigarettes smoked at baseline predicted cessation at three months and greater number of nursing contacts and weeks of NRT predicted sustained cessation at six months. Physical health status did improve in both groups together, mental health status did not statistically decline during the treatment period, and use of other substances did not increase. An 'as treated' analyses of participants from both groups, who received a prescribed 'dose' of the invention, had a 27% quit rate at three months and an 18% quit rate at the six month time point.

Both of these studies shed light on the specific challenges of addressing tobacco use in this population and, while the outcomes are directed at improving interventions at an individual level, as a pilot study, there are other implications for informing interventions at both program and system levels of change.

Intervention recommendations highlighted within Study #1

The findings of the first study provide a number of insights into understanding tobacco use and smoking behaviours within a highly marginalized population of smokers. It included analyses of specific smoking behaviours such as smoking discarded cigarette butts and smoking contraband cigarettes in relation to clinical characteristics such as the co-occurrence of substance use disorders and the level of disability and community functioning.

These findings have implications for understanding and interpreting level of nicotine dependence and in the development of appropriate interventions to address tobacco use in similar groups of smokers.

The client population in this study is typical of the client population served within community mental health programs that are mandated to support individuals with severe mental illness. Overall, the study cohort could best be described as a heterogeneous population with significant co-occurrence of substance use disorder, chronic physical health conditions, and given the pervasive poverty that is endemic with this population, housing vulnerability and homelessness.

The overall smoking prevalence in this study was reported as 72% and although this prevalence rate is alarming, it is consistent with the high prevalence of smoking reported among individuals with a mental illness (Harris, Parle & Gagne, 2007; Grant, Hasin, Chou, Stinson & Dawson, 2004; Lasser et al., 2000). With regard to diagnosis, this study reported no evidence of significant associations between smokers and non-smokers in relation to having a diagnosis of either schizophrenia or mood disorder. While the literature consistently reports higher prevalence of tobacco use among individuals with a diagnosis of schizophrenia (de Leon, 1996; de Leon & Diaz, 2005; Diaz, Velasquez, Susce & de Leon, 2008), this may have been mediated by the presence of other factors associated with elevated tobacco use. For example, this particular study sample was drawn from an agency where, at point of referral, all clients are homeless or vulnerably housed and there is a high co-occurrence of substance use disorders and overall poverty.

The smoking status of participants in the first study was not associated with reported chronic physical health conditions although intuitively one might have anticipated that

smokers would have a higher likelihood of suffering from a chronic physical illness. However, this is a particularly marginalized population where physical health status is poor regardless of smoking status. This is consistent with research that identifies compromised overall physical health status for individuals with severe mental illness and those who are homeless or vulnerably housed. (Baggett, Tobey & Rigotti, 2013b; Baggett et al., 2014; Hwang et al., 2011).

Individuals with a co-occurring substance use disorder were 9 times more likely to be a smoker than clients who did not have a co-occurring substance use disorder. Given the high prevalence of tobacco use in general among individuals with mental illness and the fact that community mental health programs serve a high proportion of individuals with concurrent disorders in particular, this speaks to the importance of assessing for tobacco dependence and developing the capacity to provide integrated treatment opportunities that focus on addictions including tobacco.

With regard to level of disability and community functioning, an analysis of scores on the Multnomah Community Ability Scale revealed that the smokers had lower levels of functioning than non-smokers. In particular, lower scores on this measure suggest potential difficulty in such areas of functioning as health, community adaptation, housing, financial stability, social skills, and behaviour. The combination of lower levels of functioning and significant co-occurrence of substance use disorders among smokers has implications for the development and implementation of treatment to address tobacco use in this population. Lower levels of functioning combined with ongoing substance abuse could have a significant impact on the ability of individuals to engage and maintain the demands of a smoking cessation treatment intervention. As such. it would be important to integrate

tobacco treatment within mental health services that are capable of addressing overall community functioning and life domain issues such as housing, family support, and psychiatric medication management. The co-occurrence of alcohol and drug use disorders also suggests the need to integrate tobacco treatment within programs that are addressing these problems and that modifications for more intensive support to meet the needs of a highly disabled population may be warranted (Khara & Okoli, 2010; Okoli & Khara, 2011; Selby et al, 2012;Williams & Ziedonis, 2004).

Understanding the extent of nicotine dependence in this population is important, and the level of nicotine dependence in this sample was considerable, with over 60% of the sample assessed on the Fagerström as having 'high' or 'very high' levels of nicotine dependence. It should be noted that there are some potential challenges in capturing an accurate assessment of nicotine dependence in marginalized groups of smokers due to specific smoking behaviours, practices, and their living environment. Existing measures of nicotine dependence do not typically inquire as to alternative smoking practices. In this study, one-third of the sample reported that they lived someplace that controlled when and where they were allowed to smoke cigarettes. Since these types of environments tend to be temporary or transient, it is possible that these individuals would consume even more cigarettes, given a completely unrestricted living environment.

While the use of contraband cigarettes on a regular basis by the general population of smokers has been reported as 13% (Mecredy et al., 2013), approximately half the sample reported either sharing cigarettes or smoking contraband cigarettes. Additionally, one in four clients reported smoking cigarettes remade from discarded cigarette butts and filters, and one in five reported smoking discarded cigarette butts. Individuals who engaged in

these smoking behaviors and practices were more likely to have a concurrent substance use disorder and to have a lower MCAS score. The combination of a lower community functioning and a concurrent disorder suggests that the sub populations who engage in these behaviours could be experiencing more chaotic life situations that could ultimately present additional challenges for practitioners providing treatment to address tobacco use. Acquiring cigarettes through these means can make it difficult to calculate exact amount smoked and ultimately determine nicotine dependence levels which are critical for administering effective treatment and designing intervention programs. These behaviours also provide valuable information regarding the "culture" of ingrained smoking practice in this population. It also highlights that engaging individuals into tobacco treatment who purchase contraband cigarettes or smoke the discarded cigarette butts of others may present unique program challenges in monitoring ongoing tobacco use.

These are all factors that can influence the accurate calculation of nicotine dependence and this could account for variations in dependency levels across similar population groups in the literature. It is essential then for practitioners to ask about these behaviours and practices when assessing for tobacco dependency within marginalized groups by incorporating these questions into assessment tools.

With regard to interest in quitting or reducing tobacco, almost half of the respondents (47%) were interested in quitting or reducing their tobacco within the next six months, and eight per cent of this group wanted to quit within the next 30 days. Overall, people who identified no interest in quitting had higher levels of nicotine dependency, lower levels of community functioning and, in this study, were more likely to have a diagnosis of schizophrenia and to be male. Combinations of factors such as these could impact on the

development of intervention strategies for building motivation and interest in tobacco cessation. Low interest in quitting combined with a high level of nicotine dependency is a challenging combination however, this could change over time as addressing tobacco use becomes a more common practice within community mental health programs.

It is evident that, even though this is a complex population to serve with a high prevalence of tobacco use and high level of nicotine dependence, people are interested and want assistance to quit or reduce smoking. Given the potential overwhelming demand for treatment from groups of marginalized smokers, information pertaining to who is more likely to engage in treatment could be useful for the targeting of scant resources. That said, it is still important to provide individuals served within community mental health programs the opportunity to be assessed for tobacco dependence, given the historic lack of focus in this area. Factors such as co-occurring substance use disorders and poor community functioning will all have to be considered when developing interventions for this population. Given the complexity of needs for this clientele, imbedding treatment for tobacco dependence within existing community mental health services that already have the mandate to provide a range of support services, could be an effective and efficient means to address these needs.

Intervention recommendations highlighted within Study #2

In the second study we were able to recruit and randomly assign a sample of clients with severe mental illness to tobacco reduction and cessation treatment. This was a cohort with high levels of nicotine dependence and concurrent physical health and substance use issues, many of whom also engaged in smoking behaviours such as smoking contraband cigarettes and smoking discarded cigarette butts. Given the grave consequences of the high

smoking prevalence for this population and the reluctance of the mental health system to engage in a comprehensive strategy to address tobacco use, it is important to demonstrate that this is a population interested and motivated to quit or reduce their use of tobacco. As a pilot study, is was important to be able to reflect on the feasibility of conducting the intervention.

The study found no statistically significant difference in the smoking cessation or smoking reduction outcomes between the SC-R and the SC+ groups, but the effect size, (*OR*=1.75 at 3-months and *OR* =1.93 at 6-months), suggests that it is possible that with a larger sample, the SC+ intervention that combined NRT with psychosocial group and MI support, could have a significant effect on overall quit rates as compared to a group where no supplemental group support was offered. The 'as treated' analysis that considered only the participants who had received a specified 'dose' of intervention, also found a trend toward significance in the quit smoking outcomes at 3-months in the direction of a higher proportion of participants in the SC+ group quitting.

The overall quit rates reported in this study among all participants (18% at three months and 10% at six months) are comparable with quit rates reported in the literature (Gallagher, Penn, Schindler & Layne, 2007;Okuyemi et al.,2013). In comparing the quit rate at six months in the study cohort (10%), with the TAU cohort that received no specific tobacco treatment intervention (5%), there was no significant difference, but given the medium effect size associated with the differences, it is possible that with larger sample sizes there could be evidence of statistical significance for providing specific treatment to address tobacco dependency. For the study participants from the two groups together who were

assessed 'as treated' (*n*=33), the overall quit rate was 27% at three months and 18% at six months (*n*=6).

All study participants had access to weekly sessions with a registered nurse and to NRT. There was no differential loss to treatment in the number of nursing contacts or weeks of NRT that participants received between the group. Both groups experienced significant reduction of tobacco use between the baseline time point and the 3-month time point. The reduction was sustained to the 6-month time point. Similarly, there was a statistically significant reduction from the Fagerström baseline score at both the 3-month and at the 6-month time points for individuals who continued smoking throughout the study. This suggests that the reduction of cigarette smoking was sustained over this time period. This overall reduction is a positive outcome as reduction of smoking has been found to increase the probability of future smoking cessation in the general population (Hughes & Carpenter, 2006) and has been suggested as a specific strategy to engage individuals with mental health and substance use disorders who may not be ready or interested in committing to a program goal of tobacco abstinence (Baker, Callister, Kelly & Kypros, 2012). There were statistically significant differences when comparing the change in FTND scores between the study cohort and the TAU group that provides further support for the benefit of providing treatment.

The other positive change over time for participants in the two treatment conditions was the statistically significant increase in physical health functioning, although this was a self-report measure with no specific objective evidence of improved health status, such as demonstrated lower blood pressure. Other measures of mental health and substance use did not significantly change over time. While no improvements were seen in these areas, it is

important to note that these areas either remained unchanged or only slightly declined between baseline and six months. Often there is concern that addressing tobacco will compromise sobriety or mental health status and, for this cohort, that did not occur in the context of the reduction in number of cigarettes smoked. Investigating the potential contribution of these factors in overall smoking reduction or quit rates was beyond the scope of this study but would be important avenues to explore in future research.

Predictors of non-smoking status at six months were related to the number of weeks of NRT treatment that an individual had received and the number of nursing contacts that they had accumulated, with quitters attending more nursing contact sessions and being allocated more weeks of NRT. Similarly, after controlling for number of cigarettes smoked at baseline, both increased amounts of NRT treatment and accumulated nursing contacts were found in separate regressions to predict reduction of cigarette smoking at three months and at six months. Both of these variables were highly correlated and therefore, it is difficult to isolate their unique contributions to quitting or cigarette reduction.

However, given that NRT has been found to be an effective smoking cessation intervention for individuals with severe mental illness (Banham & Gilbody, 2010; Prochaska et al., 2014), it is likely that of the two variables, the number of weeks of NRT treatment is the critical treatment ingredient to quitting smoking, recognizing that ongoing contact with the nursing staff likely helped to sustain the connection to treatment and long term commitment to the utilization of the NRT. Similarly, in considering that there were more quitters in the SC+ group (albeit a non-significant difference), it is important to consider the possible contribution that the addition of the MI sessions and the weekly psychosocial group intervention may have had in encouraging greater adherence to the NRT treatment.

The program resources required to facilitate this type of nursing and NRT dosing access is substantial, representing significant resources that make this level of intervention too costly for most programs. Additionally, the staffing demands to provide the necessary nursing support certainly exceeds the mandate of most current smoking cessation programs, yet if appropriate treatment is to be provided, these resource issues must be addressed.

Tobacco Use and the Inequity Paradox

Tobacco control and treatment measures have had unquestionable success in reducing the prevalence of tobacco use in Canada (CTUMS 2012; Reid, Hammond, Rynard & Burkhalter, 2014). The described 'three generations' of approaches to address tobacco use in Canada (Richard et al.2002), identify first generation interventions that focused on smoking cessation by targeting individual behaviour, followed by an evolution to second generation interventions that moved into the community realm, and a final evolution into third generation approaches that emphasized public policy interventions. While these interventions plot the trajectory of how tobacco control has ‘taken hold’ and become embedded in Canadian public health culture, clearly some populations remained less impacted, leading to greater vulnerability to health disparities brought about by continued tobacco use.

Frohlich & Potvin (2008) note in discussing Jeffery Rose’s population-based approach, that population health interventions are based on the notion that the population shares an average level of risk exposure and by applying an intervention to the population as a whole, everyone’s risk level shifts. However, Frohlich & Potvin (2008) contend that certainly not everyone in a population has the same risk exposure, and that vulnerable populations, in particular, are exposed to many additional risk factors over the life course.

For example, vulnerable populations are often exposed to poor quality social determinants of health such as deprivation in early life, lack of education, food insecurity, inadequate housing, low income, unemployment, and social exclusion (Raphael, 2009). As the health of the overall population improves (for example, as successful tobacco interventions being to impact on overall prevalence), vulnerable populations who are exposed to many risk factors, may remain less impacted by these interventions and as a result, smoking prevalence rates remain high.

Frohlich & Potvin (2008) describe this as an 'inequity paradox' where "the objective of improving population health may not necessarily be compatible with the objective of reducing health disparities" (p. 219). Pat Martens suggests that in planning complex population health interventions, shifting the overall population risk remains important, but in order to address the concern of creating more health disparities, we need to 'squish' the distribution, by developing customized interventions to respond to the specific needs of those who are less healthy (Martens et al., 2010). Certainly this concept of the 'vulnerable population' contributes to the understanding of how individuals with severe mental illness have remained marginalized by population health interventions related to tobacco use. Conditions and interventions, that have been so successful at a population level, have not been equally available or applied, often as a result of the many social determinants of health previously identified.

While most of us have experienced tobacco control through enforcement in our work or school environments, or in public and social places such as restaurants and movie theatres, for individuals with severe mental illness, who are often unemployed and living in poverty, there would be limited exposure to these restrictive environments. In fact, there

has been a lack of, or certainly lagging in the application of, non-smoking restrictions in psychiatric and substance abuse treatment facilities for the past several decades for both in-patient and community based care (Bardell & Brown, 2006; Goldstein, Steiner, McCullough, Kramer & Okun, 2009; Ortiz, Schacht & Land, 2013).

Individuals in the general population who continue to smoke can also depend on regular scolding interactions from concerned health professionals; however, in contrast, there is evidence of a lack of training in the mental health system that has led to not only a reduced capacity to treat tobacco dependency, but a general inertia toward even addressing tobacco use in this population (Hall and Prochaska, 2009; Johnson et al., 2009; Ziedonic et al. 2008; Himelhoch & Daumit, 2003). The impact of taxation of tobacco products, so effective in reducing overall demand (Stephens, Pederson, Koval & Macnab, 2001), has been found to be less effective on individuals who are poor or who are heavy smokers, perhaps due to the mitigating impact of wide scale availability of contraband cigarettes (Luk, Cohen & Ferrence, 2007). Use of contraband cigarettes in itself has been found to be associated with poorer smoking cessation outcomes and higher levels of nicotine dependence (Mecredy et al., 2013).

With regard to actual interventions, again, there is evidence that the standard approach to treatment may not provide an adequate treatment dose for this population. In general, smoking cessation intervention programs recommend a combination therapy of pharmacological intervention including nicotine replacement therapy (NRT) which comes in the form of patches, inhalers, lozenges, nasal spray and gum, psychotropic medications such as varenacline and buproprion, and psychosocial interventions (CAN-ADAPT, 2011). While there are many challenges with this standard approach to treatment, in particular, individuals

with high levels of nicotine dependence who may require higher dosing of NRT. While free NRT is available in Ontario through the Smoking Treatment for Ontario Patients (STOP) program, it is for selected patient groups (Center for Addiction and Mental Health, 2014). Intensity of psychosocial intervention is an additional concern, given what is known regarding psychosocial interventions for this population in addressing other substance use disorders (Cleary et al., 2009; Cleary et al., 2007). Individuals with a severe mental illness are likely to require long-term support, beyond the life of most eight to twelve week tobacco cessation programs. This could influence not only the level of professional interest in providing treatment to this particular cohort but could, in fact, exceed most program mandates and resources.

'Squishing' the Distribution

How then do we 'squish the distribution' or apply targeted interventions that can begin to address some of these mitigating conditions that have made the existing population health interventions for smoking cessation less available, or less effective, in reaching this particularly vulnerable population? Both Paper #1 and Paper # 2 inform the development of effective smoking cessation interventions that can be targeted at individuals with severe mental illness.

With regard to interventions, both studies demonstrate that it is possible to engage an extremely marginalized population with severe mental illness and many other concurrent conditions, and, at the very least, effect a plan to regularly assess and monitor tobacco use, tobacco dependence and intentions to quit or reduce tobacco. In doing so, it is also important to inquire as to high risk smoking behaviours that could impact on understanding levels of dependency and true smoking patterns. This level of monitoring is essential on a

number of levels. First and foremost, with locally verified data on levels of smoking prevalence and levels of dependency, it will establish the need for resources to be directed to address tobacco use. Undertaking this on a systematic level also reinforces to mental health clinicians that monitoring tobacco dependency, by using a tool such as the FTND with additional added questions regarding smoking practices, can be accomplished in less than 15 minutes.

Given the grave consequences of continuing to neglect monitoring the severity of this problem, it also provides an opportunity for practitioners to begin to see tobacco use monitoring our responsibility as part of an ethical practice. In addition, by monitoring the use of contraband cigarettes, we can advocate for and highlight the particular vulnerability that low income individuals with severe mental illness and high levels of nicotine dependence face, when few treatment options are available but contraband cigarettes are in abundance. Understanding smoking behaviours in relation to other conditions, such as co-occurring substance use disorders, is also important in that it reinforces the need to provide an integrated treatment approach where clinicians can concurrently address substance dependency. Embedding these treatment opportunities within community mental health practices also provides the opportunity for practitioners to support and address other 'social determinants of smoking cessation' that may arise, beyond substance abuse, such as housing instability, relationship problems, or financial difficulties.

With regard to the intervention study presented in the second paper, as a pilot study, the findings demonstrate that it is also possible to engage and provide tobacco cessation and reduction treatment to a very marginalized group of individuals with severe mental illness, and that there are high levels of motivation in addressing tobacco dependence within this

population. This is an important message for mental health clinicians. Clearly, the intensity of this intervention takes enormous resources and a high level of clinical expertise, but again, the study demonstrated that it is possible, and worthwhile, to develop those skills. As a pilot study, the feasibility of recruiting clients, the process for securing consent, the utilization of the data collection protocols, were all established as acceptable to the clients served. Although there was a high rate of treatment non-compliance, this is a very difficult client population to engage and maintain in treatment. There was no differential loss to treatment between the two groups, and the overall rate was still on the continuum of treatment discontinuation for psychosocial interventions as reported in the literature (Swift & Greenberg, 2012; Swift & Callahan 2011).

The second paper presents evidence that the exposure to more NRT was the most significant predictor of quitting or reducing smoking. It is possible that the addition of the individual MI sessions and the weekly support groups contributed to greater adherence to the prescribed NRT, in addition to the support garnered through the nursing contacts. Factors that may contribute to greater NRT adherence in the this population will be important areas of future research. This could include investigating if practitioners (case managers), who have clients engaged in tobacco cessation treatment, experience attitudinal changes and/or an improved commitment and capacity to address tobacco dependence. Clients of community mental health agencies have substantial contact time with their primary mental health workers. Consequently the attitudes and clinical capacity of this group are critical ingredients to health interventions such a smoking cessation programs directed to clients.

Additionally, long term follow-up of clients who were able to quit and/or reduce tobacco would be important to undertake. This could lead to a better understanding of what

enables individuals from being able to thwart a relapse and, to develop a clearer understanding if there were ongoing resources that facilitated maintenance (for example, continued use of NRT). This is somewhat related to the understudied area of long-term use of NRT as a means of ongoing reduction of overall cigarette smoking, but not abstinence. Another issue that was beyond the scope of this study but is entirely pertinent to a great number of clients within this population, is the use of cannabis in the face of trying to reduce or quit tobacco use. This is an area of great interest to clients and a frequently identified barrier by clinicians.

