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Cancer-Related Disease Factors and Smoking Cessation Treatment: Analysis of an Ongoing Clinical Trial

Allison J. Carroll, MS[1], **Anna K. Veluz-Wilkins, MA**[1], **Sonja Blazekovic, BA**[2], **Ravi Kalhan, MD**[1], **Frank T. Leone, MD**[2], **E. Paul Wileyto, PhD**[2], **Robert A. Schnoll, PhD**[2], and **Brian Hitsman, PhD**[1,*]

[1]Northwestern University Feinberg School of Medicine

[2]University of Pennsylvania Perelman School of Medicine

Abstract

Objective—Smoking cessation treatment should be an important aspect of cancer care. In this study, we evaluated whether cancer-related disease factors adversely influence smoking cessation treatment.

Methods—Smokers with cancer (within 5 years of diagnosis, any tumor site) were recruited for an ongoing trial of varenicline for smoking cessation. Disease factors, assessed at baseline, included tumor site, cancer treatment, time since diagnosis, and health-related quality of life (HRQOL). Medication adherence was defined by 132 of 165 pills taken and counseling adherence was defined by 4 of 4 behavioral counseling sessions attended. Abstinence was bioverified at Week 12. Using logistic regression analysis, we assessed the relationship between disease factors and 12-week medication adherence, counseling adherence, and abstinence.

Results—Of 144 participants, 56% were medication adherent, 74% were counseling adherent, and 39% were abstinent. HRQOL predicted medication adherence (OR: 1.08, 95% CI: 1.01-1.16, p=.019, d=0.20), but not counseling adherence or 12-week abstinence. Tumor site, cancer treatment, and time since diagnosis did not predict any smoking cessation treatment outcomes.

Conclusions—Cancer-related disease factors did not predict cancer survivors' engagement or success in smoking cessation treatment. Findings support National Comprehensive Cancer Network Clinical Practice guidelines that recommend smoking cessation treatment for all smokers with cancer, regardless of time since diagnosis.

Keywords

smoking cessation; oncology; cancer; cancer survivors; treatment adherence; varenicline; clinical trial

*Corresponding Author: Brian Hitsman, PhD; b-hitsman@northwestern.edu; Phone: 312-503-2074; Fax: 312-908-9588; Address: 680 N. Lake Shore Drive Ste 1400, Chicago IL 60611.

Conflict of interest: Dr. Schnoll and Dr. Hitsman receive medication and placebo free from Pfizer, and Dr. Schnoll has provided consultation to Pfizer and GlaxoSmithKline. Aside from providing the medication and placebo, these companies had no involvement in this study.

Background

Tobacco use is known to cause cancer in at least 13 sites, and ~30% of all cancer deaths are attributable to tobacco use [1]. Between 20-50% of adults diagnosed with cancer are smokers at the time of diagnosis [2, 3], and ~15% of cancer survivors are smokers [4, 5]. A cancer diagnosis can be a teachable moment for smoking cessation [6], as evidenced by higher quit rates among adults with a cancer diagnosis [3, 7]. Unfortunately, even if they initially quit smoking, smokers diagnosed with cancer have particularly high rates of relapse, and an estimated 50% of smokers continue to smoke after receiving a cancer diagnosis [8]. Cancer survivors who continue to smoke are less adherent to cancer treatment [9, 10] and have worse cancer outcomes [11, 12].

The National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines for tobacco cessation, established in 2015, recommend that all patients with cancer who smoke are provided with evidence-based pharmacotherapy (especially combination nicotine replacement therapies or varenicline) and behavior therapy [13]. Unfortunately, despite the NCCN guidelines, most cancer patients do not receive treatment for nicotine dependence. In an international Internet survey, 90% of thoracic oncology providers reportedly asked their patients about tobacco use at their initial visit, but fewer than half engaged in further discussion of medication options or actively provided cessation assistance [14]. From the patient's perspective, thoracic and head and neck cancer survivors reported that 87% of their physicians asked about their tobacco use, but only 39% of their physicians suggested any sort of smoking cessation treatment [15].

