

ORIGINAL INVESTIGATION

Nicotine Replacement Therapy Distribution to Light Daily Smokers Calling a Quitline

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ABSTRACT

Background: With an increasing prevalence of lighter smokers presenting for cessation assistance, outcome-based recommendations are needed to inform nicotine replacement therapy (NRT) distribution protocols by quitlines.

Methods: A quasi-experimental design was utilized to compare quit rates based on samples selected from the time period before and after NRT (gum or lozenge) was offered to light daily smokers (1–9 cigarettes) contacting the New York State Smokers' Quitline. Outcome measures included self-reported 7- and 30-day abstinence rates, numbers of daily cigarettes among continuing smokers, and cost per quit analyses.

Results: Among responders to the follow-up survey, quit rates were higher for those given NRT compared with those not offered NRT at both 7 (33.0% vs. 27.2%; Relative Risk [RR] = 2.25 [95% CI: 1.15, 4.40; $p < .05$]) and 30 days (28.0% vs. 21.9%; RR = 2.63 [95% CI: 1.25, 5.54; $p < .05$]). Similar results were obtained based on intent-to-treat analyses for both 7 (13.4% vs. 11.3%; RR = 1.92 [95% CI: 1.08, 3.39; $p < .05$]) and 30 days (11.4% vs. 9.1%; RR = 2.29 [95% CI: 1.20, 4.40; $p < .05$]). Among continuing smokers, the mean number of cigarettes smoked per day increased from enrollment to follow-up in both groups, but less so in those receiving NRT. The additional cost associated with providing a 2-week free supply of nicotine replacement to smokers was \$52 for gum and \$74 for lozenge.

Conclusions: This study demonstrates that light daily smokers (1–9 cigarettes) who contact a telephone quitline are interested in using NRT if offered and are able to achieve higher quit rates compared with those not offered NRT.

INTRODUCTION

Quitlines are a valuable resource for smokers seeking assistance to stop smoking. Research has shown that quit rates can be increased by offering nicotine replacement therapy (NRT) to smokers calling a quitline for telephone counseling support compared with those who received counseling support alone (An et al., 2006; Cummings, Hyland, et al., 2006; Miller et al., 2005). NRT helps people to stop smoking by lessening nicotine withdrawal symptoms, which typically peak in the first week of cessation, with many symptoms remitting by Week 2 for most smokers (Cummings, Giovino, Jaen, & Emrich, 1985; Hughes, 1992; Shiffman et al., 2006). The relatively short duration of nicotine withdrawal symptoms is consistent with the previously reported observation of similar quit rates among smokers given a 1-, 2-, or 6-week supplies of free nicotine patches (Cummings, Fix, et al., 2006).

Although smokers may benefit from a more individualized treatment regimen, quitlines generally offer NRT based on

a one-size-fits-all model. Strategies have tended to focus on those smokers at the highest risk of tobacco-related disease—primarily moderate to heavy smokers. Lighter smoking also poses substantial risks and adverse health outcomes that parallel dangers observed among daily, heavier smokers (Okuyemi et al., 2002; Schane, Ling, & Glantz, 2010). Indeed, with an increasing prevalence of light and nondaily smokers (Okuyemi et al., 2002; Okuyemi, Thomas, Warren, Guo, & Ahluwalia, 2010; Schane et al., 2010; Shiffman, 2009; Tindle & Shiffman, 2011), recommendations are needed to inform the development and refinement of NRT distribution protocols among light smokers utilizing quitline services. Despite the increasing proportion of light smokers, the vast majority of past studies have focused on NRT distribution among moderate and heavy smokers (Okuyemi et al., 2010). Light smoking was considered a transient practice among former heavier smokers or tobacco users trying to quit (Shiffman, 2009).