Conclusions

As community mental health programs become more concerned with issues of health equity, they are challenged to understand why tobacco use prevalence remains so high among individuals with severe mental illness. The two studies presented in this thesis provide evidence that smoking cessation and smoking reduction treatment can be successfully introduced into a very vulnerable population of individuals with severe mental illness without a decline in mental health status. With such ingrained patterns of nicotine dependence as experienced by individuals with multiple and complex needs, programs need to support reduction of cigarette smoking as an alternative, or at least a bridge to complete smoking cessation. The results of the second paper demonstrate that individuals benefit from combination and titrated doses of NRT, access to nursing support, and the availability of longer treatment periods in order to sustain treatment gains.

Given that tobacco accounts for 50% of all deaths for individuals with schizophrenia and mood disorders (Callaghan et al.,2014), it is shocking that the mental health system continues to neglect to develop any sort of comprehensive tobacco strategy for this particular

population. While the resources required to begin to undue decades of neglect may seem daunting, it is imperative that community mental health networks continue to demand equal access to treatment opportunities related to smoking cessation for the vulnerable clients served in this sector. The research undertaken for this thesis demonstrates that is it possible to make significant gains in the reduction of tobacco use for even the most marginalized individuals and that clients are motivated and interested in addressing their tobacco dependency. The prevalence of tobacco use and level of nicotine dependence in this population is exceptionally high and it will be important in going forward that community mental health agencies take on the task of monitoring tobacco prevalence and the level of nicotine dependence in the population.

Other factors such as co-morbid substance use disorder and higher levels of disability may impact on smoking status and ultimately, how treatment needs to be provided in order to keep individuals engaged in treatment. The complexity of challenges that these individuals face outside of nicotine dependence, speaks to the need for embedding tobacco treatment within the agencies that provide long term community support such as Intensive Case Management and Assertive Community Treatment teams. As other potential risk factors such as concurrent substance use, housing instability or untreated psychiatric conditions emerge and begin to impact on the ability to engage and sustain tobacco treatment, support and stabilization can be provided as part of an integrated practice.

Perhaps most importantly, similar to the population health approaches that focused on prevention and legislation in order to achieve the successful population level decline of tobacco use, the mental health system needs to invest in developing tobacco prevention

strategies that will reduce the number of new smokers currently being nurtured within the mental health system.

References

Addictions and Mental Health Ontario & Canadian Mental Health Association, Ontario Division. (2013). Concurrent disorder services in Ontario: An environmental scan. http://ontario.cmha.ca/public_policy/concurrent-disorder-services-in-ontario-an-environmental-scan/#.U_dW2SxOWew

Aloot, C. B., Vredevoe, D. L. & Brecht, M. L. (1993). Evaluation of high-risk smoking practices used by the homeless. *Cancer Nursing*, 16:123–130.

Anthenelli, R., Morris, C., Ramey, T., Dubrava, S., Tsilkos, K., Russ, C. & Yunis, C. (2013). Effects of Varenicline on smoking cessation in adults with stably treated current or past major depression. *Annals of Internal Medicine,* 159:390-400.

Apollonio, D.E. & Malone, R.E. (2005). Marketing to the marginalized: tobacco industry targeting of the homeless and mentally ill. *Tobacco Control,* 14:409-415.

Auld, MC. (2005). Causal effect of early initiation on adolescent smoking patterns. *Canadian Journal of Economics*, 38(3):709-734.

Arkowitz, H., Westra, H. A., Miller, W. R., & Rollnick, S. (2008). *Motivational interviewing in the treatment of psychological problems.* NewYork: Guilford Press.

Baggett, T.P., Anderson, R., Freyder, P.J., Jarvie, J.A. Maryman, K., Porter, J. & Rigotti, N.A. (2012). Addressing tobacco use in homeless populations: A survey of health care professionals. *Journal of Health Care for the Poor and Underserved,* 23(4):1650-1659.

Baggett, T.P., Chang, Y., Singer, S.E., Porneala, B.C., Gaeta, J.M., O'Connell, J.J. & Rigotti, N.A. (2014). Tobacco, alcohol and drug attributable deaths and their contribution to mortality disparities among homeless adults. *American Journal of Public Health,* December 18, 2014: e1-e9.

Baggett, T.P., Hwang, S., O'Connell, J.J., Porneala, B.C., Stringfellow, E.J., Orav, E.J., Singer, S.E. & Rigotti, N.A. (2013a). Mortality among homeless adults in Boston Shifts in causes of death over a 15-year period, *JAMA Internal Medicine,* 173(3):189-195.

Baggett, T.P. & Rigotti, N.A. (2010). Cigarette smoking and advice to quit in a national sample of homeless adults. *American Journal of Preventative Medicine*, 39(2):164-172.

Baggett, T.P., Tobey, M.L. & Rigotti, N.A. (2013b). Tobacco use among homeless people-addressing the neglected addiction. *The New England Journal of Medicine*, 369(3):201-204.

Baker, A., Kay-Lambkin, F., Bucci, S.S., Haile, M., Richmond, R. & Carr, V. (2004). Intervention for tobacco dependence among people with a mental illness. Centre for Mental Health Studies, Faculty of Health, the University of Newcastle, NSW, Australia NDARC Technical Report Number 192. ISBN: 1 877027 82 0.

Baker, A., Richmond, R., Haile, M., Lewin, T.J., Carr, V., Taylor, R.L., Janseons, S & Wilhelm, K. (2006). A randomized controlled trial of a smoking cessation intervention among people with a psychotic disorder. *American Journal of Psychiatry*, 163(11):1934.

Baker, A., Richmond, R., Haile, M., Lewin, T.J., Carr, V., Taylor, R.L.,....Constable, P.M. (2007). Characteristics of smokers with a psychotic disorder and implications for smoking interventions. *Psychiatry Research*, 150:141–152.

Baliunas, D., Patra, J., Rehm, J., Popova, S., Kaiserman, M. & Taylor, B. (2007). Smoking-attributable mortality and expected years of life lost in Canada 2002: Conclusions for prevention and policy. *Chronic Diseases in Canada* 27(4):154-162.

Banham, L & Gilbody, S. (2010). Smoking cessation in severe mental illness: What works? *Addiction*, 105:1176.

Bardell, T & Brown, P.M. (2006). Smoking inside Canadian acute care hospitals. *Canadian Respiratory Journal*, 13(5):266-272.

Barker, S., Barron, N., McFarland, B. H. & Bigelow, D. A. (1994a). A community ability scale for chronically mentally ill consumers Part I Reliability and validity, *Community Mental Health Journal*, 30(4), 363-383

Barker, S., Barron, N., McFarland, B. H., Bigelow, D. A. & Carnahan, T. (1994b). A community ability scale for chronically mentally ill consumers Part II Applications. *Community Mental Health Journal*, 30(5):459-472.

Barrowclough, C., Haddock, G., Tarrier, N., Lewis, S., Moring, J., O'Brien, R., Schofield, N. & McGovern, J. (2001). Randomized controlled trial of motivational interviewing, cognitive behavior therapy and family intervention for patients with comorbid schizophrenia and substance use disorders. *American Journal of Psychiatry*, 158(10):1706-1713.

Bero, L. (2003). Implications of the tobacco industry documents for public health and policy. *Annual Review of Public Health,* 24:267-288.

Bero, L. (2005). Tobacco industry manipulation of research. *Public Health Reports*. 120(2):200-208.

Bonevski, B., Baker, A., Tywman, L., Paul, C. & Bryant, J. (2012). Addressing smoking and other health risk behaviours use a novel telephone delivered intervention for homeless people: A proof of concept study. *Drug and Alcohol Review,* 31:709–713.

Boothroyd, R.A. & Chen, H.J. (2008). The psychometric properties of the Colorado Symptom Index. *Administration and Policy in Mental Health*, 35:370-378.

Borrelli, B. (2010). Smoking cessation: Next steps for special populations research and innovative treatments. *Journal of Consulting and Clinical Psychology,* 78(1):1–12.

Brown, C., Leith, J., Dikerson, F., Medoff, D., Kreyenbuhl, J., Fang, L., Goldberg, R., Potts, W. & Dixon, L. (2010). Predicators of mortality in patients with serious mental illness and co-occurring type 2 diabetes. *Psychiatry Research,* 177:250-254.

Brunette, M.F., Ferron, J.C., McHugo, G.J., Davis, K.E., Devitt, T.S., Wilkness, S.M. & Drake, R.E. (2011). An electronic decision support system to motivate people with severe mental illnesses to quit smoking. *Psychiatric Services,* 62(4):360.

Brunner, E.J., Rees, K.,Ward, K., Burke, M. & Thorogood, M. (2007). Dietary advice for reducing cardiovascular risk. *Cochrane Database of Systematic Reviews*, Issue 4. Art. No.: CD002128. DOI: 10.1002/14651858.CD002128.pub3.

Bryant, J., Bonevski, B., Paul, C., Mcelduff, P. & Attia, J. (2011). A systematic review and meta-analysis of the effectiveness of behavioural smoking cessation interventions in selected disadvantaged groups. *Addiction*, "Postprint"; doi: 10.1111/j.1360-0443.2011.03467.x

Buckley, T.C. (2006). Prevalence and consequences of the dual diagnosis of substance abuse and severe mental illness. *Journal of Clinical Psychiatry*, 67(S7):5-9.

Burling, T.A., Burling, A.S., Latini, D. & Kendall. (2001). A controlled smoking cessation trial for substance-dependent inpatients. *Journal of Consulting and Clinical Psychology*, 69(2):295-304.

Butler, J., Okuyemi, K. S., Jean, S., Nazir, N., Ahluwalia, J. S., Resnicow, K. (2002). Smoking characteristics of a homeless population. *Substance Abuse,* 23: 223–31.

Cahill, K., Stead, L.F., Lancaster, T. (2011). Nicotine receptor partial agonists for smoking cessation. *Cochrane Database of Systematic Reviews*, Issue 2. Art. No.: CD006103. DOI: 10.1002/14651858.CD006103.pub5

Callaghan, R. & Khizar, A. (2010). The incidence of cardiovascular morbidity among patients with bipolar disorder: A population-based longitudinal study in Ontario, Canada. *Journal of Affective Disorders,* 122(1-2):118-123.

Callaghan, R., Veldhuizen, S., Jeysingh, T., Orlan, C., Graham, C., Kakouris, G., Remington, G. & Gatley, J. (2014). Patterns of tobacco-related mortality among individuals diagnosed with schizophrenia, bipolar disorder, or depression. *Journal of Psychiatric Research,* 48:102e110

CAN-ADAPTT. (2011). *Canadian Smoking Cessation Clinical Practice Guideline*. Toronto, Canada: Canadian Action Network for the Advancement, Dissemination and Adoption of Practice-informed Tobacco Treatment, Centre for Addiction and Mental Health.

Canadian Tobacco Use Monitoring Survey (CTUMS) 2012. Assessed at: http://www.hc-sc.gc.ca/hc-ps/tobac-tabac/research-recherche/stat/ctums-esutc_2012-eng.php

Canada, Parliament, Senate. (2006). Standing Senate Committee on Social Affairs, Science and Technology. M.J.L. Kirby (Chair) & W.J. Keon (Deputy Chair). *Out of the shadows at last: Transforming mental health, mental illness and addiction services in Canada.* 38th Parl., 1st sess. Retrieved from http://www.parl.gc.ca/Content/SEN/Committee/391/soci/rep/rep02may06-e.htm.

Canadian Action Network for the Advancement, Dissemination and Adoption of Practice-informed Tobacco Treatment (CAN-ADAPTT). (2011). Retrieved from: http://www.can-daptt.net/English/Guideline/Mental%20Health%20and%20Other%20Addictions/Home.aspx

Canadian Center on Substance Abuse. (2009). Substance abuse in Canada: concurrent disorders. Ottawa, ON: Canadian Center on Substance Abuse.

Canadian Institute for Health Information. (2007). *Improving the Health of Canadians: Mental Health and Homelessness,* Ottawa.

Carpenter, C. & Cook, P.J. (2008). Cigarette taxes and youth smoking: new evidence from national, state and local Youth Risk Behavior Surveys. *Journal of Health Economics* 2008;27(2):287-299.

Center for Addiction and Mental Health. (2014). Smoking Treatment for Ontario Patients Program (STOP). Retrieved from the Center for Addiction and Mental Health website: https://www.nicotinedependenceclinic.com/English/stop/Pages/Home.aspx

Champlain Local Health Integration Network. (2009). Integrated Health Services Plan 2010-2013. Retrieved from: http://www.champlainlhin.on.ca/Page.aspx?id=3960&ekmensel=e2f22c9a_72_192_btnlink

Cherner, R., Aubry, T., & Sylvestre, J. (2014). *An evaluation of the 12-month outcomes of the Ottawa Supportive Housing for People with Problematic Substance Use Program.* Ottawa, Canada: University of Ottawa, Centre for Research on Educational and Community Services.

Chesterman, J., Judge, K., Bauld, L. & Ferguson, J. (2005). How effective are the English smoking treatment services in reaching disadvantaged smokers? *Addiction,*100 (Suppl.2): 36.

Cleary, M., Hunt, G.E., Matheson, S.L., Siegfried, N., Walter, G. (2007). Psychosocial interventions for people with both severe mental illness and substance misuse. *Cochrane Database of Systematic Reviews*, Issue 4. Art. No.: CD001088. DOI:10.1002/14651858.CD001088. pub2

Cleary, M., Hunt, G., Matheson, S. & Walter, G. (2009). Psychosocial treatments for people with co-occurring severe mental illness and substance misuse: systematic review. *Journal of Advanced Nursing,* 65(2):238-258.

Conrad, KJ., Yagelka, J.R., Matters, M.D., Rich, A.R., Williams, V. & Buchanan, M. (2001). Reliability and validity of a modified Colorado Symptom Index in a national homeless sample. *Mental Health Services Research*, 3(3):141-153.

Colton, C.W. & Manderscheid, R.W. (2006). Congruencies in increased mortality rates, years of potential life lost, and causes of death among public mental health clients in eight states. *Preventing Chronic Disease Public Health Research, Practice and Policy,* 3(2):1-14.

Connor, S.E., Cook, R., Herbert, M.I., Neal, S.M. & Williams, J. (2002). Smoking cessation in a homeless population: There is a will but is there a way? *Journal of General Internal Medicine,* 17:369-372.

Curkendall, S.M., Mo, J., Glasser, D.B., Stang, M. & Jones, J.K. (2004). Cardiovascular disease in patients with schizophrenia in Saskatchewan, Canada. *Journal of Clinical Psychiatry*, 65(5):715-720.

Currie, S.R., Nesbitt, K, Wood, K. & Lawson, A. (2003). Survey of smoking cessation services in Canadian addiction programs. *Journal of Substance Abuse Treatment*, 24:59-65.

de Leon, J., (1996). Smoking and vulnerability for schizophrenia. *Schizophrenia Bulletin,* 22:405–409.

de Leon, J. & Diaz, F.J. (2005). A meta-analysis of worldwide studies demonstrates an association between schizophrenia and tobacco smoking behaviors. *Schizophrenia Research,* 76:135-157.

Dennis, M.L., Chan, Y.F. & Funk, R.R. (2006). Development and validation of the GAIN Short Screener (GSS) for internalizing, externalizing and substance use disorders and crime/violence problems among adolescents and adults. *American Journal of Addiction*, 15(S1):80-91.

Diaz, F.J., Velasquez, D.M., Susce, M.T. & Leon, J. (2008). The association between schizophrenia and smoking: Unexplained by either the illness or the prodromal period. *Schizophrenia Research,* 104:214-219.

Dickerson, F., Stallings, C.R., Origoni, A.E., Schroeder, J., Khushalani, S. & Yolken, R.H. (2013). Mortality in schizophrenia: Clinical and serological predictors. *Schizophrenia Bulletin*, doi:10.1093/schbul/sbt113

DiClemente, C.C., Delahanty, J.C., Kofeldt, M.G., Dixon, L., Goldberg,R. & Lucksted, A. (2011). Stage movement following a 5A's intervention in tobacco dependent individuals with serious mental illness (SMI). *Addiction,* 36:261-264.

Dixon, L., Medoff, D., Wohlheiter, K., DiClemente, C.C., Goldberg, R., Kreyenbuhl, J., Adams, C., et al. (2007). Correlates of severity of smoking among persons with severe mental illness. *The American Journal of Addictions,* 16:101-110.

Dolgin, E. (2013). Publication checklist proposed to boost rigor of pilot trials. *Nature Medicine,* 19(7):795.

Drake, R. E., Essock, S. M., Shaner, A., Carey, K. B., Minkoff, K. & Kola, L. (2001). Implementing dual diagnoses services for clients with severe mental illness. *Psychiatric Services*, 52: 469–476.

Drake, R.E., O'Neal, E.L. & Wallach, M.A. (2008). A systematic review for psychosocial research on psychosocial interventions for people with co-occurring severe mental and substance use disorders. *Journal of Substance Abuse Treatment*, 34:123-138.

Drake, R.E. & Wallach, M.A. (2008). Conceptual models of treatment of co-occurring substance use. *Mental Health and Substance Use: dual diagnosis,* 1(3):189-193.

Drake, R. E., Wallach, M. A., Alverson, H. S. & Mueser, K. T. (2002). Psychosocial aspects of substance abuse by clients with severe mental illness. *Journal of Nervous and Mental Disease*, 190:100– 106.

el-Guebaly, N., Cathcart, J., Currie, S., Brown, D. & Gloster, S. (2002). Smoking cessation approaches for persons with mental illness or addictive disorders. *Psychiatric Services,* 53(9):1166-1170.

Els, C., Kunyk, D. & Sidhu, H. (2011). Smoking cessation and neuropsychiatric adverse events. *Canadian Family Physician,* 57:647-649.

Elton-Marshall, T., Leatherdale, S.T. & Burkhalter, R. (2011). Tobacco, alcohol and illicit drug use among Aboriginal youth living off-reserve: results from the Youth Smoking Survey. *CMAJ*, 183(8).

Eriksen, M., MacKay, J. & Ross, H. (2012). The Tobacco Atlas, 4th ed. Atlanta, GA: American Cancer Society; New York, NY: World Lung Foundation. http://www.tobaccoatlas.org/more#sthash.w8PezFvA.dpuf

Fagerström, K.O. & Aubin, H.J. (2009). Management of smoking cessation in patients with psychiatric disorders. *Current Medical Research and Opinion,* 25(2):511–518.

Fagerström, K.O. & Furberg, H. (2008). A comparison of the Fagerström Test for Nicotine Dependence and smoking prevalence across countries. *Addiction*, 103(5):841-845.

Fagerström, K.O., Kunze, M., Schoberberger, R., Breslau, N., Hughes, J.R., Hurt, R.D....Puska, D. (1996). Nicotine dependence versus smoking prevalence: comparisons among countries and categories of smokers. *Tobacco Control*, 5:52-56.

Fagiloini, A. & Goracci, A. (2009). The effects of undertreated chronic medical illnesses in patients with severe mental disorders. *Journal of Clinical Psychiatry*, 70:22-29.

Ferron, J.C., Alterman, A.I., McHugo, G.J., Brunette, M.F. & Drake, R.E. (2009). A review of research on smoking cessation interventions for adults with schizophrenia spectrum disorders. *Mental Health and Substance Use: dual diagnosis,* 2(1):64.

Ferron, J.C., Brunette, M.F., He, X., Xie, H., McHugo, G.J., & Drake, R.E. (2011). Course of smoking and quit attempts among clients with co-occurring severe mental illness and substance use disorders. *Psychiatric Services*, 62(4):353.

Filia, S.L., Baker, A., Gurvich, C., Richmond, R.L., Lewin. T.J. & Klkarni, J. (2014). Gender differences in characteristics and outcomes of smokers diagnosed with psychosis participating in a smoking cessation intervention. *Psychiatry Research*, 215(3)586-93.

Fiore, M.C., Jaén, C.R., Baker, T.B., et al. (2008). Treating tobacco use and dependence: 2008 update.Clinical practice guideline. Rockville, MD: U.S. Department of Health and Human Services. Public Health Service. May 2008.

Food and Drug Administration. (2013a). *Modifications to labeling of nicotine replacement therapy products for over the-counter human use*. Docket No. FDA-2013-N-0341.

Food and Drug Administration (2013b). *Nicotine replacement therapy labels may change. FDA Consumer Health Information*. Silver Spring, MD: U. S. Department of Health and Human Services.

Frohlich, K. & Potvin, L. (2008). The inequity paradox: The population approach and vulnerable populations. *American Journal of Public Health,* 98(2):216-221.