Providers' perceptions of patients' inability to quit or resistance to treatment may be related to characteristics of the patient's cancer and treatment. For example, previous studies showed that smokers with cancer diagnoses that are perceived to be highly attributable to tobacco use are more likely to quit smoking than those with other cancer diagnoses [16]; cancer patients who are currently or more recently undergoing treatment are less likely to be smoking than those who have completed treatment [17]; and cancer patients have prolonged relapse rates [8]. However, few studies have examined the influence of these clinical factors on smoking cessation treatment adherence among smokers with cancer.

The purpose of the present exploratory analysis of an ongoing clinical trial was to determine whether cancer-related disease factors are associated with engagement or outcomes in a clinical trial of smoking cessation using varenicline, the most effective smoking cessation pharmacotherapy and first-line pharmacological treatment recommendation among smokers with cancer [13]. We hypothesized that cancer-related disease factors (smoking-related tumor site, current cancer treatment, shorter time since diagnosis, and higher health-related quality of life) would be associated with greater odds of medication adherence, counseling adherence, and 12-week abstinence among cancer survivors who smoke.

Methods

Study design

This study was an exploratory analysis of data from an ongoing clinical trial evaluating standard versus extended duration treatment with varenicline plus behavior therapy for smoking cessation among individuals with cancer (ClinicalTrials.gov: NCT01570595). Participants who were enrolled in the trial were randomized to receive either 24 weeks of varenicline or 12 weeks of varenicline followed by 12 weeks of placebo, in combination with standard smoking cessation behavior therapy. These analyses included participants (N=144) who completed the 12-week, open-label phase of the trial between February 2013 and January 2016.

Participants

Adults who were at least 18 years of age were included in the trial if they reported smoking at least five cigarettes per week on average for the past 6 months and if they had been diagnosed with cancer or were actively in treatment for cancer within the past 5 years. Individuals were excluded or chose not to participate for: medical contraindications to using varenicline (n=36), medication concerns (n=10), practical barriers to participation (e.g., time, distance; n=31), daily use of other tobacco products (n=5), already quit or current smoking cessation treatment (n=64), DSM-IV diagnoses of psychotic disorder, bipolar disorder, or current suicidality (n=74), not meeting study eligibility criteria (e.g., no cancer diagnosis; n=36), or were otherwise uninterested (n=99).

Procedures

Participants were recruited from oncology clinics and physician referrals, print advertisements, and online postings in Chicago, IL and Philadelphia, PA. Participants completed a baseline eligibility session, and informed consent was obtained from all participants enrolled in the study. For the present analyses, all participants received 12 weeks of open-label varenicline and were offered four counseling sessions. Varenicline administration followed standard dosing, where participants were given 0.5 mg once per day for days 1 to 3, 0.5 mg twice per day for days 4 to 7, and 1.0 mg twice per day for the remainder of the study. Behavior counseling was completed at Week -1, (Pre-Quit, 60 minutes), Week 0 (Target Quit Day, 30 minutes), Week 4 (in-person booster session, 20 minutes), and Week 8 (by phone booster session, 20 minutes). Consistent with U.S. Public Health Service Guidelines [18], smoking cessation counseling comprised skills-based and supportive strategies focused on managing cravings, withdrawal symptoms, and relapse prevention, as well as discussion of medication adherence and side effect management. Study counselors completed training and weekly supervision with a licensed clinical psychologist. Finally, participants attended an in-person session at Week 12 to return medication packets, bioverify abstinence status, and complete follow-up questionnaires and safety assessments. Participants were compensated $10 for each study session and reimbursed up to $10 for travel to each in-person visit. All procedures were approved by the institutional review board at each site (Northwestern University STU00064871 and University of Pennsylvania Protocol #815687). For further details, please see Price et al. [19].

Measures

Disease factors—Four cancer-related disease factors were self-reported by participants at baseline. *Tumor site* was classified as smoking-related (lung, head and neck, and throat) or not smoking-related (genitourinary, gastrointestinal, hematological, breast, skin, kidney, pancreas, and liver) based on smokers' perceptions of the most tobacco-attributable cancers [20, 21]. *Cancer treatment* included past-month surgery, chemotherapy, radiation treatment, hormone therapy, or any combination thereof, given previous findings that smokers in active cancer treatment were more likely to be abstinent than those who had completed treatment [17]. *Time since diagnosis* was calculated as the difference between the participant's self-reported date of diagnosis and his/her intake date in days, and divided by 30 for an approximate measure of months. *Health-related quality of life (HRQOL)* was assessed via the 12-item Short Form Health Survey [SF-12], with questions such as, "During the past week, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?" Total SF-12 scores were assessed continuously from 12 (poor health) to 47 (excellent health).