Research suggests that many light smokers struggle to refrain from smoking (Etter, 2004) and have strong associations with

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situational cues (Darlow & Lobel, 2012). Despite trends that light smokers tend to be younger, more educated, have higher incomes, be less physically dependent on nicotine, and have more planned cessation efforts than heavier smokers (Levy, Biener, & Rigotti, 2009), research also shows that the quit attempts among light smokers are more likely to fail than to succeed (Zhu, Sun, Hawkins, Pierce, & Cummins, 2003). Light daily smokers also face the additional challenges of being less likely to be advised to quit smoking and to receive treatment support compared with heavier daily smokers (Koontz et al., 2004; Tong, Ong, Vittinghoff, & Perez-Stable, 2006).

Research is needed to assess the potential benefits of giving light smokers NRT and other types of pharmacotherapy, which for the most part have been evaluated primarily in moderate and heavy smokers (Okuyemi et al., 2002, 2010; Shiffman, 2005; Shiffman et al., 2002). Findings regarding smoking reductions and cessation among light smokers suggest that reducing the number of cigarettes per day prior to attempting cessation may enhance outcomes (Okuyemi et al., 2010). Studies that assessed NRT lozenge efficacy among low dependence smokers and light smokers determined no difference in efficacy compared with heavy smokers (Shiffman, 2005; Shiffman et al., 2002). Other research targeting Latino light smokers found varenicline to be associated with greater levels of abstinence at follow-up than either placebo or NRT; these authors speculated that providing higher initial doses of NRT may have made a difference (de Dios, Anderson, Stanton, Audet, & Stein, 2012). Finally, an analysis of reduced NRT protocol in a quitline environment found that light to moderate smokers benefited more than heavy smokers and yielded reductions in abstinence rates (Burns, Tong, & Levinson, 2010). Together, these examples suggest the need to strengthen existing protocols related to the recommended pharmacological product, amount, and duration of cessation treatment among light smokers.

This article presents the results of a quasi-experimental study to test the benefits of extending free NRT to light daily smokers (1–9 cigarettes/day) contacting the New York State Smokers' Quitline (NYSSQL). Since 2004, the NYSSQL has provided adult smokers calling for cessation support with a free 2-week starter kit of NRT (gum, lozenge, or patches). However, because of the lack of evidence regarding the efficacy of NRT in light smokers, only persons who report smoking 10 or more cigarettes/day were offered medication. This study was undertaken to test the hypothesis that light smokers calling the NYSSQL for quitting assistance would be interested in receiving a free supply of NRT and would demonstrate higher quit rates compared with those not offered NRT.

METHODS

Study Population

Eligible smokers consisted of a sample of 1,365 adults (18+ years), who self-identified as current daily tobacco users smoking 1–9 cigarettes and who contacted the NYSSQL seeking assistance to stop smoking between January 2010 and July 2010. This research protocol was Institutional Review Board approved and all participants provided verbal consent. Eligible study subjects were New York State residents who consented to a follow-up telephone call. Study subjects were recontacted by telephone, 7 months after their initial call to the NYSSQL, to

assess their smoking status (using 7- and 30-day point prevalence cessation rates) and to answer a brief series of questions about quit attempts and usage of the NRT.

Study Design

A quasi-experimental design was utilized to compare quit rates in light smokers based on samples selected from a time period before and after NRT was offered to light smokers. Participants included 672 eligible light smokers who called the NYSSQL between January 2010 and March 2010 and who were not given NRT and 693 light smokers who contacted the NYSSQL between April 2010 and July 2010 and were mailed a 2-week supply of either nicotine gum or lozenge (2-mg units). The NYSSQL routinely provides two counseling sessions with smokers who call (enrollment screening, plus a follow-up call with a quit coach). Callers who are given NRT are also contacted to make sure they received the medication sent to them in the mail and to provide instructions on how to use the medications correctly. Both the no-NRT and NRT groups equally participated in the standard two counseling calls; the additional call was provided only to the NRT group.