Fucito, L., Bars, M., Forray, A., Rojewski, A., Shiffman, S., Selby, P....West, R. (2014). Addressing the evidence for FDA nicotine replacement therapy label changes: a policy statement of the Association for the Treatment for Tobacco use and Dependence and the Society for Research on Nicotine and Tobacco. *Nicotine Tobacco Research*, 16(7):909-914.

Gallagher, S.M., Penn, P.E., Schindler, E. & Layne, W. (2007). A comparison of smoking cessation treatments for persons with schizophrenia and other serious mental illnesses. *Journal of Psychoactive Drugs,* 39(4):487-497.

Goering, P., Streiner, D., Adair, C., Aubry, T., Barker, J., Distasio, J., Hwang, S., Kormaroff, J., Latimer, E., Somers, J. & Zabkiewicz, D. (2011). The At Home/Chez Soi trial protocol: A pragmatic multi-site randomized controlled trial of a Housing First intervention for homeless individuals with mental illness in five Canadian Cities. *BMJ Open*, 1(2):1-18.

Goering, P., Veldhuizen, S., Watson, A., Adair, C., Kopp, B., Latimer, E.,...Nelson, G. (2014). National At Home/ Chez Soi Final Report. Calgary, AB: Mental Health Commission of Canada. Retrieved from: http://www.mentalhealthcommission.ca

Government of Ontario. (1999). *Making it happen: Operational framework for the delivery of mental health services.* Toronto, ON: Government of Ontario Publication.

Government of Ontario. (2005). *Intensive case management service standards for mental health and supports.* Toronto, ON: Government of Ontario Publication.

Government of Ontario. (2010). Legislative Assembly. *Select Committee on Mental Health and Addictions Final report, navigating the journey to wellness: the comprehensive mental health and addictions action plan for Ontarians.* Retrieved from: http://www.ontla.on.ca/committee-proceedings/committee-reports/files_pdf/Select%20Report%20ENG.pdf

Government of Ontario. (2011). *Open minds, healthy minds Ontario's comprehensive mental health and addictions strategy*. Retrieved from: http://www.health.gov.on.ca/english/public/pub/mental/pdf/openmindshealthymindsen.pdf

Grant, B.F., Hasin, D.S., Chou, S.D., Stinson, F.S. & Dawson, D.A. (2004). Nicotine dependence and psychiatric disorders in the United States Results from the National Epidemiologic Survey on Alcohol and Related Conditions. *Archives of General Psychiatry,* 61:1107-1115.

Guydish, J., Passalacqua, E., Chan, M., Tajima, B., Chun, J. & Bostrom, A. (2011). Smoking prevalence in addiction treatment: A review. *Nicotine & Tobacco Research*, 13 (6): 401-411.

Hall, S.M. & Prochaska, J.J. (2009). Treatment of smokers with co-occurring disorders: emphasis on integration in mental health and addiction treatment settings. *Annual Review of Clinical Psychology*, 5:409-431.

Harris, G.T., Parle, D. & Gagne, J. (2007). Effects of a tobacco ban on long-term psychiatric patients. *Journal of Behavioural Health services & Research* 34(1):43-55.

Hankivsky, O. & Christofferson, A. (2008). Intersectionality and the determinants of health: a Canadian perspective. *Critical Public Health*. 18(3):271-283.

Hayes, R.D., Chang, C.K., Fernandes, A.C., Begum, A., To, D., Broadbent, M., Hotopf, M. & Stewart. R. (2012). Functional status and all-cause mortality in serious mental illness. *PLOS ONE*, 7(9):e44613.

Health Canada, (2015). Retrieved from: http://www.hc-sc.gc.ca/hc-ps/tobac-tabac/quit-cesser/fact-fait/stages-etapes-eng.php

Health Canada. (2010). Retrieved from: http://www.hc-sc.gc.ca/hc-ps/tobac-tabac/res/news-/risks-risques-eng.php

Health Canada. (2014a). *The Scope on Smoking: Tobacco Youth Zone.* Retrieved from: http://www.hc-sc.gc.ca/hc-ps/tobac-tabac/youth-jeunes/scoop-primeur/index-eng.php

Health Canada. (2014b). *Canadian Guidelines for Body Weight Classification in Adults*. Retrieved from:http://www.hc-sc.gc.ca/fn-an/nutrition/weights-poids/guide-ld-adult/qa-qr-pub-eng.php#a3.

Heatherton, T.F., Kozlowski, L.T. & Fagerstrom, K.O. (1991). The Fagerstrom test for nicotine dependence: a revision of the Fagerstrom Tolerance Questionaire. *British journal of Addiction,* 86:1119-1127.

Hennekens, C. (2007). Increasing global burden of cardiovascular disease in general populations and patients with schizophrenia. *Journal of Clinical Psychiatry,* 68(suppl4):4.

Hennekens, C., Hennekens, A.R., Hollar, D. & Casey, D.E.(2005). Schizophrenia and increased risks of cardiovascular disease. *American Heart Journal*, 150(6) :1115.

Hettema, J., & Hendricks, P. (2010). Motivational interviewing for smoking cessation: A meta-analytic review. *American Psychological Association,*78(6):868-894.

Hertzman, C. & Power, C. (2003). Health and human development: Understanding from life-course research. *Developmental Neuropsychology,* 24(2&3):719-744.

Himelhoch, S. & Daumit, G. (2003). To whom do psychiatrists offer smoking-cessation counseling? *The American Journal of Psychiatry;* 160(12):2228.

Hitsman, B., Moss, T.G., Montoya, I.D. & George, T.P. (2009). Treatment of tobacco dependence in mental health and addictive disorders. *La Revue canadienne de psychiatrie,* 54(6):368.

Holt, R.I. & Peveler, R.C. (2010). Diabetes and cardiovascular risk in severe mental illness: A missed opportunity and challenge for the future. *Practical Diabetes International*, 27:79- 84.

Horsfall, J., Cleary, M., Hunt, G. & Walter, G. (2009). Psychosocial treatment for people with co-occurring sever mental illnesses and substance use disorders (dual diagnosis): A review of Empirical Evidence. *Harvard Review of Psychiatry,*17(1):24-34.

Hudson, C. (2005). Socioeconomic status and mental illness: Tests of the social causation and selection hypotheses. *American Journal of Orthopsychiatry,* 75(1):3-18.

Hughes, J.R., Stead, L.F. & Lancaster, T. (2007) Antidepressants for smoking cessation. *Cochrane Database of Systematic Reviews 2007*, Issue 1. Art. No.: CD000031. DOI: 10.1002/14651858.CD000031.pub3

Hwang, S., Aubry, T., Palepu, A., Farrell, S., Nisenbaum, R., Hubley, A.M., Klodawsky, F., Gogosis, E., Hay, E., Pidlubny, S., Dowbor, T. & Chambers, C. (2011). The health and housing in transition study: a longitudinal study of the health of homeless and vulnerably housed adults in three Canadian cities. *International Journal of Public Health*, 56(6):609-623.

Hwang, S., Wilkens, R., Tjepkema, M., O'Campo, P. & Dunn, J. (2009). Mortality among residents of shelters, rooming houses, and hotels in Canada: 11 year follow-up study. *British Medical* Journal, doi:10.1136/bmj.b4036.

Hwang, S., Stergiopoulos, V., O'Campo, P. & Gozdzik, A. (2012). Ending homelessness among people with mental illness: the At Home/Chez Soi randomized trial of a Housing First intervention in Toronto. *BMC Public Health*, 12(1):787.

Jha, P., Ramasundarahettige, C., Landsman, V., Rostron, B., Thun, M., Anderson, R., McAfee, T. & Peto, R. (2013). 21st-century hazards of smoking and benefits of cessation in the United States. *New England Journal of Medicine*. 4:341-350.

Johnson, J.L., Malchy, L.A., Ratner, P.A., Hossain, S., Procyshyn, R.M., Bottorff, J.L., Groening, M., Gibson, P., et al. (2009). Community mental healthcare providers attitudes and practices related to smoking cessation interventions for people living with severe mental illness. *Patient Education and Counseling.* 77:289-295.

Khara, M. & Okoli, C. (2010). The Tobacco-Dependence Clinic: Intensive Tobacco-Dependence Treatment in an Addiction Services Outpatient Setting. *The American Journal on Addictions*, 20: 45.

Kilbourne, A.M., Morden, N.E., Austin, K., Ilgen, M., McCarthy, J.F., Dalack, G. & Blow, F.C. (2009). Excess heart-disease-related mortality in a national study of patients with mental disorders: identifying modifiable risk factors. *General Hospital Psychiatry*, 31:555-563.

Kindig, D. (2007). Understanding Population Health Terminology. *The Millbank Quarterly,* 85(1):139-161.

Kotz, D. & West, R. (2009). Explaining the social gradient in smoking cessation: it's not in the trying, but in the succeeding. *Tobacco Control*, 18:43–46.

Krieger, N. (2008). Proximal, distal, and the politics of causation: what's level got to do with it? *American Journal of Public Health*, 98(2):221-230.

Krieger, N. (2001). Theories for social epidemiology in the 21st century: an ecosocial perspective. *International Journal of Epidemiology,* 30:668-677.

Labonte, R., Polanyi, M., Muhajarine, N., McIntosh, T. & Williams, A. (2005). Beyond the divides: toward critical population health research. *Critical Public Health*, 15(1):5-17.

Lancaster, G. (2015). Pilot and feasibility studies come of age! *Pilot and Feasibility Studies,* 1:1.

Lane, Jr., G.M., Werdel, M. B., Schacht, L., Ortiz, G, and Parks, J. (2009). Smoking polices and practices in state psychiatric facilities: Survey results from 2008. Alexandria, VA:National Association of State Mental Health Program Directors Research Institute, Inc. (NRI).

Lasser, K., Boyd, W., Woolhandler, S., Himmelstein, D., McCormick, D. & Bor, D. (2000). Smoking and mental illness A population-based prevalence study. *Journal of the American Medical Association*. 284(20):2606-2610.

Lehman, A.F. (1996). Measures of quality of life among persons with severe and persistent mental disorders. *Social Psychiatry and Epidemiology,* 31:78-88.

Leonard, S., Adler, L.E., Benhammou, K., Berger, R., Bresse, C.R., Drebing, C., Gault, J., et al. (2001). Smoking and mental illness. *Pharmacology, Biochemistry and Behavior,* 70:561-570.

Luk, R., Cohen, J.E. & Ferrence, R. (2007). Contraband Cigarettes in Ontario. *The Ontario TobaccoResearch Unit* Retrieved from: http://www.otru.org/pdf/special /special_nov_2007.pdf

Maisto, S. A., Carey, M. P., Carey, K. B., Gordon, C. M. & Gleason, J. R. (2000). Use of the AUDIT and the DAST-10 to identify alcohol and drug use disorders among adults with a severe and persistent mental illness. *Psychological Assessment, 12,* 186-192.

Martens, P., Brownell, M., MacWilliam, L., Schultz, J., Guenette,W., Elliott, L., Buchan, S., Anderson, M., Caetona, P., Metae, C., Santos, R. & Serwonka, K. (2010). Health inequities in Manitoba: Is the socioeconomic gap in health widening or narrowing over time? *The Manitoba Centre for Health Policy.* Retrieved from: http://mchp-appserv.cpe.umanitoba.ca/reference/Health_Ineq_final_WEB.pdf

Mather, C.D. & Loncar, D. (2006). Projections of global mortality and burden of disease from 2002 to 2030. *PLoS Med* 3(11):e442, 2011-2030.

Mayer, L., Stein, D., Grimsrud, A., Seedat, S. & Williams, D. (2008). Social determinants of psychological distress in a nationally-representative sample of South African adults. *Social Sciences & Medicine,* 66:1828-1840.

McChargue, D.E., Gulliver, S.E. & Hitsman, B. (2002). Would smokers with schizophrenia benefit from a more flexible approach to smoking treatment? *Addiction,* 97:785-793.

McDonell, M.G., Comtois, K.A., Voss, W.D., Morgan, A. H. & Ries, R.K. (2009). Global appraisal of individual needs short screener (GSS): Psychometric properties and performance as a screening measure in adolescents. *American journal of Drug and Alcohol Abuse*, 35(3):157-60.

McEvoy, J.P., Meyer, J.M., Goff, D.C., Nasrallah, H.A., Davis, S.M., Sullivan, L., Meltzer, H., Hsiao, J., Stroup, T.S. & Lieberman, J. (2005). Prevalence of the metabolic syndrome in patients with schizophrenia: Baseline results from the Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) schizophrenia trial and comparison with national estimates from NHANES. *Schizophrenia Research,* 80:19-32.

Mecredy, G., Diemert, L., Callaghan, R. & Cohen, J. (2013). Association between use of contraband tobacco and smoking cessation outcomes: a population-based cohort study. *Canadian Medical Association Journal*, 185(7):E287.

Mercier, C. & Picard, S. (2011). Intellectual disability and homelessness. *Journal of Intellectual Disability Research, 55(4):441-449.*

Miller, W. & Rollnick, S. (2002). *Motivational Interviewing: Preparing People for Change*, 2nd ed. New York: The Guilford Press.

Moeller-Saxon, K. (2008). Cigarette smoking and interest in quitting among consumers at a psychiatric disability rehabilitation and support service in Victoria. *Australian and New Zealand Journal of Public Health,* 32(5):479-481.

Molina-Linde, J.M. (2011). Effectiveness of smoking cessation programs for seriously mentally ill. *Actas Esp Psiquiatr*, 39(2):106-14.

Moolchan, E.T., Fagan, P., Fernander, A.F., Velicer, W.F., Hayward, M.D., King, G. & Clayton, R.R. (2007). Addressing tobacco-related health disparities. *Addiction,* 102(suppl.2):30.

Moore, D., Aveyard, P., Connock, M., Wang, D., Fry-Smith, A. & Barton, P. (2009). Effectiveness and safety of nicotine replacement therapy assisted reduction to stop smoking: systematic review and meta-analysis. *British Medical Journal,* 338:(b):1024 .

Mottillo, S., Filion, K.B., Belisle, P., Joseph, L., Gervais, A., O'Loughlin, J., Paradis, G., Pihl, R., Pilote, L., Rinfret, S.,Tremblay, M.& Eisenberg, M.J. (2009). Behavioural interventions for smoking cessation: a meta-analysis of randomized controlled trials. *European Heart Journal*, 30:718.

Moyers, T.B., Martin, T., Manuel, J.K., Miller, W.R., & Ernst, D.E. (2010). Revised global scales: motivational interviewing treatment integrity 3.1.1.(MITI 3.1.1.). *Unpublished coding manual*. University of New Mexico, Center on Alcoholism, Substance Abuse, & Addictions.

Mueser, K.T. & Brunette, M. (2010). Smoking and severe mental illness: At the intersection between psychosocial and neurobiological aspects of dual diagnosis. *Journal of Dual Diagnosis*, 6:208.

Mueser, K.T., Noordsy, D.L., Drake, R.E. & Fox, L. (2003). *Integrated treatment for dual disorders: A guide to effective practice*. New York: Guilford Press.

Mueser, K.T., Rosenberg, S.D. & Rosenberg, H.J. (2009). *Treatment of Posttraumatic Stress Disorder in Special Populations: A Cognitive Restructuring Program*, New York: The Guilford Press.

Murray, R.L., Bauld, L., Hackshaw, L.E. & McNeill, A. (2009). Improving access to smoking cessation services for disadvantaged groups: a systematic review. *Journal of Public Health*, 31(2):258.

National Association of State Mental Health Program Directors. (2007). Tobacco-free living in psychiatric settings. Retrieved from: http://www.nasmhpd.org/general_files /publications/NASMHPD.toolkitfinalupdated90707.pdf

Non-Smokers' Rights Association. (2014). A map and table comparing cigarette prices in Canada (June 5, 2014). Retrieved from: http://www.nsra-adnf.ca/cms/file/files/140605_map_and_table.pdf

Okoli, C. & Khara, M. (2011). Smoking cessation among persons with co-occurring substance use disorder and mental illness. *Journal of Smoking Cessation,* 6(01):58-64.

Okoli, C. & Khara, M. (2014). Smoking cessation outcomes and predictors among individuals with co-occurring substance use and/or psychiatric disorders. *Journal of Dual Diagnosis, 10*(1), 9–18.

Okoli, , C., Khara, M., Torchalla, I., Ensom, M., Oliffe, J., Bottorff, J. & Stanley, P. (2011). Sex differences in smoking cessation outcomes of a tailored program for individuals with substance use disorders and mental illness *Addictive Behaviors* 36 (2011) 523-526.

Okuyemi, K.S., Goldade, K., Whenbolua, G-L., Thomas, J., Eischen, S., Sewali, B., Guo, H., Connett, J.,...Jarlais, D.D. (2014). Motivational interviewing to enhance nicotine patch treatment for smoking cessation among homeless smokers: a randomized controlled trial. *Addiction*, 108:1136-1144.

Okuyemi, K. S., Thomas, J. L., Hall, S., Nollen, N. L., Richter, K. P., Jeffries, S. K., Caldwell, A. & Ahluwalia, J. (2006). Smoking cessation in homeless populations: a pilot clinical trial. *Nicotine and Tobacco Research,* 8:689–99.

Olufade, A.O., Shaw, J.W., Foster, S.A., Leischow, S.J., Hays, R.D, & Coons, S.J. (1999). Development of the smoking cessation quality of life questionaire. *Clinical Therapeutics,* 21(12):2113.

Ontario Federation of Community Mental Health and Addiction Programs (1999). *Canadian Version IAPSR PSR Toolkit*. Toronto, ON: Authors.

Ontario Medical Association. (2008). Re-thinking stop-smoking medications: treatment myths and medical realities. Retrieved from: https://www.oma.org/Resources /Documents/e2008RethinkingStop-SmokingMedications.pdf

Orpana, H., Lemyre, L. & Gravel, R. (2009). Income and psychological distress: the role of the social environment. *Component of Statistics Canada Catalogue* no. 82-003-X.

Parks, J., Svendsen, D., Singer, P. & Foti, M.E. (2006). Morbidity and mortality in people with serious mental illness. *National Association of State Mental Health Program Directors*. Retrieved from www.nasmhpd.org

Patra, J., Taylor, B, Rehm, J., Baliuna, D. & Popova, S. (2007). Substance attributable morbidity and mortality changes to Canada in a epidemiological profile: measurable differences over a ten-year period. *Canadian Journal of Public Health*, 98(3):228-234.

Payne, T. J., Smith, P. O., McCracken, L. M., McSherry, W. C. & Antony, M. M. (1994). Assessing nicotine dependence: A comparison of the Fagerström Tolerance Questionnaire (FTQ) with the Fagerström Test for Nicotine Dependence (FTND) in a clinical sample. Addictive Behaviors, 19(3), 307–317.

Personal Health Information Protection Act, 2004 (2010, c. 11, s. 128). Retrieved from the Government of Ontario website: http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_04p03_e.htm

Perkins, K.A. & Scott, J. (2008). Sex differences in long-term smoking cessation rates due to nicotine patch. *Nicotine & Tobacco Research*, 10(7):1245-1251.

Phutane, V.H., Tek, C., Chwastiak, L., Ratliff, J.C., Ozyuksel, B., Woods, S.W. & Srihari, V. (2011). Cardiovascular risk in a first-episode psychosis sample: A 'critical period' for prevention? *Schizophrenia Research*, 127:257–261.

Pomerleau, C.S., Carton, S.M., Lutzke, M.L., Flessland, K.A. & Pomerleau, D.F. (1994). Reliability of the Fagerström tolerance Questionnaire and the Fagerström test for nicotine dependence. *Addictive Behaviors*, 19(I):33-39.

Prochaska, J.J., Hall, S.E., Delucchi, K. & Hall, S.M. (2014). Efficacy of initiating tobacco dependence treatment in inpatient psychiatry: A randomized controlled trial. *Research and Practice,* 104(8):1557-1565.

Prochaska, J.J., Delucchi, K. & Hall, S.M. (2004). A meta-analysis of smoking cessation interventions with individuals in substance abuse treatment or recovery. *Journal of Consulting and Clinical Psychology*,72(6):1144–1156.

Prochaska, J.J., Hall, S.M. & Bero, L. (2008). Tobacco use among individuals with schizophrenia:What role has the tobacco industry played? *Schizophrenia Bulletin,* 34(3):555–567.

Prochaska, J.J., Leek, D., Hall, S.M. & Hall, S.E. (2007). Cognitive interviews for measurement evaluation of the Fagerström Test for Nicotine Dependence (FTND) in smokers with schizophrenia spectrum disorders. *Addictive Behavior,* 32:793–802.

Prochaska, J.O. & DiClemente, C.C. (1984). The Transtheoretical Approach: Towards a Systematic Eclectic Framework . Dow Jones Irwin , Homewood, IL, USA.