Smoking cessation treatment adherence—*Medication adherence* was determined by pill count and timeline follow-back through Week 12. Timeline follow-back was completed at each session and covered the time since the last session the participant attended. Participants were classified as adherent if they reported ≥80% medication adherence (at least 132 of 165 pills), as done in previous studies of varenicline [22]. *Counseling adherence* was determined by number of counseling sessions attended out of 4 (Pre-quit, Target Quit Day, Week 4, and Week 8). Participants were classified as adherent if they attended all 4 counseling sessions. We intended to define counseling adherence as 3 or 4 sessions attended (≥75%) to more closely align with the definition for medication adherence, but of the 20 participants who only attended 1-2 counseling sessions, none were abstinent at Week 12.

Abstinence—Participants were classified as abstinent at Week 12 if they: 1) did not report smoking any cigarettes in the past 7 days and 2) provided a CO breath sample <10 ppm. Using an intent-to-treat model, participants were considered to be smoking if they: 1) reported smoking any cigarettes in the past 7 days, 2) provided a CO breath sample ≥10 ppm, or 3) were unable to be reached or did not provide a breath sample.

Covariates—Sociodemographic variables were self-reported at baseline, including sex, race/ethnicity (white vs. racial/ethnic minority), age (years), education (≤ high school degree or GED vs. ≥ some college), and employment status (employed vs. retired/unemployed). Participants were queried as to their average number of cigarettes smoked per day and number of years smoking. Nicotine dependence was assessed on the Fagerström Test of Nicotine Dependence (FTND) [23], which is scored from 0 (not dependent) to 10 (highly dependent).

Data analysis

All data analyses were conducted using IBM SPSS Statistics Version 23. We first explored the prevalence and distribution of participant sociodemographics, nicotine dependence, and cancer-related disease factors. Three logistic regression analyses were used to evaluate the

relationships between disease factors and each of the smoking cessation outcomes, including medication adherence, counseling adherence, and smoking status. All models were adjusted for sociodemographic and nicotine dependence covariates. The abstinence model was also adjusted for medication adherence and counseling adherence. The parent study sample (projected N=374) provided power to detect a one-sample effect size of d=0.145, or a difference of approximately 15% for a binary predictor. This subsample (N=144) provided power to detect a one-sample effect size of d=0.235, or a difference of 22 to 24%. A threshold of $p<.05$ was used to determine significance.

Results

Sample characteristics

Characteristics of the sample (N=144) are presented in Table 1. Participants reported smoking 15 cigarettes per day on average (range: 3 to 40 cigarettes/day) for approximately 40 years (range: 7 to 53 years), and they were moderately nicotine dependent (FTND scores range: 0 to 10). Participants enrolled in the trial between 3 and 3125 days (~8.6 years) after they were diagnosed with cancer, and on average they enrolled a little over 1.5 years post-diagnosis. Tumor sites included lung (n=20), head/neck/throat (n=9), genitourinary (n=35), gastrointestinal (n=9), hematological (n=15), breast (n=30), skin (n=18), and kidney/pancreas/liver (n=8). Of the 59 participants who reported that they were receiving current/recent cancer treatment, 18 reported undergoing surgery, 26 reported receiving chemotherapy, 9 reported receiving radiation treatment, and 18 reported using hormone therapy. On the SF-12, scores ranged from 20-47 with a mean score of 37 (SD=6), indicating relatively high HRQOL.

Smoking cessation treatment adherence

Participants reported taking between 5 and 165 (out of 165) pills by Week 12. On average, participants took 118 (SD=55) pills, and 81 participants (56%) were classified as ≥80% adherent to varenicline. Four participants were excluded from analyses because they did not attend any sessions past the Pre-Quit session at which they received the medication, and therefore did not report any medication timeline follow-back. Participants attended between 1 and 4 counseling sessions, with the majority of participants attending all four sessions (N=108, 75%). There was a strong relationship between pill count and counseling attendance: participants who were adherent to medication were also likely to be adherent to counseling, $r=.76$, $p<.001$.