Follow-up Survey

Participants were recontacted by telephone 7 months after enrollment in the study to assess their smoking status and answer questions about quit attempts and usage of the NRT provided to them; staff placing these calls were blinded to the group assignment (no NRT offered vs. NRT offered). In an effort to boost response rates, participants received a letter in advance of the 7-month telephone survey alerting them to the planned callback. In addition, up to 15 callback attempts, at various times, were made to each of the participants. Overall, a total of 561 (41%) of the study participants completed the follow-up interview. Response rates were similar between the no-NRT group (41.5%) and NRT group (40.7%).

Outcome Variables

Use of nicotine gum or lozenge was assessed by asking participants at the time of their follow-up survey to report how much of the free NRT they had used, and whether they had purchased additional NRT. Participants were also asked about their frequency of NRT use. Quit status was defined as a report of not smoking at all for 7 days prior to the follow-up interview based on responses to these questions: "Have you smoked a cigarette, even a puff, in the last 30 days?" and "Have you smoked a cigarette, even a puff, in the last 7 days?"

Seven- and 30-day point nonsmoking prevalence rates were assessed at the 7-month follow-up call and were computed in two ways. First, we computed the quit rates at the time of the 7-month follow-up interview based on the achieved sample (as prespecified in our study protocol), under the assumption that those lost to follow-up were missing at random. Second, we computed the rates for each group based on the assumption that those lost to follow-up had all returned to smoking (a more conservative "intent-to-treat" approach).

Daily amount smoked (cigarettes per day) was assessed at baseline and follow-up, and the net difference in consumption was determined as well as whether reductions of 50% or more had occurred. The added costs per participant were computed

NRT distribution to light daily smokers

for the NRT group in comparison with the group receiving standard care (no NRT). These charges consisted of the NRT product, mailing costs, and follow-up calls associated with receiving NRT. The cost per attributable quit was computed as the difference between the quit rates for the two groups, determining how many additional quitters were yielded and at what additional cost. Upper and lower bound *CI*s were computed around quit rates to estimate all potential cost ranges.

Data Analysis

All data analyses were completed using SPSS v. 16.0. Descriptive statistics from the follow-up telephone surveys were computed to assess patterns of NRT use and to describe smoking outcomes for each group. Independent sample *t* tests were used to compare differences in the baseline characteristics of the two groups for continuously measured variables (i.e., age, amount smoked per day). Chi-square analysis was used for categorical measures (i.e., gender, race, etc.). Secondary analyses were performed using paired sample *t* tests to investigate reduction in cigarette use among continuing smokers.

All treatment groups were verified to be comparable across demographic and tobacco-related variables. The main outcome tested for the difference in the proportion of quitters between the two groups as assessed during the 7-month follow-up survey using logistic regression analyses. Additional stratifications of the data occurred across varying levels of educational attainment and insurance status, the identified proxy measures for socioeconomic status.

Nonresponders were similar across all baseline characteristics, with the only differences being slightly higher percentages of younger smokers (57% vs. 43%; $p < .01$) and more smokers reporting less than 10 years of tobacco use (60% vs. 54%; $p < .01$).

RESULTS

Demographic and smoking behavior characteristics at baseline are summarized in Table 1. Significant differences were found between the two groups when comparing race/ethnicity, age group, number of years smoked, and cigarettes smoked per day at baseline. The NRT group tended to be older, smoking for more than 10 years, and had higher percentages using 7–9 cigarettes/day.

Interest In and Use of NRT

Totally, 720 smokers, who reported smoking 1–9 cigarettes/day, contacted the NYSSQL and were offered NRT as part of this study; 96.2% ($n = 693$) accepted the offer. Of those who accepted, 55.3% ($n = 383$) chose the lozenge formulation and 44.7% (310) selected the gum (resin). Over three quarters of respondents (78%) rated the offer of a free supply of NRT as “very important”; 25% reported using all of the provided NRT and 38% reported using about one half of the supply. Light smokers typically reported using the NRT “only when I had a craving” (70%) and that the NRT helped with managing strong cravings. About one in five reported concurrent use of NRT along with continued smoking. Less than 9% reported use of additional NRT beyond the 2-week supply provided.