Rae, J., Pettey, D., Aubry, T. & Stol, S. (2015). Smoking cessation interventions for people with severe mental illness: A qualitative inquiry. *Journal of Dual Diagnosis*, 11(1):42-49.

Raphael, D. (2009). Restructuring society in the service of mental health promotion: Are we willing to address the social determinants of mental health? *International Journal of Mental Health Promotion* 11(3)18-31.

Rapp, C. & Goscha, R. (2008). *The strengths model*. New York: Oxford University Press.

Regier, D. A., Farmer, M.E., Rae, D.S., Locke, B.Z. Keither, S.J., Judd, L.L. & Goodwin, F.K. (1990). Comorbidity of mental disorders with alcohol and other drug abuse: Results for the Epidemiologic Catchment Area (ECA) study. *Journal of the American Medical Association,* 264 (19):2511-2518.

Reid, J.L., Hammond, D., Rynard, V.L. & Burkhalter, R. (2014). *Tobacco Use in Canada: Patterns and Trends, 2014 Edition*. Waterloo, ON: Propel Centre for Population Health Impact, University of Waterloo.

Reid, R.D., Pipe, A.L., Riley, D.L. & Sorensen, M. (2009). Sex differences in attitudes and experiences concerning smoking and cessation: Results from an international survey. *Patient Education and Counseling*, 76:99-105.

Richard, L., Lehoux, P., Breton, E., Denis, J.L., Labrie, L. & Leonard, C. (2004). Implementing the ecological approach in tobacco control programs: results of a case study. *Evaluation and Program Planning* 27:409–421.

Richard, L., Potvin, L., Denis, J.L. & Kishchuk, N. (2002). Integration of the ecological approach in tobacco programs for youth: A survey of Canadian public health organizations. *Health Promotion Practice*, 3(3): 397-409.

Rush, B. & Koegl, C.J. (2008). Prevalence and profile of people with co-occurring mental and substance use disorders within a comprehensive mental health system. *La Revue canadienne de psychiatrie*, 53(12):810-821.

Rush, B., Urbanski, K., Bassani, D., Castel, S., Cameron, T., Strike, CC., Kimberly, D. & Somers, J. (2008). Prevalence of co-occurring substance use and other mental disorders in the Canadian population. *La Revue canadienne de psychiatrie*, 53(12):800-809.

Russo, I., Trujillo, C.A., Wingerson, D., Decker, K., Ries, R., Wetzler, H., et al. (1998). The MOS 36-item Short Form Health Survey. Reliability, validity, and preliminary findings in schizophrenic outpatients. Brief Report. *Medical Care*, 36:752-6.

Saha, S., Chant, D. & McGrath, J. (2007). A systematic review of mortality in schizophrenia. *Archives of General Psychiatry*, 64:1123-1131.

Salyers, M.P., Bosworth, H.B., Swanson, J.W., Lamb-Pagone, J. & Osher, F. (2000). Reliability and validity of the SF-12 Health Survey among people with severe mental illness. *Medical Care*, 38(11):1141-1150.

Schroeder, S.A. & Morris, C.O. (2010). Confronting a neglected epidemic: tobacco cessation for persons with mental illnesses and substance abuse problems. *Annual Review Public Health*, 31:297–314

Selby, P., Voci, S.C., Zawertailo, L.A., George, T.P. & Brands, B. (2010). Individualized smoking cessation treatment in an outpatient setting: Predictors of outcome in a sample with psychiatric and addictions co-morbidity. *Addictive Behavior,s* 35:811.

Shanyinde, M., Pikering, R. & Weatherall, M. (2011). Questions asked and answered in pilot and feasibility randomized controlled trials. *BMC Medical Research Methodology,* 11:117.

Shelley, D., Cantrell, J.,Wong, S. & Warn, D. (2010). Smoking cessation among sheltered homeless: a pilot. *American Journal of Health Behaviors,* 34: 544–52.

Shern, D.L., Wilson, N.Z., Coen, A.S., Patrick, D.C., Foster, M., Bartsch, D.A. & Demmler, J. (1994). Client outcomes II: Longitudinal client data from the Colorado Treatment Outcome Study. *The Milbank Quarterly*, 72, 123–148.

Siru, R., Hulse, G.K. & Tait, R.J. (2009). Assessing motivation to quit smoking in people with mental illness: a review. *Addiction*, 104:719.

Stapleton, J.A., Watson, L., Spirling, L., Smith, R., Milbandt, A., Ratcliffe, M. & Sutherland, G. (2008). Verenicline in the routine treatment of tobacco dependence: a pre-post comparison with nicotine replacement therapy and an evaluation in those with mental illness. *Addiction,* 103:146.

Stead, L., Perera, R., Bullen, C., Mant, D. & Lancaster, T. (2008). Nicotine replacement therapy for smoking cessation. *Cochrane Database of Systematic Reviews*: Issue 1 John Wiley & Sons, Ltd Chichester, UK DOI: 10.1002/14651858.CD000146.pub3

Stefanic, A., Tsemberis, S., Messeri, P., Drake, R.E. & Goering, P. (2013). The Pathways Housing First Fidelity Scale for Individuals With Psychiatric Disabilities. *American Journal of Psychiatric Rehabilitation,* 16(4):240-261.

Steinberg, M.B., Bover, M.T., Richardson, D.L., Schmelzer, A.C., Williams, J.M. & Foulds, J. (2011). Abstinence and psychological distress in co-morbid smokers using various pharacotherapies. *Drug and Alcohol Dependence,* 114:77-81.

Steinberg, M.L., Williams, J.M., Steinberg, H.R., Krejci, J.A. & Ziedonis, D.M. (2005). Applicability of the Fagerström Test for Nicotine Dependence in smokers with schizophrenia. *Addictive Behaviors,* 30:49–59.

Stephens, T., Pederson, L.L., Koval, J.J. & Macnab, J. (2001). Comprehensive tobacco control policies and the smoking behaviour of Canadian adults. *Tobacco Control*, 10:317-322.

Substance Abuse and Mental Health Services Administration. (2009). *Integrated Treatment for Co-Occurring Disorders: How to Use the Evidence-Based Practices KITs.* DHHS Pub. No. SMA-08-4366, Rockville, MD: Center for Mental Health Services, Substance Abuse and Mental Health Services Administration, U.S. Department of Health and Human Services.

Swift, J. & Greenberg, R. (2012). Premature Discontinuation in adult psychotherapy. *Journal of Consulting and Clinical Psychology*, 80(4):547-559.

Swift, J. & Callahan, J. (2011). Decreasing treatment dropout by addressing expectations for treatment length. *Psychotherapy Research*, 21:193-200.

Tsoi, D.T., Porwal, M. & Webster, A.C. (2010). Efficacy and safety of bupropion for smoking cessation and reduction in schizophrenia: a systematic review and meta-analysis. *The British Journal of Psychiatry,* 196:346.

Tsoi, D.T., Porwal, M. & Webster, A.C. (2013). Interventions for smoking cessation and reduction in individuals with schizophrenia. *Cochrane Database of Systematic Reviews*, Issue 2.Art. No.: CD007253. DOI: 10.1002/14651858.CD007253.pub3.

Tunis, S.L., Croghan, T.W., Heilman, D.K., Johnstone, B.M. & Obenchain, R.L. (1999). Reliability, validity, and application of the medical outcomes study 36-Item Short-Form Health Survey (SF-36) in schizophrenic patients treated with Olanzapine versus Haloperidol. *Medical Care,*37(7):678-691

United States Department of Health and Human Services. (2008). Treating Tobacco Use and Dependence: 2008 Update. Retrieved from: http://www.surgeongeneral.gov/tobacco/treating_tobacco_use08.pdf

Uttaro, T. & Lehman, A. (1999). Graded response modeling of the Quality of Life Interview. Evaluation and Program Planning, 22(1):41-52.

Vagg, R. & Chapman,S. (2005). Nicotine analogues: a review of tobacco industry interests *Addiction,* 100:701-712.

van der Meer, R., Willemsen, M., Smit, F. & Cuijpers, P. (2013). Smoking cessation interventions for smokers with current or past depression. *Cochrane Database of Systematic Reviews,* Issue 8. Art. No.: CD006102. DOI: 10.1002/14651858.CD006102.pub2.

von Tigerstrom, B. (2008).Tobacco control and the law in Canada in *Public Health Law and Policy in Canada* (2nd Edition) Bailey, Caulfield & Ries (eds) LexisNexis Canada Inc: p.247-300.

Ware, J., Kosinski, M. & Gandek, B. (2002). *SF-36 Health Survey: Manual & Interpretation Guide*. Lincoln, RI: QualityMetric Incorporated, 1993, 2000.

Weinberger, A.H., Reutenauer, E.L., Allen, T.M., Termine, A., Vessicchio, J.K., Sacco, K.A., Easton, C.J., McKee, S.A., & George, T.P. (2007). Reliability of the Fagerström test for nicotine dependence, Minnesota nicotine withdrawal scale, and tiffany questionnaire for smoking urges in smokers with and without schizophrenia. *Drug and Alcohol Dependence,* 86:278–282.

Westra, H. & Arkowitx, H. (2011). Integrating motivational interviewing with cognitive behavioral therapy for a range of mental health problems. *Cognitive and Behavioral Practice,* 18:1-4.

Williams, J.M., Steinberg, M.L., Zimmermann, M.H., Gandhi, K.K., Stipelman, B., Budsock, P.D., Ziedonis, D. (2010). Comparison of two intensities of tobacco dependence counselling in schizophrenia and schizoaffective disorder. *Journal of Substance Abuse Treatment*, 38:384.

Williams, J.M. & Ziedonis, D. (2004). Addressing tobacco among individuals with a mental illness or an addiction. *Addictive Behaviors* 29:1067–1083.

Wilton, R. (2004). Putting policy into practice? Poverty and people with serious mental illness. *Social Science and Medicine,* 58:25-39.

Wilton, R. (2003). Poverty and mental health: a qualitative study of residential care facility tenants. *Community Mental Health Journal*, 39(2):139-156.

Wood, G.C., Bentall, R.P., Göpfert, M. & Edwards, R.H. (1991). A comparative psychiatric assessment of patients with chronic fatigue syndrome and muscle disease. *Psychological Medicine,* 21, 619-628.

World Health Organization. (2002). The World Health Report 2002- Reducing risks, promoting healthy life. Geneva, Switzerland.

World Health Organization. (2013). WHO report on the global tobacco epidemic, 2013: enforcing bans on tobacco advertising, promotion and sponsorship. Geneva, Switzerland.

Yang, Y., McEvoy, J.P., Wilson, W.H., Levin, E.D. & Rose, J.E. (2003). Reliabilities and intercorrelations of reported and objective measures of smoking in patients with schizophrenia. *Schizophrenia Research*. 60:9–12.

Zani, B., Mcfarland, B., Wachal, M., Barker, S. & Barron, N. (1999). Statewide replication of predictive validation for the Multnomah Community Ability Scale. *Community Mental Health Journal*, 35(3):223-229.

Ziedonis, D., Hitsman, B., Beckman, J.C., Zvolensky, M., Adler, L.E., Audrain-MrGovern, J., et al. (2008). Tobacco use and cessation in psychiatric disorders: National institute of mental health report. *Society of Research on Nicotine and Tobacco,* 10(12):1691-1715.

Ziedonis, D., Williams, J.M. & Smelson, D. (2003). Serious mental illness and tobacco addiction: A model program to address this common but neglected issue. *The American Journal of the Medical Sciences.* 326(4): 223-230.

Appendix A Consent Form

Client Information Sheet and Consent Form

Pilot Study of the Development of Effective Smoking Cessation Treatment Interventions for Individuals with Severe Mental Illness Who are Homeless or Vulnerably Housed

Investigators:

Principal Investigator: Donna L. Pettey MSW RSW 613-737-7791
PhD Candidate, Population Health
University of Ottawa

Supervisor: Tim Aubry Ph.D., C.Psych 613-562-5800
Professor, School of Psychology
Director Centre for Research on Educational and Community Services, University of Ottawa

Sponsor: Canadian Mental Health Association Ottawa

Please read this Information Sheet and Consent Form carefully and ask as many questions as you like before deciding whether to participate in this research study.

Introduction

You have been asked if you would be interested in participating in a research project entitled: *Pilot Study of the Development of Effective Smoking Cessation Treatment Interventions for Individuals with Severe Mental Illness Who are Homeless or Vulnerably Housed.* You are being approached to participate in this study because you are a current smoker.

The purpose of this project is to determine which of the following smoking cessation interventions are the most effective in helping people who have a mental illness to quit or reduce smoking: 1) nicotine replacement therapy (NRT) – in available forms such as patch, gum, inhaler 2) nicotine replacement therapy (NRT) – in available forms such as patch, gum, inhaler, PLUS individual and group support sessions.

Your participation will help us to evaluate these interventions and to better understand how we can develop better interventions to support people who have a mental illness to stop or reduce smoking

This study is being conducted at the Canadian Mental Health Association Ottawa Branch. The research is being conducted as part of the requirement for a PhD thesis. About 60 participants who are current clients of CMHA will be in the study. The study will begin in January 2012 and the intervention will run for 6 months.

Procedure:

If you agree to participate in this study, a letter will be sent to your treating physician(s) by the CMHA Nurse Practitioner informing them of the study. You will complete questionnaires about your smoking history and previous attempts to quit, level of nicotine dependence, and symptoms of nicotine withdrawal. We will also ask you questions about your medical history and current medications, your current level of substance use, as well as psychological symptoms that you may be experiencing (e.g., depression, anxiety) and overall quality of life. If you are a woman of childbearing age, you will have a pregnancy test done to ensure that you are not pregnant before the study begins. In addition, you will also be asked to provide a breath sample to measure the amount of carbon monoxide levels in your lungs. This procedure consists of you blowing into a mouthpiece that is connected to a Smokerlyzer for 10 seconds. There are no risks involved with this procedure.

Once these measures are completed, you will be randomly placed in one of the two groups (determined like pulling names from a hat): Group 1) up to 24 weeks of cost free treatment with Nicotine Replacement Therapy (NRT) Group 2) up to 24 weeks of cost free treatment with Nicotine Replacement Therapy (NRT) Plus up to 2 individual counselling sessions with a Mental Health and Addictions workers and up to 24 weeks of weekly support group sessions.

Participation in this study does not effect the ongoing regular services that you receive from CMHA. Your CMHA workers will support you to participate in this program just as they would support you to participate in any program designed to help you with your recovery plans.

NRT only group

If you are randomly placed in the NRT group, you will meet with the CMHA Nurse Practitioner to set your *target quit/reduction date.* You will meet with the Nursing staff every week to discuss your quit/reduction progress and to receive your weekly NRT. Doses of NRT will depend on how much you smoke and are done in consultation with the Nurse Practitioner. The Nursing staff will also monitor CO levels regularly with the carbon monoxide monitor.

NRT+ group

If you are randomly placed in the NRT+ group, you will meet with the CMHA Nurse Practitioner to set your *target quit/reduction date.* You will meet with the Nursing staff every week to discuss your quit/reduction progress and to receive your weekly NRT. Doses of NRT will depend on how much you smoke and are done in

consultation with the Nurse Practitioner. The Nursing staff will also monitor CO levels regularly with the carbon monoxide monitor.

You will also have the opportunity to meet individually with a Mental Health and Addiction worker for up to 2 sessions to plan and discussion your quit/reduction strategies. You will also be assigned to a weekly support group co-facilitated by a peer specialist and a Mental Health and Addiction worker with specialized training in tobacco cessation that will focus on practical strategies to quit (e.g., identify triggers to smoking, problem solving). If you are unable to make it to one of your assigned weekly groups due to an emergency, we will try to accommodate you in another group for that week.

Follow-up Interviews
After your initial interview, you will be asked to complete the same questionnaires that you completed at your initial interview at the 3 month and 6 month mark

Risks and Discomforts of Participation:

Withdrawal Symptoms: It is important to note that smoking cessation with or without treatment is associated with various withdrawal symptoms. For example, depressed mood, insomnia, irritability, frustration, anger, hostility, anxiety, difficulty concentrating, restlessness, decreased heart rates, increased appetite or weight gain have been reported by patients attempting to stop smoking. Symptoms associated with withdrawal tend to last in most smokers 7-10 days.

There are some side effects which may occur in some patients using quit smoking medications. Most side effects are mild to moderate and generally occur in the first weeks of treatment. Side effects can be managed by adjusting the dose of the medication.

Below is a summary of the side effects for quit smoking medications and the frequency with which they **typically** occur in people who use it:

Medication	Side Effect (Percentage of Patients Reporting Side Effect)
NRT Patch	Headache (16%), trouble sleeping (15.7%), dizziness (7%), nausea (5.4%), diarrhea (2.3%), skin irritation (2%), stomach upset (1.7%), cold sweats (1.6%), vomitting (1.3%)
NRT Inhaler	Headache (26%), mouth/throat irritation (24%), sore throat (15%), nausea (10%)
NRT Gum	Mouth soreness (37%), jaw pain (18.1%), nausea (18%), hiccups (15%)

For patients using nicotine replacement therapy, symptoms that may indicate you have taken too much medication include: bad headaches, dizziness, nausea,

abdominal pain, drooling, vomiting, diarrhea, cold sweats, disturbed hearing or vision, mental confusion, weakness and fainting, rapid heartbeat and difficulty breathing.

If you experience any of these rare side-effects or symptoms indicating you have taken too much medication, stop using the medication and contact your doctor and your CMHA worker and the CMHA Nursing team immediately.

Effectiveness of NRT

NRT has been found to be effective in treating nicotine dependence. A recent scientific review of over 132 studies that examined how effective NRT was in helping people to quit smoking found that NRT increased the rate of quitting smoking by 50%-70%[19]. If you have more questions, the nursing staff and researchers can provide you with additional information on NRT.

Pregnancy & Contraception

There is no adequate clinical research in pregnant women and smoking cessation treatments. For women using medications to quit smoking, if you are pregnant or become pregnant during the study, these risks could affect you or the unborn child. Therefore, women who are pregnant, breastfeeding or are planning a pregnancy within the next year will be excluded from the study. If you are a woman of childbearing age, you will have a pregnancy test done to ensure that you are not pregnant before the study begins. In discussions with the CMHA Nurse, additional pregnancy tests may be done during the study if needed.

Benefits of Participation:

You may or may not receive any direct benefit from your participation in this study. You will also help researchers better understand the experiences and symptoms of smokers as they are attempting to quit. It is hoped that your participation in this study may allow the researchers to provide evidence of the impact of providing quit smoking medications to promote smoking cessation which may be of benefit to future individuals with mental illness.

Alternative Treatment(s) Available

There are other treatments available for smoking cessation if you choose not to participate in this study. These include but are not limited to: quitting "cold turkey" without NRT, Varenicline (Champix®), or counselling; attending counselling at the Heart Institute or elsewhere; purchasing and using NRT or varenicline on your own; getting a prescription for bupropion (Zyban®) from your doctor; consulting a

[19] Stead, Perera, Bullen, Chris, Mant, & Lancaster. (2008). Nicotine replacement therapy for smoking cessation. Cochrane Database of Systematic Reviews: Issue 1 John Wiley & Sons, Ltd Chichester, UK DOI: 10.1002/14651858.CD000146.pub3

naturopathic doctor regarding natural or herbal medications for smoking cessation. If you agree to participate in this study, you will not be able to participate in any of the other treatment options listed above during the time you are participating in the study.

Medication

Smoking cigarettes can alter the way that your psychiatric medications work. Nicotine and smoking cessation may increase or decrease the dosage of medication required, and therefore it is important that your symptoms of mental health and well being are monitored throughout the treatment program.

Compensation/Remuneration

You will be provided with bus tickets if required in order to attend sessions with the Nurse and /or the groups.

Confidentiality

All personal health information will be kept confidential, unless release is required by law. As part of this research protocol, the Principal Investigator and research staff will review your client file at CMHA. Your coded data will be kept confidential in the locked office on a password protected computer of the research coordinator at CMHA. As this is research that is being conducted as part of the requirements of a PhD thesis, the original hard (paper) copies of the interview protocol and a copy of all research data will be kept at the Centre for Research on Educational and Community Services at the University of Ottawa. No identifying information will leave CMHA. With your consent, a notification letter will be sent to your family physician and/or psychiatrist to advise them of your involvement in the study, your prescribed medication and dosage, as well as any psychiatric diagnoses and/or suicidal ideation if applicable. If you do not have a family physician, your CMHA worker will work with you to find a physician. CMHA also has 2 psychiatrists who provide consultation services to our clients and staff.