In the unadjusted model of cancer-related disease factors predicting medication adherence ($\chi^2(4, N=140)=7.03$, $p=.135$), SF-12 score was the only predictor of adherence, where participants who endorsed higher HRQOL were more likely to be adherent to medication (odds ratio [OR]: 1.08, 95% confidence internal [CI]: 10.2-1.15, $p=.015$). This effect remained after adjusting for sociodemographic variables and nicotine dependence (OR: 1.08, 95% CI: 1.01-1.16, $p=.019$, $d=0.20$; adjusted model χ^2 (10, N=139)=10.07, $p=.434$). None of the cancer-related disease factors predicted adherence to counseling in either the unadjusted or adjusted models (unadjusted model $\chi^2(4, N=144)=4.40$, $p=.354$; adjusted model $\chi^2(10, N=143)=6.25$, $p=.794$). Likewise, none of the sociodemographic variables or

nicotine dependence predicted either medication or counseling adherence. The results of the fully adjusted logistic regression models predicting adherence to medication and counseling are presented in Table 2.

12-week abstinence outcomes

At the Week 12 visit, 56 participants (38.6%) reported bioverified, 7-day point prevalence abstinence. In the unadjusted logistic regression model ($\chi^2(4, N=144)=8.73$, $p=.068$), only the SF-12 score predicted 12-week abstinence (OR: 1.08, 1.02-1.15, $p=.012$). However, this effect was not present in the fully adjusted logistic regression model (OR: 1.06, 95% CI: 0.98-1.15, $p=.176$; (adjusted model $\chi^2(12, N=139)=48.56$, $p<.05$; full model results presented in Table 2). Other predictors of abstinence in the fully adjusted model included white race ($d=0.17$), lower nicotine dependence ($d=0.20$), medication adherence ($d=0.25$), and counseling adherence ($d=0.17$).

Discussion

Despite the 2015 NCCN Clinical Practice Guidelines for tobacco cessation that all smokers with cancer be provided evidence-based cessation treatment, cancer-related disease factors may be viewed by oncology healthcare providers as barriers to successful cessation. In this study, we did not find tumor site, cancer treatment, or time since diagnosis to be associated with adherence to smoking cessation treatment or, ultimately, successful abstinence in a 12-week smoking cessation program of varenicline and behavior counseling. In fact, the only association between a cancer-related disease factor and smoking cessation treatment outcome was between HRQOL and medication adherence, where cancer survivors with higher HRQOL were more likely to be at least 80% adherent to varenicline, with nearly a 10% greater odds of adherence per 1-point on the SF-12.

The rate of medication adherence observed in this sample (56% were ≥80% adherent) was similar to the rates of adherence to varenicline among smokers in the general population [22], patients in primary care [24] and a trial of varenicline among adults with thoracic cancer [25]. Counseling attendance rates were high, and 3 out of 4 participants attended all four counseling sessions. The importance of adherence is underscored by previous studies which have linked higher treatment adherence to a greater likelihood of smoking cessation [22], including among the current sample of cancer survivors [19]. That HRQOL was associated with medication adherence is not surprising – HRQOL is often associated with smoking cessation treatment adherence, including among chronic disease populations [26]. In this sample in particular, those participants reporting lower HRQOL may have been experiencing more cancer-related side effects and therefore were less able to tolerate the side effects associated with varenicline, especially nausea [22].

We did not find cancer site to be predictive of treatment adherence or abstinence, similar to observations of large prospective cohort studies [7, 27] and among participants in a tumor-site specific combined smoking, alcohol, and depression intervention [28]. Other findings have been mixed, where some have shown higher cessation rates among smokers with well-known smoking-related cancers (e.g., lung cancer) versus other tumor sites (e.g., breast cancer: [16]) while others observed that those diagnosed with lung cancer were >10 times

more likely to continue smoking than smokers with other tumors [29]. Time since diagnosis and current cancer treatment, including recent surgery, chemotherapy, radiation treatment, or hormone therapy did not predict adherence or abstinence. In contrast, a previous study of smokers with head and neck or lung cancer diagnoses found that those with a more recent diagnosis had greater motivation to quit than those who were further from their diagnosis and had completed treatment [30], suggesting that, in some cases, cancer treatment may prolong the window of the teachable moment [6]. Future studies should examine other clinical factors that may influence smoking cessation treatment adherence (e.g., cancer stage: local vs. metastatic disease).