There were no significant differences in responses by NRT formulation (gum vs. lozenge).

Quit Rates

Table 2 displays the 7-month follow-up interview self-reported quit rates comparing NRT to no-NRT group. Among responders to the follow-up survey, quit rates were higher for those given NRT compared with those not offered NRT based on both 7-day point prevalence (33.0% vs. 27.2%; $RR = 2.25$ [95% *CI*: 1.15, 4.40; $p < .05$]) and 30-day point prevalence (28.0% vs. 21.9%; $RR = 2.63$ [95% *CI*: 1.25, 5.54; $p < .05$]).

Similar results were obtained based on intent-to-treat analysis among all participants at both 7 (13.4% vs. 11.3%; $RR = 1.92$ [95% *CI*: 1.08, 3.39; $p < .05$]) and 30 days (11.4% vs. 9.1%; $RR = 2.29$ [95% *CI*: 1.20, 4.40; $p < .05$]). Logistic regression analyses, which adjusted for gender, years smoked, race, time to first cigarette, education, and insurance, yielded comparable findings (see Table 2). Quit rates did not differ among nicotine lozenge users compared with gum users ($p > .05$).

Continuing Tobacco Usage

Among those who reported continued tobacco use in the follow-up interview, we examined the change in reported cigarette consumption from time of enrollment to time of follow-up. The mean number of cigarettes smoked per day increased at 7-month follow-up in both the no-NRT group (from 5.48 cigarettes to 11.97 cigarettes; net of +6.49 cigarettes/day, $p < .001$) and the NRT group (from 5.79 cigarettes to 8.54 cigarettes; net of +2.75 cigarettes/day, $p = .053$). Additionally, the group receiving NRT reported a higher proportion of 50% or greater reductions in daily cigarette consumption compared with those not offered NRT (33.2% vs. 21.6%, $p = .012$).

Cost Analyses

The additional expense associated with providing NRT to light smokers was \$51.78 per person for those receiving nicotine gum and \$73.78 per person for those receiving the nicotine lozenge. These costs included purchasing and mailing of NRT (either lozenge or gum) plus one additional follow-up call. These extra costs of providing free NRT in addition to standard counseling protocol were estimated and evaluated against the number of participants who reported not smoking at follow-up. Table 3 summarizes the potential impact and costs of providing NRT to light smokers.

DISCUSSION

This study demonstrates that lighter daily smokers (1–9 cigarettes) who call a telephone quitline are interested in using NRT if offered and benefit from its use in terms of higher quit rates. The findings from this study are consistent with two clinical trials assessing nicotine lozenge use among light smokers using the 2-mg lozenge (Shiffman, 2005; Shiffman et al., 2002), which found significantly higher abstinence rates at 6 weeks compared with placebo. The present observational study, conducted in a community setting, adds to a growing

Table 1. Baseline Characteristics of Light Smokers by Treatment Group, New York State Smokers' Quitline