You and your client file will not be identifiable in publications or presentations. Your initials will not be used to identify you. Your health information will be kept confidential, unless release is required by law. At the end of the retention period (7 years), all paper records will be disposed of in confidential waste or shredded, and all electronic records will be deleted.

Voluntary Participation

Your participation in this study is voluntary. You are free to choose to participate or not to participate in this research study. You will be informed if new information becomes available that may affect your willingness to participate in this study. If you agree to participate in this study, you may choose to withdraw your participation at any time. This will not affect your present or future care at CMHA. You may also refuse to answer any specific questions.

Ethics

The Research Ethics Board – Science and Health Sciences (REB) of the University of Ottawa has reviewed this protocol. The REB considers the ethical aspects of research projects involving human subjects. If you wish, you may contact the Office Research Ethics and Integrity at Tel.: (613) 562-5387

Consent Form

Pilot Study of the Development of Effective Smoking Cessation Treatment Interventions for Individuals with Severe Mental Illness Who are Homeless or Vulnerably Housed

Consent to Participate in Research

I understand that I am being asked to participate in a research study to determine which of the following smoking cessation interventions are the most effective in helping people who have a mental illness to quit or reduce smoking: 1) nicotine replacement therapy (NRT) – in available forms such as patch, gum, inhaler 2) nicotine replacement therapy (NRT) – in available forms such as patch, gum, inhaler PLUS individual and group support sessions. This study has been explained to me by one of the project staff, _____.

I have read this six (6) page Information Sheet and Consent Form. All my questions have been answered to my satisfaction. If I have any further questions about the study, I may contact Donna L. Pettey 613-737-7791 or Annette Bradfield, Nurse Practitioner 733-7793.

If I have any questions regarding the confidentiality policies of Canadian Mental Health Association Ottawa Branch, I may contact Andrew Fainer, Privacy Officer at 613-737-7791.

I will receive a signed copy of this Client Information Sheet and Consent Form. I voluntarily agree to participate in this study.

_____ _____

Client's Name (Please Print) Date

_____ _____

Client's Signature Date

Investigator Statement (or Person Explaining the Consent)

I have carefully explained to the research participant the nature of the above research study. To the best of my knowledge, the research participant signing this consent form understands the nature, demands, risks and benefits involved in participating in this study. I acknowledge my responsibility for the care and well being of the above research participant, to respect the rights and wishes of

the research participant, and to conduct the study according to applicable Good Clinical Practice guidelines and regulations.

_____
Name of Investigator/Delegate (Please Print)

_____ _____
Signature of Investigator/Delegate Date

Appendix B University of Ottawa Heart Institute Primary Care smoking Cessation Program Nicotine Replacement Therapy (NRT) Protocal

University of Ottawa Heart Institute
Primary Care Smoking Cessation Program
Nicotine Replacement Therapy (NRT) Protocol

NRT works by reducing withdrawal symptoms (anxiety, irritability, headaches, and difficulty concentrating…) that typically occur when people quit smoking as well as reduce your urge to smoke. The idea is that the NRT will assist patient with dealing with cravings and withdrawal symptoms – and week by week, will reduce the amount of NRT while adapting to life as a non-smoker.

The advantages of using NRT instead of smoking:
:. You will receive much less nicotine than if you were to continue smoking;
:. Gradual reduction in nicotine delivered to the brain allowing cravings and withdrawal symptoms to be more tolerable;
:. Your body is not exposed to the 4,000+ chemicals in cigarette smoke.

NRT PATCH

Smokes >30 minutes of waking	Smokes within 30 minutes of waking	Treatment Plan	Instructions
<10		:. 7 mg for 6 weeks OR; :. use gum, lozenge or inhaler alone	:. Apply the patch to a clean, dry, non hairy area on the upper part of your body (arms, chest, back). :. Replace the patch with a new one every 24 hours. :. Be sure to remove the old patch before putting on a new one. :. If you have difficulty sleeping remove your nicotine patch at bedtime.
10-19	**<10**	:. 14mg daily for 6 weeks then; :. 7mg daily for 2 to 4 weeks	
20-29	**10-19**	:. 21mg daily for 6 weeks then; :. 14mg daily for 2 weeks then; :. 7mg daily for 2 weeks or longer	
30-39	**20-29**	:. 28mg (21mg + 7mg) daily for 6 weeks then; :. 21mg daily for 4 weeks then; :. 14mg daily for 2 weeks then; :. 7mg daily for 2 weeks or longer	
	30-40	:. 35mg (21mg + 14mg) daily for 6 weeks then; :. 21mg daily for 4 weeks then; :. 14mg daily for 2 weeks then; :. 7mg daily for 2 weeks or longer	
40+		:.42mg (21mg x 2) daily for 6 weeks then; :. 35mg (21mg + 14mg) daily for 2 weeks then; :. 21mg daily for 2 weeks then; :. 14mg daily for 2 weeks then; :. 7mg daily for 2 weeks or longer	

Managing cravings

If after 24 hours of starting NRT you are still experiencing moderate to severe withdrawal symptoms, try adding a short acting NRT like gum or the inhaler. If this is not enough, add one 7 mg patch to your treatment plan. Call the Quit Smoking Specialist if symptoms persist 24 hours following this change.

Considerations

- **There is good evidence to show that higher dose NRTs will increase success with quitting.**
- 56% of smokers will require more than the standard dosing of NRT to meet their nicotine needs for managing cravings and withdrawal.
- NRTs are not as effective of delivering nicotine to the brain centres as cigarettes and as such higher dose NRT products may be required to deliver sufficient nicotine to smokers who quit.

Selecting the Initial Dose

Selecting an NRT treatment plan to match a smoker's unique needs is required to enhance success with smoking cessation. :

- exposed environmental cues to smoke, OR
- have experienced difficulty with withdrawal when quitting in the past, OR
- smoke within 30 minutes form waking will require less NRT than other smokers.

Guiding Principles in selecting starting dose:

- Number of Cigarettes per day
- Time to First Cigarette
- Cues in Environment
- Past experience with quitting and NRTs

Titration – Dose and Duration

In addition to addiction and environmental or social cues which need to be considered when selecting the patients NRT treatment plan, genetics plays a role in determining how quickly nicotine is metabolizers. There are slow and fast metabolizers and these individuals may react differently to NRTs explaining why number of cigarettes alone does not determine how easy it will be quit or what type of withdrawal symptoms will be experienced. Monitoring patients in the days and weeks following quitting to ensure the does selected meets their needs is important. Titration of nicotine (up or down) is often required in order to tailor the treatment plan. Many patients will also require the use of NRTs beyond the standard 10 to 12 weeks in order to be successful with quitting.

Self-Management

NRT is an over the counter product. Patients should be educated on how to self-titrate their dose of NRT by adding a 7mg patch or adding a short acting NRT to manage cravings or withdrawal as they occur.

Combination Therapy

- NRT comes in the form of a patch, gum, inhaler or lozenge. Each form can be used alone and often two forms of NRT are used together.
- Combining NR T patch with a short acting form such as the gum, lozenge or inhaler can be useful to help minimize withdrawal symptoms.
- Short Acting NRTs can be a great way to address the NRT needs of patients who fall in between treatment categories for number of cigarettes smoked.
- The NRT inhaler is particularly useful to patients who are looking to replace the hand to mouth action of smoking after quitting.

LONG ACTING
NRT Patch

Provides baseline dose of NRT throughout the day

SHORT ACTING
Inhaler
Lozenge
Gum

Provides rapid relief from cravings and other withdrawal symptoms

Inhaler ☐

Treatment Plan	Instructions	Possible Side Effects
2mg of nicotine per cartridge WHEN USING ALONE :· Use 6-12 cartridges per day for first 6 weeks; :· Reduce the amount of cartridges used per day in weeks 6-12; :· Some smokers require 1-2 cartridges per day beyond 12 weeks Replaces hand to mouth motion of smoking	:· You puff as needed to manage cravings :· Inhale 80 puffs over 20 minutes or until cravings are gone. Often, using the inhaler for 5 minutes is enough. :· Take slow puffs to avoid throat burn. :· Avoid eating or drinking 15 minutes before or during use.	:· headache :· nausea :· mouth/throat irritation $40/week

Lozenge ☐

Treatment Plan	Instructions	Possible Side Effects
☐ 2mg (if you smoke your first cigarette 30 minutes after you wake up) ☐ 4 mg (if you smoke your first cigarette within 30 minutes of waking up) :· One piece every 1-2 hours for weeks 1 through 6 then; :· One piece every 2-4 hours for weeks 7 through 6, then; :· One piece every 4-8 hours for weeks 9, through 12.	:· Place the lozenge in your mouth and let it dissolve, moving it back and forth from time to time. :· Each lozenge will last about 20-30 minutes. :· Avoid eating or drinking 15 minutes before or during using lozenge.	:· nausea :· headache :· heartburn :· coughing :· hiccups $40-55/week

Gum ☐

Treatment Plan	Instructions	Possible Side Effects
☐ 2mg (if you smoke your first cigarette 30 minutes after you wake up) ☐ 4 mg (if you smoke your first cigarette within 30 minutes of waking up) :· One piece every 1-2 hours for weeks 1 through 6 then; :· One piece every 2-4 hours for weeks 7 through 6, then; :· One piece every 4-8 hours for weeks 9, through 12.	:· Nicotine gum should be chewed slowly until you can taste the nicotine or feel a slight tingling in your mouth, then stop chewing. :· Place the gum between your cheek and gum. After one minute, repeat the process until cravings are resolved. :· Chew each piece for about 30 minutes. :· Avoid eating or drinking 15 minutes before or during use.	:· clings to dental work :· nausea :· hiccups :· jaw pain :· mouth soreness $40-55/week

Appendix C Baseline "Take a Breath" Interview

SMOKING CESSATION PILOT RCT STUDY: "TAKE A BREATH"

TAB

Baseline Survey Instrument
January, 2012

Survey Number*	**Date of Survey**	**Interviewer's Initials**
☐☐☐☐ (1 2 3 4)	___ ___ / ___ ___ / ___ ___ (d d / m m / y y)	☐☐
Start Time: ☐☐ : ☐☐	**Finish Time:** ☐☐ : ☐☐	**Total Time:** ☐☐☐ Mins *do not include breaks

To be completed by Research Coordinator	
Forms returned	☐ Consent form
Data entered	☐ Qualitative data ☐ Quantitative data

*1. Baseline = 1, Follow-up 1 = 2, Follow-up 2 = 3
2. SC-R = 1, SC+ = 2
3,4 Participant number = 1-60

INSTRUCTIONS FOR INTERVIEWERS

A. Every time you see [**REFER TO SCALE**] you should turn to the appropriate page of the scales booklet and present the new scale to the participant.

B. Any text inside parenthesis and/or in italic is a note for the interviewer; you should NOT read it to the participant.
Example: *(Ask these questions even if the participant is sleeping anywhere outside).*

C. Bolded text has the objective of drawing the interviewer's attention to part of a sentence or an entire sentence.
Example: I want you to think about where you have been living **in the past 12 months**.

D. Skip patterns are properly indicated throughout the survey (see example below). If no skip pattern is indicated go to the following question.

A	In the **past 12 months**, have you used drugs other than those required for medical reasons?	1	2 **(Skip to 9.3)**	996	997	998

E. To select an answer circle corresponding code number. See examples below:

2	In the past month, how often have you felt depressed? **1** Not at all; **2** Once during the month; **3** Several times during the month; **4** Several times a week; **5** At least every day	996. N/A 997. Refused 998. D/K

4	In the past month, how often have others told you that you acted "paranoid" or "suspicious"? **1** Not at all; **2** Once during the month; **3** Several times during the month; **4** Several times a week; **5** At least every day	996. N/A 997. Refused 998. D/K

F. There are N/A (996), REFUSED (997) and D/K (998) options available in every question. Do not present these as options for respondents. It is important not to overuse these options. N/A answers should be extremely rare, since the survey has a planned skip pattern built in. Both the D/K option and the N/A option should only be selected after proper probing. The refused option should be selected when necessary. Refusal to answer a question should also be rare, but, if it happens, the interviewer should respect the participant's desire and not probe again.

G. When writing qualitative open-ended answers record verbatim and make sure your printing is clear. If the answer is too long to record fully, record key points using the participant's own language and read back to the participant to validate.

H. Note that ☆ indicates that there is a cue card that corresponds to the question being asked. The interviewer should offer a new cue card to the participant every time ☆ appears next to a question.

SECTION 1 – DEMOGRAPHICS, SERVICE & HOUSING HISTORY

Now I'll start with the interview questions - first some questions about your gender, where you were born, and your background.

1 What is your gender? Do you identify as:

1 Male | **2** Female | **3** Transgender | **4** Transexual | **5** Other

996. N/A
997. Refused
998. D/K

2 Where were you born, that is, what country? *Do not read list. If Canada, ask 2.b then skip to 3, if other than Canada, ask 2.c and 2.d.*

1 Canada	**2** Albania	**3** Afghanistan	**4** Bangladesh	**5** China
6 Guyana	7 Hong Kong	**8** India	**9** Iran	**10** Jamaica
11 Pakistan	**12** Philippines	**13** Romania	**14** Russia	**15** Somalia
16 South Korea	17 Sri Lanka	**18** Ukraine	**19** United States	**20** Vietnam
21 Yugoslavia	**22 O**ther, specify: _____			

996. N/A
997. Refused
998. D/K

2b. Within Canada, what is your original home community, that is, where did you live after you were born and for your early years? *Record what they tell you*.

_____

996. N/A
997. Refused
998. D/K

2c. When did you arrive in Canada? *Landing date, please estimate, if not known exactly.*

___ ___ / ___ ___ / ___ ___
d d m m y y

996. N/A
997. Refused
998. D/K

2d. When you arrived in Canada, what was your status?

1 Landed Immigrant | **2** Visitor with intent to apply | **3** Student | **4** Temporary status (work permit, domestic help) | **5** Refugee Claimant (awaiting hearing)

6. Other, specify: _____

996. N/A
997. Refused
998. D/K

3 Where were your parents born, that is, what countries? *Check one for each parent, unless they were born in the same country*.

1 Albania	**2** Afghanistan	**3** Bangladesh	**4** Canada	**5** China
6 Guyana	7 Hong Kong	**8** India	**9** Iran	**10** Jamaica
11 Pakistan	**12** Philippines	**13** Romania	**14** Russia	**15** Somalia
16 South Korea	17 Sri Lanka	**18** Ukraine	**19** United States	**20** Vietnam
21 Yugoslavia	**22** Other, specify: _____			

996. N/A
997. Refused
998. D/K

4 What is the language you first learned to speak at home in childhood and still understand? *Do not read list*.

1 Albanian	**2** Arabic	**3** Bengali	**4** Cantonese	**5** Mandarin
6 Dari	7 English	**8** French	**9** Greek	**10** Gujarati
11 Hindi	**12** Korean	**13** Ojibway	**14** Persian (Farsi)	**15** Portugese
16 Punjabi	17 Russian	**18** Serbian	**19** Somali	**20** Spanish

996. N/A
997. Refused
998. D/K

	21 Tagalog; 22 Tamil; **23** Urdu; **24** Vietnamese **25** Other, specify: _____	
5	What is your ethnic or cultural identity? *Do not read list, if Aboriginal, ask 5.c* **1** Aboriginal ***(Skip to 6)***; **2** Asian - East* (e.g. China, Japan, Korea); **3** Asian - South* (e.g. India, Pakistan, Sri Lanka); **4** Asian - South East* (e.g. Malaysia, Philippines, Vietnam); **5** Black - Africa* (e.g. Ghana, Kenya, Somalia) **6** Black - Canada*; **7** Black - Caribbean Region* (e.g. Jamaica, Trinidad, Tobago); **8** Latin American* (e.g. Argentina, Chile, Costa Rica); **9** Indian-Caribbean* (i.e. Guyana with origins in India); **10** Middle Eastern* (e.g. Egypt, Iran, Israel, Palestine) **11** White - Canada; **12** White - Europe (e.g. England, Greece, Italy, Portugal, Serbia); **13** Mixed Background - with at least 1 of groups marked with an asterisk(*) (specify) **(Skip to 5a)**; **14** Mixed Background - without any of the groups marked with an asterisk(*) (specify) **(Skip to 5b)** **15** Other, specify: _____ 5.a If mixed, *with at least 1 of groups marked with an asterisk(*)* specify: _____ 5.b If mixed, *without any of the groups marked with an asterisk(*)* specify: _____	996. N/A 997. Refused 998. D/K
5.c	If Aboriginal, are you (*check all that apply*): **1** Inuit; **2** Metis; **3** First Nations Status; **4** First Nations Non-status; **5** Indigenous from outside Canada 6 Other, specify: _____	996. N/A 997. Refused 998. D/K
6	So just to confirm, how would you describe your ethnic or cultural background in your own words? *Record what they tell you, including if more than one background*. _____	996. N/A 997. Refused 998. D/K
7	Do you identify yourself as Canadian? (You do not have to be born in Canada to think of yourself as Canadian) **1** Yes; **2** No	996. N/A 997. Refused 998. D/K
Next some questions about schooling, marital status and parenting.		
8	Not counting kindergarten, how many years of school did you complete? _____	996. N/A 997. Refused 998. D/K
9	What is your level of education? **1** Completed grade 4 or less; **2** Completed grades 5 to 8; **3** Attended High School, not completed; **4** Completed High School; **5** Attended business, trade, technical school (incl. CEGEP) **6** Completed business, trade, technical school (incl. CEGEP); **7** Attended University, not completed; **8** Completed University (Bachelor's degree); **9** Attended Graduate School, not completed; **10** Completed Graduate School	996. N/A 997. Refused 998. D/K

10	Are you currently... **[Refer to scale]** **1** Single, never married **2** Married **3** Separated **4** Divorced **5** Cohabitating with a partner **6** Widowed	996. N/A 997. Refused 998. D/K
11	How many children do you have under the age of 18? (Include whether or not they live with you) *If 1 or more, ask 11.a, and 11.b. If NO Skip to 12.* **0** **1** **2** **3** **4** **>4**	996. N/A 997. Refused 998. D/K
11.a	How many of these children do you currently provide full or partial support to? _____	996. N/A 997. Refused 998. D/K
11.b	What is your relationship to your child or children? Record all that apply. **1** Biological parent **2** Parent's partner (living together) **3** Adoptive parent **4** Foster parent **5** Stepparent **6** Other adult, specify: _____	996. N/A 997. Refused 998. D/K

Now I will be asking some questions about your work history.

12	Have you worked continuously for at least one year in the past? **1** Yes **2** No	996. N/A 997. Refused 998. D/K
13	Have you ever had any wartime service in the military forces of Canada or its allies? *If they have had other military experiences, allow them to tell you about that experience, but record only Canadian or allies service* **1** Yes **2** No	996. N/A 997. Refused 998. D/K
14	What is your current PRIMARY employment status? *If unemployed, ask 14.a through 14.e, if student skip to 14.f through 14 h and all else, skip to 15.* **1** Unemployed work, unpaid **(Skip to 14.a)** **2** Employed (including self-employed) **(Skip to 15)** **3** Volunteer **(Skip to 15)** **4** Employed in a special work program **(Skip to 15)** **5** Retired **(Skip to 15)** **6** Student **(Skip to 14.f)** **7** Housewife/ Husband **(Skip to 15)** **8** Other, specify: _____	996. N/A 997. Refused 998. D/K
14.a	What is the main reason you are not working? *Don't read, code based on what they tell you*. **1** Mental Illness **2** Physical Illness **3** Fear of loss of benefits **4** Both mental and physical illness **5** Transportation problems **6** Other, specify: _____	996. N/A 997. Refused 998. D/K
14.b	Would you like to have a paid job in the community? If yes, ask 14.c through 14.e then skip to 15 **1** Yes **2** No **(Skip to 15)**	996. N/A 997. Refused 998. D/K
14.c	What kind of job or jobs? *Record what they tell you.* _____	996. N/A 997. Refused 998. D/K
14.d	How many hours per week? _____	996. N/A 997. Refused 998. D/K

14.e	Wage per hour? *Enter in dollars, round up to the nearest dollar. We are looking for their desired hourly wage that is reasonable for that type of work.* _____ ***(Skip to 15)***	996. N/A 997. Refused 998. D/K
14.f	Where are you studying? _____	996. N/A 997. Refused 998. D/K
14.g	How many credits per semester are you currently registered for? _____	996. N/A 997. Refused 998. D/K
14.h	How many hours per week are you currently registered for? _____	996. N/A 997. Refused 998. D/K
15.	What are your current sources of income? *Record all that apply. Use the Other category for consumer run-business income, family support, student loans etc. Regular work is a fixed number of hours per week, casual is no fixed number of hours per week.* **1** Earnings from regular work **2** Earnings from casual work **3** Unemployment insurance **4** Disability income (ODSP) **5** Welfare/income assistance (OW) **6** Pension, incl. old age security, CPP, Veteran's pension **7** Long-term Disability **8** Personal Needs Allowance **9** Selling papers, souvenirs, crafts **10** Pan-handling **11** Busking (entertaining for cash) **12** Squeegeeing **13** Collecting/recycling (bottles scrap metal, etc.) **14** Other, specify: _____	996. N/A 997. Refused 998. D/K
16	In the study, we recognize that there may be other sources of income that you may have used to survive on the street. Please know that your confidentiality is protected if you would like to tell me about these sources of income, but like the other questions you do not have to tell me about them. *Record what they tell you. Provide examples "such as sex work or selling or running drugs" if needed.* _____	996. N/A 997. Refused 998. D/K
17	What was your total income, last month? *Enter as dollars, round up to the nearest dollar. If clarification is required, we are looking for gross income, before tax.* ----------	996. N/A 997. Refused 998. D/K
18	Do you have a provincial health card number? **1** No **2** Yes, in possession **3** Yes, but not here **RECORD IN SECTION 9**	996. N/A 997. Refused 998. D/K

Thanks for all your answers so far. We have only about 10 questions left in this section; some of these last questions can be quite personal to some people, but they are important to ask at the beginning so that we will be able to see how things might change for people as the study goes along.