Limitations

There are limitations to this study that warrant discussion. First, we were unable to examine subgroups (e.g., exact tumor site) given the small numbers available for these groups. However, dividing the sample by tobacco-related site is of clinical relevance to oncology healthcare providers. Furthermore, we believe the diversity of our sample is a strength, as it represented diverse cancer-related characteristics and sociodemographic factors. Second, although we consider medication adherence and counseling adherence to be measuring two distinct constructs, there is inherent overlap in these measures, especially because the behavioral treatment included counseling regarding medication adherence. Third, our inclusion criteria allowed participants who reported smoking as few as 5 cigarettes per week to enroll, which may have limited our ability to reliably bioverify abstinence using exhaled carbon monoxide. However, participants reported smoking 14 cigarettes per day on average, with a minimum of 3 cigarettes per day, suggesting it is unlikely that participants were frequently misclassified by our bioverification. Fourth, all the cancer-related disease factors were self-reported because, although we collaborated with cancer centers, we recruited a community sample for this study; more accurate data may be obtained via chart review in future studies. Finally, while the analysis was powered to detect small to medium effects, this was an exploratory analysis of an ongoing clinical trial and therefore it was not powered specifically to test the proposed hypothesis; however, these results represent good estimates of effect sizes that can be used to develop future proposals.

Clinical Implications

Our findings support the NCCN clinical practice guideline recommendations that first-line smoking cessation treatments should be offered to all cancer survivors, regardless of tumor site, current treatment, or time since diagnosis [13]. Unfortunately, most targeted smoking cessation interventions among cancer survivors do not effectively increase abstinence rates among these high-risk patients [8, 31]. One-time behavioral counseling does not significantly increase abstinence rates [32, 33], suggesting that more intensive interventions may be needed. The high level of adherence in the present study, especially to behavioral treatment, and previous findings that nearly 50% of smokers approached for cancer-related smoking cessation research studies agree to enroll [19, 25], suggest that many cancer survivors who smoke would be open to receiving more intensive smoking cessation assistance.

With regard to varenicline, few trials have been conducted in oncology populations, despite NCCN guidelines that recommend varenicline as a first-line treatment for smoking cessation [13]. Gosselin and colleagues evaluated a naturalistic smoking cessation program among 81 patients with head and neck cancer, and 14 of the 16 participants who reported abstinence at one month were prescribed varenicline [34]. In a 12-week feasibility trial, Park and colleagues observed higher quit rates among patients with thoracic tumors in a combined behavioral and varenicline intervention (34% abstinent) compared to usual care (14%) [25]. In a large cohort of patients participating in a smoking cessation program in an oncology clinic, ~50% of patients in the intervention group received varenicline with behavioral therapy, and those who took varenicline had greater odds of abstinence 6 months after the end of treatment compared to those who used nicotine replacement therapies [35]. The NCCN guidelines also recommend varenicline for patients who are not currently ready to quit smoking to facilitate reduction, with the ultimate goal of complete cessation [13]. Finally, lower doses of varenicline may reduce side effects, particularly among cancer patients undergoing treatment [36].

Conclusion

In a sample of smokers with any cancer diagnosis in the past 5 years, only HRQOL was associated with adherence to varenicline. Our findings show that cancer survivors who smoke, regardless of tumor site, current cancer treatment, or time since diagnosis, were able to engage in and benefit from smoking cessation treatment, with nearly 40% of participants achieving abstinence after 12 weeks. These findings support the NCCN guidelines that all smokers diagnosed with cancer, regardless of cancer-related characteristics, should be offered evidence-based smoking cessation treatment. In a healthcare system that supports provider education and training in first-line smoking cessation treatment, all smokers diagnosed with cancer should be encouraged to quit and offered first-line pharmacological and behavioral support to increase their chances of successfully quitting.