Characteristic	Not offered NRT (<i>n</i> = 672)		Offered NRT (<i>n</i> = 693)		Significance
	<i>n</i>	%	<i>n</i>	%	<i>p</i> value
Gender					<i>p</i> = .873
Male	243	38.1%	261	37.7%	
Female	395	61.9%	432	62.3%	
Race/ethnicity**					<i>p</i> < .001
White non-Hispanic	249	37.1%	248	35.8%	
Black non-Hispanic	178	26.5%	228	32.9%	
Hispanic	78	11.6%	148	21.4%	
Other	167	24.9%	69	10.0%	
Age, years*					<i>p</i> = .016
18–24	103	15.5%	74	10.8%	
25–34	145	21.9%	158	23.0%	
35–44	106	16.0%	108	15.7%	
45–54	177	26.7%	177	25.8%	
55–64	100	15.1%	110	16.0%	
65+	32	4.8%	60	8.7%	
Education					<i>p</i> = .736
Less than high school	72	18.0%	100	16.3%	
High school	165	41.3%	245	39.9%	
Some college	103	25.8%	164	26.7%	
College or more	60	15.0%	105	17.1%	
Years smoked**					<i>p</i> < .000
Less than 1 year	10	1.5%	11	1.6%	
1–5 years	289	43.5%	67	9.7%	
6–10 years	276	41.6%	129	18.7%	
11–15 years	14	2.1%	108	15.7%	
16–20 years	17	2.6%	106	15.4%	
21 or more	58	8.7%	269	39.0%	
Time to first cigarette					<i>p</i> = .406
Within 5 min	168	30.0%	191	27.8%	
Within 6–30 min	163	29.1%	200	29.2%	
Within 31–60 min	73	13.0%	112	16.3%	
>60 min	156	27.9%	183	26.7%	
Cigarettes smoked daily*					<i>p</i> = .028
1–2	40	6.0%	39	5.6%	
3–4	134	19.9%	120	17.3%	
5–6	291	43.3%	267	38.5%	
7–9	207	30.8%	267	38.5%	
Response rate					<i>p</i> = .757
Completed 7-month follow-up	279	41.5%	282	40.7%	

Note. NRT = nicotine replacement therapy.

Significant differences between groups at **p* < .05 or ***p* < .001 based on Pearson chi-square.

literature suggesting that nicotine replacement is effective among the population of light smokers.

The majority of light smokers found the offer of free NRT to be very important and 63% of light smokers reported using one half or more of the NRT product. It is possible that higher quit rates might have been observed if more participants took the gum or lozenge on fixed dose regimens, instead of only in response to cravings as reported by a majority of NRT users. Treatment adherence is limited in the cessation field and there are mixed results where some studies have shown a positive relationship between quantity of NRT and abstinence, whereas others have not (An et al., 2009; Mooney, Babb, Jensen, & Hatsukami, 2005). In addition, providing additional counseling calls to promote cessation and fuller use of NRT is a potential option. However, one study failed to find a benefit with

additional proactive calls because many clients are difficult to reach beyond two calls (Carlin-Menter et al., 2011).

During the 7-month follow-up interval, light smokers who continued to smoke reported increased daily smoking (2.75 additional cigarettes in the NRT group and 6.49 additional cigarettes in the no-NRT group) suggesting that baseline daily consumption may have been underestimated. However, it is also likely that many smokers calling a quitline for cessation assistance may have been cutting back on their cigarette consumption prior to their actual quit attempt; thus the baseline assessment of smoking rate may not be an accurate reflective of usual consumption patterns. Regardless, the increased rate of smoking observed from baseline to follow-up was significantly lower in those provided NRT compared with those not offered NRT, suggesting that the offer of NRT contributed to

Table 2. Quit Rates Among Light Smokers at 7-Month Follow-up by Group, New York State Smokers' Quitline

Outcome measures	No NRT (n = 279)	Any NRT (n = 281)	NRT gum (n = 122)	NRT lozenge (n = 160)	OR ^a (95% CI)
7-day nonsmoker, responder (according to protocol)	27.2%	33.0%	28.7%	36.3%	Any NRT: 2.25 (1.15, 4.40) ^b ; NRT gum: 1.55 (0.67, 3.60); NRT lozenge: 3.57 (1.57, 8.13) ^b
7-day nonsmoker, intent-to-treat ^c	11.3%	13.4%	11.3%	15.1%	Any NRT: 1.92 (1.08, 3.39) ^b ; NRT gum: 1.28 (0.63, 2.62); NRT lozenge: 2.67 (1.37, 5.21) ^b
30-day nonsmoker, responder (according to protocol)	21.9%	28.0%	23.0%	31.9%	Any NRT: 2.63 (1.25, 5.54) ^b ; NRT gum: 1.72 (0.64, 4.66); NRT lozenge: 4.53 (1.84, 11.17) ^b
30-day nonsmoker, intent-to-treat ^c	9.1%	11.4%	9.0%	13.3%	Any NRT: 2.29 (1.20, 4.40) ^b ; NRT gum: 1.46 (0.62, 3.40); NRT lozenge: 3.39 (1.62, 7.10) ^b

Note. OR = odds ratio, CI = confidence interval, NRT = nicotine replacement therapy.