19	In the past 5 years, have you been hospitalized for a mental illness at any time for longer than 6 months? **1** Yes **2** No	996. N/A 997. Refused 998. D/K

20	In the past 5 years, have you been hospitalized 2 or more times in any one year period for a mental illness? *Only count hospitalizations that lasted at least one night.* **1** Yes **2** No	996. N/A 997. Refused 998. D/K
21	Have you ever received treatment, counseling or harm reduction services for your use of alcohol or any drug, not counting cigarettes? **1** Yes **2** No	996. N/A 997. Refused 998. D/K
22	In the past 6 months, have you been arrested for criminal activity more than once, or been imprisoned at least once, or served probation or other community sanction? **1** Yes **2** No	996. N/A 997. Refused 998. D/K
23	In the past 6 months, did you spend one or more nights in a hospital, detox centre, jail or shelter? *If Yes, ask 23.a through 23.f.* **1** Yes **2** No **(Skip to 24)**	996. N/A 997. Refused 998. D/K
23.a	For the most recent stay, what is the name of the hospital, detox centre, jail or shelter? _____	996. N/A 997. Refused 998. D/K
23.b	Approximately how many days were you in [location name]? *If Participant stayed more than one time in this location, enter total days in past 6 months.* _____	996. N/A 997. Refused 998. D/K
23.c	For the stay before that, what is the name of the hospital, detox centre, jail or shelter? Enter 996 if they did not have a second stay. _____	996. N/A 997. Refused 998. D/K
23.d	Approximately how many days were you in [location name]? *If Participant stayed more than one time in this location, enter total days in past 6 months.* _____	996. N/A 997. Refused 998. D/K
23.e	And for the stay before that, what is the name of the hospital, detox centre, jail or shelter? Enter N/A if they did not have a third stay. _____	996. N/A 997. Refused 998. D/K
23.f	Approximately how many days were you in [location name]? *Enter N/A if they did not have a third stay. If Participant stayed more than one time in this location, enter total days in past 6 months*. _____	996. N/A 997. Refused 998. D/K
24	When did you first become homeless (year)? _____	996. N/A 997. Refused 998. D/K

25	In your lifetime, what is the total amount of time you have been homeless (months)? _____	996. N/A 997. Refused 998. D/K
26	How long was your longest single period of homelessness (months)? _____	996. N/A 997. Refused 998. D/K
27	When did your last period of homelessness end? ***Ask for precariously housed only****. Please estimate if not known exactly.* ____ ____ / ____ ____ / ____ ____ d d m m y y	996. N/A 997. Refused 998. D/K

SECTION 2 – HOUSING

2.1 Housing History (Dartmouth Follow-Back Calendar)

The first question I'll be asking has to do with where you have been living for the last while… *(Ask these questions even if the participant is sleeping anywhere outside.)*

I want you to think about where you have been living **past 2 years**. Let's look at this calendar together [**REFER TO CALENDAR**], and I'll make notes as you talk. This is **(current date),** so the time we'll be talking about is between **(date 2 years ago)** and today. Ok, let's begin. Now I want to read you a list of living situations and I want you to tell me if you have been living in any of these, even if only for one night over the **past 2 years.** Why don't we start with where you are living now and work backward from there, month by month.

Prompts: *Own house, apartment, temporary stay with friends and/or relatives, homeless shelter, homeless (on the streets, in the park/ravine, in a car or other vehicle, abandoned buildings, public places such as bus/train stations), rooming house, boarding home, group home, single room occupancy unit, medical hospital, psychiatric hospital, substance abuse treatment facility, halfway house, nursing home, motel or hotel, jail or prison.)*

2.1.1 Current Location			**N/A**	**Refused**	**DK**
A	Location *(If participant doesn't know the address ask for major intersection or neighbourhood)*		996	997	998
B	Type of residence		996	997	998
C	Date moved in (dd/mm/yyyy)	___ ___ / ___ ___ / ___ ___ ___ ___	996	997	998
(If type of residence is a shelter, street, treatment facility, hospital or jail go to G)					
D	Is this …	1. Your own place 2. A place belonging to friends or family → Do you pay rent? 1. Yes 2. No → **Skip to G**	996	997	998
E	How much do YOU pay for rent? *(participants share of rent - monthly amount)*		996	997	998
F	Is this subsidized housing?**	1. Yes 2. No	996	997	998
G	Why did you move to this place? (I*f participant hasn't moved in the past 24 months, skip to **1.2***) _____ _____		996	997	998
H	Do you live with a smoker/smokers?	1. Yes 2. No			

*** If participant does not know whether their housing is **subsidized**, ask: "Is part or all of your rent being paid by the government, a community agency, or another organization? In other words, are you receiving support to pay your rent above and beyond any income you have."*

2.1.2			**N/A**	**Refused**	**DK**
A	Location		996	997	998
B	Type of residence		996	997	998
C	Date moved in (dd/mm/yyyy)	___ ___ / ___ ___ / ___ ___ ___ ___	996	997	998
D	Date moved out (dd/mm/yyyy)	___ ___ / ___ ___ / ___ ___ ___ ___	996	997	998
(If type of residence is a shelter, street, treatment facility, hospital or jail go to G)					
E	Was this …	1. Your own place 2. A place belonging to friends or family → Did you pay rent? 1. Yes 2. No	996	997	998
F	Was this subsidized housing? **	1. Yes 2. No	996	997	998
G	Do you remember why you moved to this place? _____ _____		996	997	998
H	Did you live with a smoker/smokers?	1. Yes 2. No	996	997	998

2.1.3			**N/A**	**Refused**	**DK**
A	Location		996	997	998
B	Type of residence		996	997	998
C	Date moved in (dd/mm/yyyy)	___ ___ / ___ ___ / ___ ___ ___ ___	996	997	998
D	Date moved out (dd/mm/yyyy)	___ ___ / ___ ___ / ___ ___ ___ ___	996	997	998
(If type of residence is a shelter, street, treatment facility, hospital or jail go to G)					
E	Was this …	1. Your own place 2. A place belonging to friends or family → Did you pay rent? 1. Yes 2. No	996	997	998
F	Was this subsidized housing? **	1. Yes 2. No	996	997	998
G	Do you remember why you moved to this place? _____ _____		996	997	998

H	Did you live with a smoker/smokers? 1. Yes 2. No	996	997	998

*** If participant does not know whether their housing is **subsidized**, ask: "Is part or all of your rent being paid by the government, a community agency, or another organization? In other words, are you receiving support to pay your rent above and beyond any income you have."*

2.1.4			**N/A**	**Refused**	**DK**
A	Location		996	997	998
B	Type of residence		996	997	998
C	Date moved in (dd/mm/yyyy)	___ ___ / ___ ___ / ___ ___ ___ ___	996	997	998
D	Date moved out (dd/mm/yyyy)	___ ___ / ___ ___ / ___ ___ ___ ___	996	997	998
(If type of residence is a shelter, street, treatment facility, hospital or jail go to G)					
E	Was this …	1. Your own place 2. A place belonging to friends or family → Did you pay rent? 1. Yes 2. No	996	997	998
F	Was this subsidized housing? **	1. Yes 2. No	996	997	998
G	Do you remember why you moved to this place? _____ _____		996	997	998
H	Did you live with a smoker/smokers? 1. Yes 2. No		996	997	998

2.1.5			**N/A**	**Refused**	**DK**
A	Location		996	997	998
B	Type of residence		996	997	998
C	Date moved in (dd/mm/yyyy)	___ ___ / ___ ___ / ___ ___ ___ ___	996	997	998
D	Date moved out (dd/mm/yyyy)	___ ___ / ___ ___ / ___ ___ ___ ___	996	997	998
(If type of residence is a shelter, street, treatment facility, hospital or jail go to G)					
E	Was this …	1. Your own place 2. A place belonging to friends or family → Did you pay rent? 1. Yes 2. No	996	997	998

F	Was this subsidized housing? **	1. Yes 2. No	996	997	998
G	Do you remember why you moved to this place? _____ _____		996	997	998
H	Did you live with a smoker/smokers? 1. Yes 2. No		996	997	998

*** If participant does not know whether their housing is **subsidized**, ask: "Is part or all of your rent being paid by the government, a community agency, or another organization? In other words, are you receiving support to pay your rent above and beyond any income you have."*

2.1.6			**N/A**	**Refused**	**DK**
A	Location		996	997	998
B	Type of residence		996	997	998
C	Date moved in (dd/mm/yyyy)	___ ___ / ___ ___ / ___ ___ ___ ___	996	997	998
D	Date moved out (dd/mm/yyyy)	___ ___ / ___ ___ / ___ ___ ___ ___	996	997	998
	(If type of residence is a shelter, street, treatment facility, hospital or jail go to G)				
E	Was this …	1. Your own place 2. A place belonging to friends or family → Did you pay rent? 2. Yes 2. No	996	997	998
F	Was this subsidized housing? **	3. Yes 4. No	996	997	998
G	Do you remember why you moved to this place? _____ _____		996	997	998
H	Did you live with a smoker/smokers? 1. Yes 2. No		996	997	998

2.1.7			**N/A**	**Refused**	**DK**
A	Location		996	997	998
B	Type of residence		996	997	998
C	Date moved in (dd/mm/yyyy)	___ ___ / ___ ___ / ___ ___ ___ ___	996	997	998

D	Date moved out (dd/mm/yyyy)	___ ___ / ___ ___ / ___ ___ ___ ___	996	997	998
(If type of residence is a shelter, street, treatment facility, hospital or jail go to G)					
E	Was this …	1. Your own place 2. A place belonging to friends or family → Did you pay rent? 1. Yes 2. No	996	997	998
F	Was this subsidized housing? **	1. Yes 2. No	996	997	998
G	Do you remember why you moved to this place? _____ _____		996	997	998
H	Did you live with a smoker/smokers? 1. Yes 2. No		996	997	998

*** If participant does not know whether their housing is **subsidized**, ask: "Is part or all of your rent being paid by the government, a community agency, or another organization? In other words, are you receiving support to pay your rent above and beyond any income you have."*

2.1.8			**N/A**	**Refused**	**DK**
A	Location		996	997	998
B	Type of residence		996	997	998
C	Date moved in (dd/mm/yyyy)	___ ___ / ___ ___ / ___ ___ ___ ___	996	997	998
D	Date moved out (dd/mm/yyyy)	___ ___ / ___ ___ / ___ ___ ___ ___	996	997	998
(If type of residence is a shelter, street, treatment facility, hospital or jail go to G)					
E	Was this …	1. Your own place 2. A place belonging to friends or family → Did you pay rent? 1. Yes 2. No	996	997	998
F	Was this subsidized housing? **	1. Yes 2. No	996	997	998
G	Do you remember why you moved to this place? _____ _____		996	997	998
H	Did you live with a smoker/smokers? 1. Yes 2. No		996	997	998

2.1.9	**N/A**	**Refused**	**DK**

A	Location		996	997	998
B	Type of residence		996	997	998
C	Date moved in (dd/mm/yyyy)	___ ___ / ___ ___ / ___ ___ ___ ___	996	997	998
D	Date moved out (dd/mm/yyyy)	___ ___ / ___ ___ / ___ ___ ___ ___	996	997	998
	(If type of residence is a shelter, street, treatment facility, hospital or jail go to G)				
E	Was this …	1. Your own place 2. A place belonging to friends or family → Did you pay rent? 1. Yes 2. No	996	997	998
F	Was this subsidized housing? **	1. Yes 2. No	996	997	998
G	Do you remember why you moved to this place? _____ _____		996	997	998
H	Did you live with a smoker/smokers? 1. Yes 2. No		996	997	998

*** If participant does not know whether their housing is **subsidized**, ask: "Is part or all of your rent being paid by the government, a community agency, or another organization? In other words, are you receiving support to pay your rent above and beyond any income you have."*

SECTION 3 – HEALTH

3.1 SCQoL-15 SMOKING CESSATION QUALITY OF LIFE (SCQoL)

These next questions are about your health status. Please try to answer every question as accurately as you can. [REFER TO SCALE]

1 ☆	In general, would you say your health is... **1** Excellent **2** Very good **3** Good **4** Fair **5** Poor	996. N/A 997. Refused 998. D/K
2 ☆	Compared to one year ago, how would you rate your health in general now? **[REFER TO SCALE]** **1** Much Better than 1 year ago **2** Somewhat better than 1 year ago **3** About the same As 1 year ago **4** Somewhat worse now than 1 year ago **5** Much worse now than 1 year ago	996. N/A 997. Refused 998. D/K

3. The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much? [REFER TO SCALE]

A ☆	Vigorous activities such as running, lifting heavy objects, participating in strenuous sports *(If participant says s/he does not do activity, probe: Is that because of your health?)* **1** Yes, limited a lot **2** Yes, limited a little **3** No, not limited at all	996. N/A 997. Refused 998. D/K
B	…moderate activities such as moving a table, pushing a vacuum cleaner, bowling? Does your health now limit you a lot, limit you a little, or not limit you at all?(*If participant says s/he does not do activity, probe: Is that because of your health?)* **1** Yes, limited a lot **2** Yes, limited a little **3** No, not limited at all	996. N/A 997. Refused 998. D/K
C	Lifting or carrying groceries **1** Yes, limited a lot **2** Yes, limited a little **3** No, not limited at all	996. N/A 997. Refused 998. D/K
D	…climbing several flights of stairs. Does your health now limit you a lot, limit you a little, or not limit you at all? *(If participant says s/he does not do activity, probe: Is that because of your health?)* **1** Yes, limited a lot **2** Yes, limited a little **3** No, not limited at all	996. N/A 997. Refused 998. D/K
E	Climbing 1 flight of stairs? **1** Yes, limited a lot **2** Yes, limited a little **3** No, not limited at all	996. N/A 997. Refused 998. D/K
F	Bending, keeling or stooping? **1** Yes, limited a lot **2** Yes, limited a little **3** No, not limited at all	996. N/A 997. Refused 998. D/K
G	Walking more than 1 mile? **1** Yes, limited a lot **2** Yes, limited a little **3** No, not limited at all	996. N/A 997. Refused 998. D/K

H	Walking several blocks? **1** Yes, limited a lot **2** Yes, limited a little **3** No, not limited at all	996. N/A 997. Refused 998. D/K
I	Walking 1 block? **1** Yes, limited a lot **2** Yes, limited a little **3** No, not limited at all	996. N/A 997. Refused 998. D/K
j	Bathing or dressing yourself? **1** Yes, limited a lot **2** Yes, limited a little **3** No, not limited at all	996. N/A 997. Refused 998. D/K
4. The following questions that I will ask you are about your physical health and your daily activities during the past 4 weeks. [REFER TO SCALE]		
A ☆	During the **past 4 weeks**, have you cut down on the amount of work you spent on work or other activities as a result of your physical health? **1** Yes **2** No	996. N/A 997. Refused 998. D/K
B	During the **past 4 weeks**, have you accomplished less than you would like as a result of your physical health? **1** Yes **2** No	996. N/A 997. Refused 998. D/K
C	During the **past 4 weeks**, were you limited in the kind of work or other regular daily activities you do as a result of your physical health? **1** Yes **2** No	996. N/A 997. Refused 998. D/K
D	During the **past 4 weeks**, did you have difficulty performing work or other activities (for example, it took extra effort)? as a result of your physical health? **1** Yes **2** No	996. N/A 997. Refused 998. D/K
5. The following questions that I ask you are about your emotions and your daily activities during the past 4 weeks. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems? [REFER TO SCALE]		
A	During the **past 4 weeks**, did you cut down on the **amount of time** you spent on work or other activities as a result of any emotional problems, such as feeling depressed or anxious? **1** Yes **2** No	996. N/A 997. Refused 998. D/K
B	During the **past 4 weeks**, did you accomplish less than you would like as a result of any emotional problems, such as feeling depressed or anxious? **1** Yes **2** No	996. N/A 997. Refused 998. D/K

C	During the **past 4 weeks**, did you not do work or other activities as **carefully as usual** as a result of any emotional problems, such as feeling depressed or anxious? **1** Yes **2** No	996. N/A 997. Refused 998. D/K

The next questions are also about your physical and emotional health during the **past 4 weeks**. **[REFER TO SCALE]**

6 ☆	During the **past 4 weeks**, to what extent has your physical health or emotional problems interfered with you normal social activities with family, friends, neighbors, or groups? **1** Not at all **2** Slightly **3** Moderately **4** Quite a bit **5** Extremely	996. N/A 997. Refused 998. D/K
7 ☆	How much physical pain have you had during the past 4 weeks? **1** None **2** Very Mild **3** Mild **4** Moderate **5** Severe **6** Very Severe	996. N/A 997. Refused 998. D/K
8 ☆	During the **past 4 weeks**, how much did pain interfere with your normal work, including both outside and inside the home? Did it interfere. ... *(Pain refers to physical pain only)* **1** Not at all **2** Slightly **3** Moderately **4** Quite a bit **5** Extremely	996. N/A 997. Refused 998. D/K

9. The next questions are about how you feel and how things have been with you during the past 4 weeks. As I read each statement, please give me the answer that comes closest to the way you have been feeling: Is it all of the time, most of the time, a good bit of the time, some of the time, a little of the time, or none of the time? [REFER TO SCALE]

A ☆	How much of the time during the **past 4 weeks**...Did you feel full of life? **1** All of the time **2** Most of the time **3** A good bit of the time **4** Some of the time **5** A little of the time **6** None of the time	996. N/A 997. Refused 998. D/K
B	How much of the time during the **past 4 weeks**...Have you been a very nervous person? **1** All of the time **2** Most of the time **3** A good bit of the time **4** Some of the time **5** A little of the time **6** None of the time	996. N/A 997. Refused 998. D/K
C	How much of the time during the **past 4 weeks**...Have you felt so down in the dumps that nothing could cheer you up? **1** All of the time **2** Most of the time **3** A good bit of the time **4** Some of the time **5** A little of the time **6** None of the time	996. N/A 997. Refused 998. D/K
D	How much of the time during the **past 4 weeks**...have you felt calm and peaceful? **1** All of the time **2** Most of the time **3** A good bit of the time **4** Some of the time **5** A little of the time **6** None of the time	996. N/A 997. Refused 998. D/K
E	How much of the time during the **past 4 weeks**...did you have a lot of energy?	