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Table 1

Participant Characteristics, N=144

Variable	N(%) or Mean(SD)
Sociodemographic and smoking variables	
Gender (female), N(%)	72 (50.0%)
Race/ethnicity (minority),[a] N(%)	48 (33.3%)
Age (years), M(SD)	58.7 (8.9)
Education (≤ high school degree), N(%)	35 (24.3%)
Employment status (unemployed/retired), N(%)	62 (41.6%)
Cigarettes/day, M(SD)	14.9 (7.7)
Years smoking (years), M(SD)	40.8 (11.1)
Nicotine dependence (FTND score), M(SD)	4.6 (2.1)
Cancer-related disease factors	
Tumor site (smoking-related),[b] N(%)	29 (20.0%)
Cancer treatment (current, past month),[c] N(%)	59 (41.0%)
Time since diagnosis (months), M(SD)	19.8 (18.9)
<1 year, n(%)	70 (47.0%)
≥1 year and <4 years, n(%)	62 (41.6%)
≥4 years, n(%)	17 (11.4%)
Health-related quality of life (SF-12 score),[d] M(SD)	36.9 (6.0)
Smoking cessation treatment outcomes	
Medication adherence (adherent),[e] N(%)	81 (56.3%)
Counseling adherence (adherent), N(%)	107 (74.3%)
12-week abstinence (abstinent), N(%)	56 (38.9%)

[a]Racial/ethnic minority included: 41 (27.5%) Black/African American, 1 (0.7%) American Indian/Alaska Native, 1 (0.7%) more than one race, 3 (2.0%) and unknown/not reported; 6 (4.0%) participants reported that they were Hispanic/Latino.

[b]Smoking-related tumor sites included lung, head and neck, and throat.

[c]Cancer treatment included surgery, chemotherapy, radiation treatment, and hormone therapy.

[d]The SF-12 scores in this sample ranged from 20-47 (out of a possible range of 12-47); higher scores indicate greater health-related quality of life.

[e]N=140: Four participants who completed the baseline and Pre-quit sessions did not attend any follow-up visits and did not report medication u.

Abbreviations: M, mean. SD, standard deviation. FTND, Fagerström Test of Nicotine Dependence. SF-12, 12-item Short Form Health Survey.

Table 2

Cancer-related disease factors predicting 12-week smoking cessation outcomes.

Variable (referent)	Medication adherence		Counseling adherence		Abstinence	
	OR (95% CI)	*p*-value	OR (95% CI)	*p*-value	OR (95% CI)	*p*-value
Sex (female)	1.05 (0.48-2.29)	.901	0.95 (0.41-2.22)	.912	0.70 (0.28-1.75)	.447
Race/ethnicity (minority)	0.98 (0.43-2.22)	.954	0.78 (0.31-1.95)	.595	**2.85 (1.05-7.73)**	**.040**
Age, 1 year	1.02 (0.98-1.07)	.356	0.98 (0.94-1.03)	.490	1.04 (0.99-1.10)	.121
Education (≤ high school degree)	1.37 (0.55-3.37)	.499	0.83 (0.30-2.27)	.720	0.52 (0.18-1.52)	.232
Employment status (unemployed/retired)	0.65 (0.29-1.46)	.300	0.84 (0.35-2.00)	.686	0.73 (0.29-1.85)	.504
Nicotine dependence, FTND score	0.98 (0.82-1.18)	.828	0.92 (0.75-1.12)	.408	**0.76 (0.60-0.95)**	**.016**
Medication adherence (nonadherent)	—	—	—	—	**4.58 (1.66-12.68)**	**.003**
Counseling adherence (nonadherent)	—	—	—	—	**4.53 (1.07-19.20)**	**.040**
Tumor site (not tobacco-related)	1.25 (0.50-3.11)	.629	1.05 (0.38-2.86)	.929	1.99 (0.69-5.74)	.205
Cancer treatment (no current treatment)	1.53 (0.72-3.23)	.268	1.16 (0.52-2.60)	.718	1.14 (0.47-2.75)	.775
Time since diagnosis, 30 days	1.00 (0.98-1.02)	.933	0.99 (0.97-1.01)	.393	1.00 (0.98-1.03)	.743
Health-related quality of life, SF-12 score	**1.08 (1.01-1.16)**	**.019**	1.07 (0.99-1.14)	.080	1.06 (0.98-1.15)	.176

Bold indicates significance at $p<.05$. Abbreviations: OR, odds ratio. CI, confidence interval. FTND, Fagerström Test of Nicotine Dependence. SF-12, 12-item Short Form Health Survey.