^aLogistic models adjusted for gender, years smoked, race, time to first cigarette, education, and insurance.

^bSignificant differences for any NRT versus no NRT ($p < .05$).

^cAssumes that those lost to follow-up are current smokers at follow-up.

Table 3. Outcomes and Cost Analyses: NRT Versus No NRT Based on 30-Day Quit Rates

Light smoker group	30-day nonsmoking point prevalence	95% CI	NRT cost per 100 clients	No. of additional quitters with NRT based on 100 clients	Best estimate of added cost per additional quit ^a	Best case/worst case for added costs per additional quit ^a
No NRT ^b	21.9	(17.1%, 26.8%)	\$0	NA	NA	NA
NRT	28.0	(22.8%, 33.2%)	\$6,399	6	\$1,049	\$395–1,600

Note. NRT = nicotine replacement therapy, CI = confidence interval.

^aThe added cost per additional quit is based on the range of difference from the 95% CI bounds. Best estimate is based on the 30-day point prevalence rate differences. Best case is based on the highest difference, whereas worst case is based on the smallest difference.

^bThis row represents the current standard treatment for in the New York State Smokers' Quitline for smokers of <10 cigarettes/day. The quit rate observed in this group is the comparison for the other groups.

lower levels of smoking even among those not able to quit completely.

Limitations of the present study include nonrandomization, outcomes that were based on self-reported data, and modest response rates of 41%–42% at 7-month follow-up. This observed response rate is slightly below the Northern American Quitline Consortium recommended response rates of at least 50% (An et al., 2009), despite multiple attempts to reach all participants. However, it is unlikely that differences in demographics and smoking behaviors noted at baseline between the two comparison groups in this study are responsible for the observed outcomes given that these differences are modest and adjustment for demographic factors in our logistic regression model did not alter the outcomes observed.

The consistency of results, across a variety of outcomes including an intent-to-treat analysis whereby all those lost to follow-up were conservatively counted as smoking, supports the conclusion that the offer of NRT increased quit rates. Our findings are also robust, as multivariate analyses that examined multiple models demonstrated consistency of findings.

A unique strength of this study is the use of a quasi-experimental design implemented in a real world, community setting of a state quitline. Smoking cessation represents a highly cost-effective intervention because the health consequences of smoking are enormously expensive and compound over time. In New York State, the annual direct economic costs attributable to smoking were in excess of \$20.6 billion, including

workplace productivity losses of 3.9 billion, premature death losses of approximately \$6.9 billion, and direct medical expenditures of \$9.8 billion (Rumberger, Hollenbeak, & Kline, 2010). Providing light smokers with NRT increases the likelihood of cessation and costs approximately \$1,049 per additional quitter (range: \$395–\$1,600). Overall, we conclude that the provision of NRT appears to be a good return on investment.

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DECLARATION OF INTERESTS

Dr. Cummings provides expert testimony in litigation against cigarette manufacturers, provides consulting advice and has received grants from Pfizer, and previously served as a co-investigator on a multi-center trial evaluating a nicotine vaccine from Nabi Biopharmaceuticals. Dr. Mahoney has provided expert testimony in litigation against cigarette manufacturers, has received research grants and speaker fees from Pfizer, and served as an investigator on a multi-center trial evaluating the

potential efficacy a nicotine vaccine for cessation sponsored by Nabi Biopharmaceuticals.

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