	1 All of the time; **2** Most of the time; **3** A good bit of the time; **4** Some of the time; **5** A little of the time; **6** None of the time	996. N/A 997. Refused 998. D/K
F	How much of the time during the **past 4 weeks**...have you felt downhearted and blue? **1** All of the time; **2** Most of the time; **3** A good bit of the time; **4** Some of the time; **5** A little of the time; **6** None of the time	996. N/A 997. Refused 998. D/K
G	How much of the time during the **past 4 weeks**...Did you feel worn out? **1** All of the time; **2** Most of the time; **3** A good bit of the time; **4** Some of the time; **5** A little of the time; **6** None of the time	996. N/A 997. Refused 998. D/K
H	How much of the time during the **past 4 weeks**...Have you been a happy person? **1** All of the time; **2** Most of the time; **3** A good bit of the time; **4** Some of the time; **5** A little of the time; **6** None of the time	996. N/A 997. Refused 998. D/K
I	How much of the time during the **past 4 weeks**...Did you feel tired? **1** All of the time; **2** Most of the time; **3** A good bit of the time; **4** Some of the time; **5** A little of the time; **6** None of the time	996. N/A 997. Refused 998. D/K
10 ☆	During the **past 4 weeks**, how much of the time has your physical health or emotional problems interfered with your social activities like visiting with friends or relatives? **[REFER TO SCALE]** **1** All of the time; **2** Most of the time; **3** Some of the time; **4** A little of the time; **5** None of the time	996. N/A 997. Refused 998. D/K

11. How true or false is each of the following statements for you?

A ☆	I seem to get sick a little easier than other people **1** Definitely True; **2** Mostly True; **3** Don't Know; **4** Mostly False; **5** Definitely False	996. N/A 997. Refused 998. D/K
B	I am as healthy as anybody I know **1** Definitely True; **2** Mostly True; **3** Don't Know; **4** Mostly False; **5** Definitely False	996. N/A 997. Refused 998. D/K
C	I expect my health to get worse **1** Definitely True; **2** Mostly True; **3** Don't Know; **4** Mostly False; **5** Definitely False	996. N/A 997. Refused 998. D/K
D	My health is excellent **1** Definitely True; **2** Mostly True; **3** Don't Know; **4** Mostly False; **5** Definitely False	996. N/A 997. Refused 998. D/K

12. These questions are about how you feel and how things have been going during the past week.

For each question, please give the one answer that comes closest to the way you have been feeling during the past week:

A	**During the past week.....**Did you isolate yourself from people around you? **1** Definitely True **2** Mostly True **3** Don't Know **4** Mostly False **5** Definitely False	996. N/A 997. Refused 998. D/K
B	**During the past week.....**Did you act irritable toward those around you? **1** Definitely True **2** Mostly True **3** Don't Know **4** Mostly False **5** Definitely False	996. N/A 997. Refused 998. D/K
C	**During the past week.....**Did you get along well with other people? **1** Definitely True **2** Mostly True **3** Don't Know **4** Mostly False **5** Definitely False	996. N/A 997. Refused 998. D/K
D	**During the past week.....**Did you have difficulty concentrating? **1** Definitely True **2** Mostly True **3** Don't Know **4** Mostly False **5** Definitely False	996. N/A 997. Refused 998. D/K
E	**During the past week.....**Were you obsessed by thoughts of smoking? **1** Definitely True **2** Mostly True **3** Don't Know **4** Mostly False **5** Definitely False	996. N/A 997. Refused 998. D/K
F	**During the past week.....**Did you have difficulty thinking and solving problems? **1** Definitely True **2** Mostly True **3** Don't Know **4** Mostly False **5** Definitely False	996. N/A 997. Refused 998. D/K
G	**During the past week.....**Did you fell restless? **1** Definitely True **2** Mostly True **3** Don't Know **4** Mostly False **5** Definitely False	996. N/A 997. Refused 998. D/K
H	**During the past week.....**Did you feel anxious or worried? **1** Definitely True **2** Mostly True **3** Don't Know **4** Mostly False **5** Definitely False	996. N/A 997. Refused 998. D/K
I	**During the past week.....**Did you have difficulty remembering things? **1** Definitely True **2** Mostly True **3** Don't Know **4** Mostly False **5** Definitely False	996. N/A 997. Refused 998. D/K
13.	**During the past week did you:**	
A	**.....Have trouble falling asleep?** **1** Definitely True **2** Mostly True **3** Don't Know **4** Mostly False **5** Definitely False	996. N/A 997. Refused 998. D/K
B	**.....**Awaken during the night and have trouble falling asleep? **1** Definitely True **2** Mostly True **3** Don't Know **4** Mostly False **5** Definitely False	996. N/A 997. Refused 998. D/K
C	**.....**Have trouble staying awake during the day? **1** Definitely True **2** Mostly True **3** Don't Know **4** Mostly False **5** Definitely False	996. N/A 997. Refused 998. D/K

D	……..Get the amount of sleep you needed? **1** Definitely True **2** Mostly True **3** Don't Know **4** Mostly False **5** Definitely False	996. N/A 997. Refused 998. D/K

14. In regard to smoking, how true or false is each of the following statement for you over the past week?

A	I have very little willpower **1** Definitely True **2** Mostly True **3** Don't Know **4** Mostly False **5** Definitely False	996. N/A 997. Refused 998. D/K
B	I am in control of whether I smoke or not **1** Definitely True **2** Mostly True **3** Don't Know **4** Mostly False **5** Definitely False	996. N/A 997. Refused 998. D/K
C	I am worried that I will start smoking again **1** Definitely True **2** Mostly True **3** Don't Know **4** Mostly False **5** Definitely False	996. N/A 997. Refused 998. D/K
D	I am worried about gaining weight if I stop smoking **1** Definitely True **2** Mostly True **3** Don't Know **4** Mostly False **5** Definitely False	996. N/A 997. Refused 998. D/K
E	The urge to smoke overwhelms me **1** Definitely True **2** Mostly True **3** Don't Know **4** Mostly False **5** Definitely False	996. N/A 997. Refused 998. D/K

15. How much of a problem was each of the following in the past week?

A ☆	Lack of interest in sex 1 Not a problem **2** A little problem 3 Somewhat of a problem **4** Very much of a problem **5** Severe problem	996. N/A 997. Refused 998. D/K
B	Lack of sexual energy **1** Not a problem **2** A little problem 3 Somewhat of a problem **4** Very much of a problem **5** Severe problem	996. N/A 997. Refused 998. D/K
C	Unable to relax and enjoy sex 1 Not a problem **2** A little problem 3 Somewhat of a problem **4** Very much of a problem **5** Severe problem	996. N/A 997. Refused 998. D/K

3.2 Comorbid Conditions

Thanks so much for your cooperation in answering so many questions! In this next part I'd like to ask about certain health conditions which you may have. Here I am interested in "long-term conditions" which are expected to last or have already lasted 6 months or more and have been diagnosed by a health professional. Do you have: *(Interviewer: Code "somewhat" or similar response as "yes".)*

	Comorbid Conditions	Yes	No	N/A	Refused	DK
1	Asthma?	1	2	996	997	998
2	Chronic Bronchitis or emphysema?	1	2	996	997	998
3	TB (tuberculosis)?	1	2	996	997	998
4	Hepatitis C?	1	2	996	997	998
5	Hepatitis B?	1	2	996	997	998
6	HIV/AIDS?	1	2	996	997	998
7	Any other sexually transmitted disease (STD)?	1	2	996	997	998
8	Migraine headaches	1	2	996	997	998
9	Epilepsy or seizures?	1	2	996	997	998
10	The effects of a stroke?	1	2	996	997	998
11	Alzheimer's disease or dementia?	1	2	996	997	998
12	Back problems?	1	2	996	997	998
13	Dental problems?	1	2	996	997	998
14	Foot problems?	1	2	996	997	998
15	Skin problems?	1	2	996	997	998
16	Lice, scabies, bed bugs or similar infestations?	1	2	996	997	998
17	Arthritis (joint problems)?	1	2	996	997	998
18	An ulcer (stomach or intestine)?	1	2	996	997	998
19	Bowel problems (such as Crohn's disease or colitis)?	1	2	996	997	998
20	Kidney or bladder trouble?	1	2	996	997	998
21	An inability to hold urine (urinary incontinence)?	1	2	996	997	998
22	High blood pressure?	1	2	996	997	998
23	A thyroid condition?	1	2	996	997	998
24	Heart disease?	1	2	996	997	998
25	Diabetes?	1	2	996	997	998
26	Liver disease (other than hepatitis)?	1	2	996	997	998
27	Cancer?	1	2	996	997	998
28	Low iron in the blood (anemia)	1	2	996	997	998

29	Do you have gynecological problems? (FEMALES ONLY)	1	2	996	997	998
30	Are you pregnant? (FEMALES ONLY?)	1	2	996	997	998
31	Do you have ANY other serious medical condition? If YES, what is it? _____	1	2	996	997	998
32	Interviewer Observations. *Record any observable physical health problems* _____ _____ _____					

3.3 Traumatic Brain Injury

1	Have you ever had an injury to the head which knocked you out or left you dazed, confused or disoriented? *If Yes, ask 2, 3, and 4. If NO skip to 3.4* **1** Yes **2** No **(Skip to 3.4)**	996. N/A 997. Refused 998. D/K
2	How many injuries like this have you had over your lifetime? _____	996. N/A 997. Refused 998. D/K
3	Were you, in fact, knocked out or unconscious after [this head injury (if 1) / or any of these head injuries (if>1)]? **1** Yes **2** No **(Skip to 3.4)**	996. N/A 997. Refused 998. D/K
4	About how long were you unconscious or knocked out after [this head injury (if 1) / these head injuries (if >1)]? *Enter in hours and part hours with a decimal point and two places of decimal e.g. 4.45 hours. If >this # of injuries ask about duration for most recent to previous.* **1** First Injury ____ **2** Second Injury ____ **3** Third Injury ____ **4** Fourth Injury ____ **5** Fifth Injury ____	996. N/A 997. Refused 998. D/K

3.4 Mental Health

1	Have you ever been diagnosed with a mental health problem? **1** Yes **2** No **(Skip to 3.5)**	996. N/A 997. Refused 998. D/K
2	Can you tell me what was or were the mental health problems? *Do not read list. Check all that apply* **1** Bipolar Disorder **2** Depression/ Major Depression/ Dysthymia **3** Developmental or Intellectual Deficiency **4** Generalized Anxiety Disorder **5** Manic Disorder **6** Obsessive-Compulsive Disorder 7 Panic Disorder **8** Personality Disorder **9** Schizophrenia **10** Psychotic Disorder Other than Schizophrenia **11** Phobia **12** Post Traumatic Stress Disorder (PTSD) **13** If other, specify: _____	996. N/A 997. Refused 998. D/K

3.5 Colorado Symptom Index

Now I am going to ask you about some mental health problems or issues that you might have had in the past month. Some of these questions may seem personal, if you choose not to answer any of them just let me know. Your answers will be kept strictly confidential. This includes [month/date to month/date]. The answer choices are on this card. *(Read out choices once).*

	[REFER TO SCALE] 	Not at all	Once during the month	Several times during the month	Several times a week	At least every day	N/A	Refused	DK
A	In the past month, how often have you felt nervous, worried, or frustrated?	1	2	3	4	5	996	997	998
B	In the past month, how often have you felt depressed?	1	2	3	4	5	996	997	998
C	In the past month, how often have you felt lonely?	1	2	3	4	5	996	997	998
D	In the past month, how often have others told you that you acted "paranoid" or "suspicious"?	1	2	3	4	5	996	997	998
E	In the past month, how often did you hear voices, or hear or see things that other people didn't think were there?	1	2	3	4	5	996	997	998
F	In the past month, how often did you have trouble making up your mind, or deciding about something?	1	2	3	4	5	996	997	998
G	In the past month, how often did you have trouble thinking straight, concentrating, or remembering?	1	2	3	4	5	996	997	998
H	In the past month, how often did you feel that your behaviour or actions were strange or different from that of other people?	1	2	3	4	5	996	997	998
I	In the past month, how often did you feel out of place or like you did not fit in?	1	2	3	4	5	996	997	998
J	In the past month, how often did you forget important things?	1	2	3	4	5	996	997	998
K	In the past month, how often did you have problems with thinking too fast (thoughts racing)?	1	2	3	4	5	996	997	998
L	In the past month, how often did you feel suspicious or paranoid?	1	2	3	4	5	996	997	998
M	In the past month, how often did you feel like hurting or killing yourself? *Once during the month or more indicates a safety concern; contact participant's case worker.*	1	2	3	4	5	996	997	998
N	In the past month, how often have you felt like seriously hurting someone else? *Once during the month or more indicates a safety concern; contact respondent's case worker.*	1	2	3	4	5	996	997	998

3.6 Access to Care Thank you again for your answers so far. Now a few questions about access to healthcare.

1	Do you have a regular medical doctor? (by regular medical doctor we mean a family doctor or GP who is familiar with you and your medical history) **1** Yes **(Skip to 2)** **2** No	996. N/A 997. Refused 998. D/K

1.a	Why do you not have a regular medical doctor? *Do not read list: record all that apply* **1** No medical doctors available in the area **2** Medical doctors in the area not taking new patients **3** Have not tried to contact one **4** Had a medical doctor who left or retired **5** Seldom or never get sick **6** Recently moved into the area **7** Likes to go to different places for different health needs **8** Have moved around a lot (within the area) **9** D/K where to go for care **10** Don't use doctors/ treat myself **11** Don't have a health card **12** Don't have a telephone number **13** Have had negative experience(s) with doctors in the past **14** Too busy finding food, shelter or other necessities **15** Have no transportation **16** The wait for an appointment is too long **17** Clinic hours are inconvenient **18** Usual source of health care in the area is no longer available **19** Other, specify: _____	996. N/A 997. Refused 998. D/K
2	Is there a place that you usually go to when you are sick or need advice about your health? *If Yes, ask 2.a; if NO, Skip to 3.* **1** Yes **2** No **(Go to 3)**	996. N/A 997. Refused 998. D/K
2.a	What kind of place is it? Give examples from your site. If the Participant indicates more than one usual place, then ask: What kind of place do you go to most often? **1** Doctor's office **2** Community health Centre **3** Walk-in clinic (where you need to show ID) **4** Health clinic (requiring an appointment) **5** Telephone health line **6** Hospital emergency room 7 Outpatient clinic **8** Health clinic at a shelter, hostel, drop in, etc. **9** Aboriginal health centre **10** Alternative heal centre (e.g. naturopath, Chinese medicine clinic) **11** Other, specify: _____	996. N/A 997. Refused 998. D/K
3	In the past 6 months, was there ever a time when you felt that you needed health care but you didn't receive it? *If Yes, ask 3.a. If NO go to Section 4* **1** Yes **2** No **(Skip to 4)**	996. N/A 997. Refused 998. D/K
3.a	Thinking of the most recent time. Why didn't you get care? *Do not read list. Enter all that apply based on participant's response.* **1** Health care was too far away **2** The wait for an appointment was too long **3** Cost **4** Didn't know where to go **5** Language barriers **6** Dislike/mistrust doctors/ afraid **7** Doctor didn't think it was necessary **8** Didn't have a phone number **9** Too busy for other reasons **10** Looking for work **11** Was too depressed/ not up for going **12** Don't have a family doctor **13** Addiction Issues **14** Not available at time required (e.g. doctor on holidays, inconvenient hours) **15** Felt would be inadequate **16** Didn't get around to it/didn't bother **17** Had no transportation **18** Personal or family responsibilities **19** Decided not to seek care **20** Didn't have health card **21** Was too busy finding food, shelter or other necessities **22** Couldn't get time off work **23** Couldn't get child care **24** Was refused services **25** Negative past experiences, treated poorly or with disrespect by HC provider **26** If other, specify: _____	996. N/A 997. Refused 998. D/K

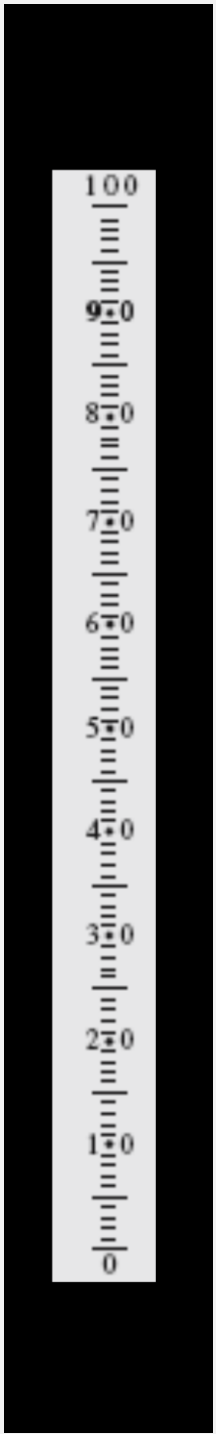
3.7 Vas Scale

To help people say how good or bad their state of health is, we have drawn a scale (rather like a thermometer) in which the best state you can imagine is marked 100 and worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point in the scale indicates how good or bad your state of health is today (*Ask participant to say the number and record it next to the scale*).

996. N/A
997. Refused
998. D/K

Your own state of health today



Section 4: Substance Abuse

4.1 DAST

The following questions concern information about your potential involvement with drugs NOT including alcoholic beverages during the past 12 months. When the words "drug use" are utilized, they refer to the use of prescribed or over-the-counter drugs in excess of the directions, and any nonmedical use of drugs. The various classes of drugs may include cannabis (marijuana, hashish), solvents (paint thinner), tranquilizers (Valium), barbiturates, cocaine, stimulants (speed), hallucinogens (LSD), or narcotics (heroin). Remember that the questions do not include alcoholic beverages.

		Yes	No	N/A	Refused	DK
A	In the **past 12 months**, have you used drugs other than those required for medical reasons?	1	2 **(Skip to 5.3)**	996	997	998
B	In the **past 12 months**, did you use more than one drug at a time?	1	2	996	997	998
C	In the **past 12 months**, were you always able to stop using drugs when you wanted to?	1	2	996	997	998
D	In the **past 12 months**, have you had 'blackouts' or 'flashbacks' as a result of drug use?	1	2	996	997	998
E	In the **past 12 months**, did you ever feel bad or guilty about your drug use?	1	2	996	997	998
F	In the **past 12 months**, have you had any contact with your partner (or spouse or parents)?	1	2 **(Skip to H)**	996	997	998
G	If **YES**, did your partner (or spouse or parents) ever complain about your involvement with drugs?	1	2	996	997	998
H	In the **past 12 months**, have you neglected your family because of your use of drugs?	1	2	996	997	998
I	In the **past 12 months**, have you engaged in illegal activities - other than buying the drugs - in order to obtain drugs?	1	2	996	997	998
J	In the **past 12 months**, have you ever experienced withdrawal symptoms (felt sick) when you stopped taking drugs?	1	2	996	997	998
K	In the **past 12 months**, have you had medical problems as a result of your drug use (e.g., memory loss, convulsions, bleeding)?	1	2	996	997	998

4.2 Gain-SPS Next we'll go over a list of common problems related to alcohol or other drug use. After each of the following questions, we would like you to tell us the last time you had this problem. Answer whether it was in the past month, 2 to 12 months ago, 1 or more years ago, or never. *Alcohol includes all alcoholic beverages. Other drugs includes street drugs, and any non-medical use of prescription-type drugs. It does not include prescription drugs used under the direction of a doctor* **[REFER TO SCALE]**

[REFER TO SCALE]

		Past month	2-12 months ago	1 or more years ago	Never	N/A	Refused	Don't know
1	When was the last time that you used alcohol or other drugs weekly or more often?	1	2	3	4	996	997	998
2	When was the last time that you kept using alcohol or drugs even though it was causing social problems, leading to fights, or getting you into trouble with other people?	1	2	3	4	996	997	998
3	When was the last time that your use of alcohol or other drugs caused you to give up, reduce orhave problems at important activities at work, school, home or social events?	1	2	3	4	996	997	998
4	When was the last time that you spent a lot of time either getting alcohol or other drugs, using alcohol or other drugs, or feeling the effects of alcohol or other drugs (high, sick)?	1	2	3	4	996	997	998
5	When was the last time that you had withdrawal problems from alcohol or other drugs like shaky hands, throwing up, having trouble sitting still or sleeping, or you used any alcohol or other drugs to stop being sick or avoid withdrawal problems? *If Participant answers Never to 1 through 5, enter N/A for 6 and 7, ask 8 and 9 and enter 996 for N/A for the remainder of the items on this questionnaire*	1	2	3	4	996	997	998
6	When was the last time your alcohol or other drug use caused you to have numbness, tingling, shakes, blackouts, hepatitis, TB, sexually transmitted disease, or any other health problems?	1	2	3	4	996	997	998
7	When was the last time that your alcohol or other drug use caused you to have repeated problems with the law?	1	2	3	4	996	997	998
8	How old were you when you FIRST got drunk? _____							996. N/A 997. Refused 998. D/K
9	How old were you when you FIRST used drugs? _____							996. N/A 997. Refused 998. D/K
10	How much money would you say you spent during the past 30 days on alcohol? *Enter in dollars and round up to the nearest dollar.* _____							996. N/A 997. Refused 998. D/K
11	How much money would you say you spent during the past 30 days on drugs? (Not counting prescription drugs). *Enter in dollars and round up to the nearest dollar.* _____							996. N/A 997. Refused 998. D/K
12	How many days in the past 30 have you experienced alcohol problems? By problems we mean: craving, withdrawal symptoms, disturbing effects of use, or wanting to stop and being unable to. _____							996. N/A 997. Refused 998. D/K
13	How many days in the past 30 have you experienced drug problems? By problems we mean: craving, withdrawal symptoms, disturbing effects of use, or wanting to stop and being unable to. _____							996. N/A 997. Refused 998. D/K

4.3 Smoking. The following questions are about smoking tobacco

A ☆

On a scale from 1-10, how important is it for you to quit/reduce smoking? **[REFER TO SCALE]**

0 Not at all | 1 | 2 | 3 | 4 | 5 Average importance | 6 | 7 | 8 | 9 | 10 Extremely Important

996. N/A
997. Refused
998. D/K

B

What age were you when you first started using tobacco? **[REFER TO SCALE]**

1 < 7yo | 2 7 – 10 yo | 3 12 – 18 yo | 4 18-29 yo | 5 > 29 yo

996. N/A
997. Refused
998. D/K

C

Do you smoke inside your home/ apartment/ residence?

1 Yes | 2 No, I am not permitted to smoke in my room | 3 No, I smoke outdoors

996. N/A
997. Refused
998. D/K

D

How many times a week do you wake up in the night to smoke? **[REFER TO SCALE]**

1 Never | 2 1-3/ week | 3 4-6/ week | 4 Every night

996. N/A
997. Refused
998. D/K

E

How many times have you tried to quit smoking? **[REFER TO SCALE]**

1 Never | 2 1 - 3 | 3 3 - 6 | 4 > 6

996. N/A
997. Refused
998. D/K

F

What is the longest period of time you have stopped smoking? **[REFER TO SCALE]**

1 One hour | 2 One Day | 3 2 – 14 days | 4 15 – 30 days | 5 1 – 12 months | 6 > 1 year

996. N/A
997. Refused
998. D/K

G ☆

What was helpful for quitting smoking in the past? **[REFER TO SCALE]**

Check all that apply:

1 Nothing, I did it on my own | **2** Support from friends & family | **3** Support from a health professional | **4** Medications (oral) | **5** Nicotine replacement therapy (patch, gum, inhaler etc)

6 Support group | 7 Other (specify)

996. N/A
997. Refused
998. D/K

H ☆

What do you think would be helpful this time?

Check all that apply:

1 Nothing, I did it on my own | **2** Support from friends & family | **3** Support from a health professional | **4** Medications (oral) | **5** Nicotine replacement therapy (patch, gum, inhaler etc)

996. N/A
997. Refused
998. D/K

	6 Other (Specify)	
I ☆	If you have been able to stop smoking in the past, what led to relapse? *Check all that apply:* **1** I don't know; **2** Little support from friends & family; **3** Some of my friends smoke; **4** Anxiety/ Stress; **5** Depression **6** Other (Specify)	996. N/A 997. Refused 998. D/K
J	How soon after you wake up do you smoke your first cigarette? **[REFER TO SCALE]** 1 Within 5 minutes; 2 5-30 minutes; 3 31-60 minutes; 4 After 60 minutes	996. N/A 997. Refused 998. D/K
K	Do you find it difficult not to smoke in places where you shouldn't, such as in church or school, in a movie, at the library, on a bus, in court or in a hospital? 1 Yes; 2 No	996. N/A 997. Refused 998. D/K
L	Which cigarette would you most hate to give up; which cigarette do you treasure the most? 1 The first one in the morning; 2 Any other one	996. N/A 997. Refused 998. D/K
M	How many cigarettes do you smoke each day? 1 10 or fewer; 2 11-20; 3 21-30; 4 31 or more	996. N/A 997. Refused 998. D/K
N	Do you smoke more during the first few hours after waking up than during the rest of the day? 1 Yes; 2 No	996. N/A 997. Refused 998. D/K
O	Do you still smoke if you are so sick that you are in bed most of the day, or if you have a cold or the flu and have trouble breathing? 1 Yes; 2 No	996. N/A 997. Refused 998. D/K
P	Do you live or are you currently staying someplace that limits when and where you are allowed to smoke? (for example, a hospital, shelter, supervised boarding home). 1 Yes; 2 No	996. N/A 997. Refused 998. D/K
Q ☆	Please check the box next to any statement that describes your smoking practices: **[REFER TO SCALE]** 1 I share cigarettes; 2 I smoke cigarettes remade from discarded cigarette butts and filters; 3 I smoke cigarettes remade by others (not by the regular tobacco companies); 4 I smoke discarded cigarette butts; 5 I block filter vents or tear off filters	996. N/A 997. Refused 998. D/K
R ☆	Please check the box next to the one statement that best describes your current situation: **[REFER TO SCALE]** 1 I am seriously considering quitting in the next 6 months but not in; 2 I am interested in drastically reducing the number of cigarettes I currently smoke (reducing by half or more), ; 3 I am interested in quitting smoking/tobacco use in the next month and I would be interested in; 4 I currently smoke/use tobacco and I do not want to quit in the next 6	996. N/A 997. Refused 998. D/K

the next 30 days	but am not interested in quitting totally	any assistance I could get	months

S	During the past 12 months, did any health professional advise you to stop smoking for more than 1 day? 1 Yes 2 No	996. N/A 997. Refused 998. D/K
T ☆	On a scale from 1-10, how confident are you that you will succeed in stopping your tobacco use? (**REFER TO SCALE)** 0 Not at all 1 2 3 4 5 Average confidence 6 7 8 9 10 Extremely confident	

5. Quality of Life Inventory 20 Now I'll read a list of things about your life overall. I recognize that some of these things may be hard to talk about for some people so I appreciate your patience. For each item, I'd like you to tell me how you feel, on a scale of 1 to 7, where 1=terrible and 7=delighted.

[REFER TO SCALE] ☆		Terrible	Unhappy	Mostly dissatisfied	Neither dissatisfied nor satisfied	Mostly satisfied	Pleased	Delighted	N/A	Refused	DK
A	How do you feel about your family in general?	1	2	3	4	5	6	7	996	997	998
B	How do you feel about how often you have contact with your family?	1	2	3	4	5	6	7	996	997	998
C	How do you feel about the way you and your family act toward each other?	1	2	3	4	5	6	7	996	997	998
D	How do you feel about the way things are in general between you and your family?	1	2	3	4	5	6	7	996	997	998
E	How do you feel about how comfortable and well off you are financially?	1	2	3	4	5	6	7	996	997	998
F	How do you feel about the amount of money you have available to spend for fun?	1	2	3	4	5	6	7	996	997	998
G	How do you feel about the way you spend your spare time?	1	2	3	4	5	6	7	996	997	998
H	How do you feel about the amount of time you have to do the things you want to do?	1	2	3	4	5	6	7	996	997	998
I	How do you feel about the chance you have to enjoy pleasant or beautiful things?	1	2	3	4	5	6	7	996	997	998
J	How do you feel about the amount of fun you have?	1	2	3	4	5	6	7	996	997	998
K	How do you feel about the amount of relaxation in your life?	1	2	3	4	5	6	7	996	997	998
L	How do you feel about the living arrangements where you live?	1	2	3	4	5	6	7	996	997	998
M	How do you feel about how safe you are in your neighbourhood?	1	2	3	4	5	6	7	996	997	998
N	How do you feel about how safe you are	1	2	3	4	5	6	7	996	997	998

	where you live?										
O	How do you feel about the chance of finding someone to help in an emergency?	1	2	3	4	5	6	7	996	997	998
P	How do you feel about your personal safety?	1	2	3	4	5	6	7	996	997	998
Q	How do you feel about the things you do with other people?	1	2	3	4	5	6	7	996	997	998
Now two questions about relationships.											
R	Do you have a close confidante, that is, someone you can share sensitive personal information with? *Health, social service or other providers do not count as close confidantes.*					1 Yes	2 No **(Skip to 8)**		996	997	998
S	Do you see this person at least once a month? 'See' can include having contact on the phone or online as well as seeing the confidante in person.					1 Yes	2 No		996	997	998

SECTION 6 – Community Integration

I am now going to ask you how often you have been involved in different kinds of community activities during the **past month**. Please give me the word that best describes how frequently you have participated in the following community activities.

6.1 Physical Integration Scale. In the past month, how many times have you:

	[REFER TO SCALE] 	Never	Rarely	Sometimes	Often	Very Often	N/A	Refused	DK
A	Attended a movie or concert?	1	2	3	4	5	996	997	998
B	Participated in outside sports or recreation?	1	2	3	4	5	996	997	998
C	Gone to meet people at a restaurant or coffee shop?	1	2	3	4	5	996	997	998
D	Participated in a community event?	1	2	3	4	5	996	997	998
E	Gone to a place of worship or participated in a spiritual ceremony?	1	2	3	4	5	996	997	998
F	Participated in a volunteer activity?	1	2	3	4	5	996	997	998
G	Gone to a library?	1	2	3	4	5	996	997	998

6.2 Psychological Integration Scale (Sense of Belonging) The next four questions are about how you feel about where you live. Here the answer choices are from 1 to 5, where 1 is Strongly Disagree and 5 is Strongly Agree.

	[REFER TO SCALE] ★	Strongly disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly agree	N/A	Refused	DK
A	I know most of the people who live near me. *("Near me" is intended to be Participant-defined but if they press you can indicate that it means "in their building and the immediate area nearby)*	1	2	3	4	5	996	997	998
B	I interact with the people who live near me	1	2	3	4	5	996	997	998
C	I feel at home where I live	1	2	3	4	5	996	997	998
D	I feel like I belong where I live	1	2	3	4	5	996	997	998

Section 7: Multnomah Community Ability Scale

Now rate the MCAS items based on all of the information from the screening interview, this interview, and your observations [GENERATE REPORT]. If you need to use the probes for a few items, explain that you just need to clarify a couple of things to finish up the interview.

1 Physical health *How impaired is the participant by his/her health status?*

1	2	3	4	5
Extreme health impairment (Major medical problem that precludes participant's participation in most daily activities)	Marked health impairment (Major medical problem that interferes with most of participant's activities, e.g. multiple sclerosis that requires use of walker)	Moderate health impairment (Medical problem that interferes some with participant's activities, e.g. an uncontrolled seizure condition)	Slight health impairment (e.g., Controlled seizure condition or recent tooth abscess)	No health impairment

2 Intellectual functioning *What is the participant's level of general intellectual functioning?*

1	2	3	4	5
IQ < 60, Extremely low intellectual functioning (Not literate)	IQ in the 60's, Moderately low intellectual functioning (Mild mental retardation or has literacy problems or major deficits in orientation)	IQ in the 70's, Low intellectual functioning (Borderline intellectual functioning; very limited conceptual thinking; 2 or more deficits in orientation)	IQ in the 80's, Slightly low intellectual functioning (Low average IQ; mild deficits in organization)	IQ in the 90's and above, Normal or above intellectual functioning (Well oriented; cognitive skills demonstrated in interview)

3 Thought processes/psychosis *How impaired are the participant's thought processes as evidenced by such symptoms as hallucinations, delusions, tangentiality, loose associations, response latencies, ambivalence, incoherence, etc.?*

1	2	3	4	5
Extremely impaired though processes (Speech word salad or inability to focus on anything but psychotic ideas)	Markedly impaired thought processes (Speech which is difficult to follow or preoccupation with psychotic ideas)	Moderately impaired thought processes (Hallucinations, delusions, or disorganization which interfere with functioning some of the time)	Slightly impaired thought processes (Mild hallucinations or disorganized thinking or occasional delusional thinking)	No impairment, normal thought processes

4 Mood abnormality *How abnormal is the participant's mood as evidenced by such symptoms as constricted mood, extreme mood swings, depression, rage, mania, etc.?*

1	2	3	4	5
Extremely abnormal mood (Despondence or uncontrolled mania or rage)	Markedly abnormal mood (Mania or marked irritability or severe depression)	Moderately abnormal mood (Moderate depression or marked blunted affect or significant irritability or passive suicidal ideation)	Slightly abnormal mood (Mild depression or mild blunted affect or mild irritability)	No impairment, normal mood

5 Response to stress and anxiety *How impaired is the participant by inappropriate and/or dysfunctional responses to stress and anxiety?*

1 Extremely impaired response (Extreme reactiveness to stressors, from acting out to paralysis, resulting in inability to adapt)	2 Markedly impaired response (Marked reactiveness; very limited problem solving in response to stress; need for large amount of support and intervention from others; daily panic attacks or severe anxiety)	3 Moderately impaired response (Moderately reactive to stress; needs assistance in order to cope)	4 Slightly impaired response (Somewhat reactive to stress; has some coping skills; responsive to limited intervention)	5 Normal response

6 Ability to manage money *How successfully does the participant manage his/her money and control expenditures?*

1 Almost never manages money successfully (Only manages pocket money)	2 Seldom manages money successfully (Only manages money which is handed out daily)	3 Sometimes manages money successfully (Money doled out weekly by supervised housing or family; can buy food, cigarettes and manage that money okay; or, manages money on own, but with difficulty)	4 Manages money successfully a fair amount of the time (Does more than a 3 rating, i.e., pays for rent, treatment, or other bills by self; or, manages all monthly bills with assistance)	5 Almost always manages money successfully (Generally independent in managing money)

7 Independence in daily living *How well does the participant perform independently in day-to-day living? ADL = activities of daily living*

1 Almost never performs independently (Minimal to no ADLs even with repeated staff interventions)	2 Often does not perform independently (Completes only some ADLs, even with prompt and direction)	3 Sometimes performs independently (Needs consistent prompts for ADLs, but usually does complete most of them)	4 Often performs independently (May need occasional prompts or has difficulty in one area of ADLs)	5 Almost always performs independently

8 Acceptance of illness *How well does the participant accept (as opposed to deny) his/her psychiatric disability?*

1 Almost never accepts disability (Adamantly denies illness and need for treatment)	2 Infrequently accepts disability (Consistently misunderstands illness or symptoms)	3 Sometimes accepts disability (Some denial evident in attributing problems to external factors or minimizing seriousness or denying specific symptoms)	4 Accepts disability a fair amount of the time (Much of the time acknowledges having an illness and/or some specific symptoms)	5 Almost always accepts disability (Identifies illness and symptoms consistently)

9 Social acceptability *In general, what are other people's reactions to the participant?*

1 Very negative (Consistently elicits avoidant reaction from others)	2 Fairly negative (Presentation elicits some negative reaction from others)	3 Mixed, mildly negative to mildly positive	4 Fairly positive (Presentation slightly impaired, but can navigate in public without attracting negative attention)	5 Very positive (No outward appearance of mental illness or impairment)

10	Social interest *How frequently does the participant initiate social contact or respond to other's initiation of social contact?*				
	1 Very infrequently (Almost never participates in social activities; usually avoids available social situations)	2 Fairly infrequently (Limited response to invitation or opportunity for social interaction; does not go on recreation outings; e.g., passive interation with others when smoking)	3 Occasionally (Sometimes initiates and responds to social activities; e.g., goes on outings with program which are arranged by staff, may have some withdrawal from others)	4 Fairly frequently (Respond consistently and initiates occasionally; e.g., has some social contacts outside of activities which are organized by staff)	5 Very frequently (Ongoing initiation and responses to social interactions; e.g., actively maintains social activities outside of household)
11	Social effectiveness *How effectively does the participant interact with others?*				
	1 Very ineffectively (Lacking in almost any social skills; inappropriate response to social cues)	2 Ineffectively (Uses only minimal social skills, can not engage in give-and-take of instrumental or social conversations; limited response to social cues)	3 Mixed or dubious effectiveness (Marginal social skills, not always appropriate)	4 Effectively (Is generally able to carry out social interactions with minor deficits, can generally engage in give-and-take conversation with only minor disruption)	5 Very effectively (Social skills are within the normal range)
12	Social network *How extensive is the participant's social support network?*				
	1 Very limited network (Nobody)	2 Limited network (Family member or case manager)	3 Moderately extensive network (Family member AND: case manager, friend, or socialization group)	4 Extensive network (Family member and case manager AND: friend or socialization group)	5 Very extensive network (Most of the above and close friends or a partner with some experience of intimacy)
13	Meaningful activity *How frequently is the participant involved in meaningful activities that are satisfying to him or her? (Rate the participant's perception)*				
	1 Almost never involved (Does nothing outside of meeting basic needs)	2 Seldom involved (May be involved in some passive activities with little enthusiasm)	3 Sometimes involved (Does passive activities such as listening to music, watching TV, with some enthusiasm; at day program, has only passive involvement or skips groups)	4 Often involved (Has some constructive activities with others which are identified as meaningful; active involvement at day program, may include part-time sheltered work activity at day program)	5 Almost always involved (Consistently involved in an interactive activity like work, school, or volunteering outside of a sheltered psychiatric setting)
14	Medication compliance *How frequently does the participant comply with his/her prescribed*				

medication regimen? Note: if participant has NOT agreed to take offered medication in the HF intervention , pick "N/A" except at baseline when a rating is needed.

1	2	3	4	5
Almost never complies	Infrequently complies (Does not take medication independently; staff directly monitors self-administration of all medications)	Sometimes complies (Takes medication on own, but misses frequently and/or needs periodic checks, monitoring, or help with packing medications)	Usually complies (Takes medication perfectly with prompting, or takes medication on their own, but misses occasionally)	Almost always complies (Takes medication completely independently or compliantly)

15 Cooperation with treatment providers *How freq does the participant cooperate, e.g., with appts., complying with tx plans, and following through on reasonable requests? Note: If participant has NOT agreed to take tx in the HF intervention gp then use NA except at baseline.*

1	2	3	4	5
Almost never cooperates (Does not cooperate at all with treatment plans or keep appointments)	Infrequently cooperates (Non-compliant with treatment efforts; does not follow daily schedule, though may keep some appointments)	Sometimes cooperates (Follows through some of the time with daily schedule or other treatment activities; is minimally involved in treatment planning)	Usually cooperates (Usually keeps doctor's appointments and attends day programs on scheduled days; involved in treatment planning)	Almost always cooperates (Rarely misses appointments or scheduled activities, actively engaged in treatment planning/goal setting)

16 Alcohol/drug abuse *How frequently does the participant abuse drugs and/or alcohol?*

1	2	3	4	5
Frequently abuses (Drug/alcohol dependence; daily abuse of alcohol or drugs which causes severe impairment of functioning; inability to function in community secondary to alcohol/drug abuse)	Often abuses (Recurrent use of alcohol or abuse of drugs which causes significant effect on functioning)	Sometimes abuses (Some use of alcohol or abuse of drugs with some effect on functioning)	Infrequently abuses (Occasional use of alcohol or abuse of drugs without impairment)	Almost never abuses (Abstinence; no use of alcohol or drugs during rating period)

17 Impulse control *How frequently does the participant exhibit episodes of extreme acting out?*

1	2	3	4	5
Frequently acts out (Frequent and/or severe acting out behavior; e.g., behaviors which could lead to criminal charges)	Acts out fairly often (Impulsive acts which are fairly often and/or of moderate severity)	Sometimes acts out (Some acting out behavior; moderate severity; at least one episode of behavior that is dangerous or threatening)	Infrequently acts out (Maybe one or two lapses of impulse control; minor acting out, such as attention-seeking behavior which is not threatening or dangerous)	Almost never acts out (No noteworthy incidents)

SECTION 8 – INTERVIEWER'S COMMENTS – As soon as the participant has left, please rate his/her orientation to the interview on a scale of 1 to 5 where 1 is very poor and 5 is very good on the following items

8.1		Very poor	Poor	Average	Good	Very good
A	Interest	1	2	3	4	5
B	Cooperation	1	2	3	4	5
C	Ability to understand	1	2	3	4	5
D	Ability to recall	1	2	3	4	5
E	Ability to formulate/articulate a response	1	2	3	4	5
F	Sincerity/Truthfulness	1	2	3	4	5

8.2	Did the participant show any signs of difficulty in reading the response cards/calendar? 1 No 2 Some 3 A lot
8.3	Did the Participant show any signs of drug or alcohol intoxication during the interview 1 No 2 Some 3 A lot
8.4	Did the Participant show any signs of psychotic symptoms 1 No 2 Some 3 A lot
8.5	How confident are you in the overall validity of the information collected in this interview? 1 Completely confident 2 Some Doubts 3 No Confidence
8.6	Other comments. _____ _____ _____ _____

END OF THE SURVEY - PLEASE REMEMBER TO:

- ❑ Double check that you have the signed consent form

After participant leaves:

- ❑ Fill in the survey number on each page of the questionnaire
- ❑ Fill in start, finish, and total time on the first page of the questionnaire

Appendix D NRT Dosing

NRT mg Dosing Totals for SC-R (n=29) and SC+ (n=32)

Patches-R	Patches=+	Lozenges-R	Lozenges-+	Gum-R	Gum-+	Inhaler-R	Inhaler-+	All NRT-SC-R	All NRT-SC+
NRT mg	NRT mg	NRT mg	NRT mg	NRT mg	NRT mg	NRT mg	NRT mg	NRT mg	NRT mg
54460	51065	5168	7910	13496	24096	9761	6700	**82,885**	**89,771**
								2,858 (average dose per participant)	2,805 (average dose per participant)

NRT mg Dosing Totals for SC-R (n=29) and SC+ (n=32)