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A Novel Recruitment Message to Increase Enrollment into a Smoking Cessation Treatment Program: Preliminary Results from a Randomized Trial[a]

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Abstract

Most smokers do not utilize approved interventions for nicotine dependence, reducing the probability of cessation. Smoking cessation programs typically use recruitment messages emphasizing the health threats of smoking. Augmenting this threat message by describing the genetic aspects of nicotine addiction may enhance enrollment into a cessation program. During telephone recruitment, 125 treatment-seeking smokers were randomized to receive by phone either a standard threat message or a threat plus genetic prime message and were offered open-label varenicline and counseling. There was a greater rate of enrollment into the cessation program for the threat plus genetic prime participants (51.7%) vs. the threat-only participants (37.7%; $p = .03$). Smokers who self-identified from racial/ethnic minority groups were less likely to enroll in the cessation program ($p = .01$) vs. smokers who self-identified as Caucasian. These preliminary data suggest that a simple, affordable, and transportable communication approach enhances enrollment of smokers into a smoking cessation program. A larger clinical trial to evaluate a genetic prime message for improving recruitment into smoking cessation programs is warranted.

Introduction

In addition to behavioral counseling, the United States Food and Drug Administration (FDA) has approved nicotine replacement therapies, bupropion, and varenicline for treating nicotine dependence (Schnoll & Lerman, 2006). However, most smokers prefer to try to quit smoking on their own without a smoking cessation product and/or counseling (Fiore et al.,

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2000; Hammond et al., 2004; Pierce & Gilpin, 2002). Similarly, 50–63% of smokers who are evaluated for smoking cessation treatment programs fail to attend the treatment program following eligibility screening (Dahm et al., 2009; Gariti et al., 2008; Schnoll et al., 2004). Unfortunately, choosing to quit smoking without formal assistance in the form of counseling and pharmacotherapy yields very low quit rates (Fiore et al., 2000). Therefore, strategies are needed to enhance smokers' willingness to enroll in formal smoking cessation treatment programs.

Most smoking cessation treatment programs utilize recruitment messages to encourage treatment-seeking smokers to enroll. The typical recruitment message for these programs review the health threats of smoking (e.g., cancer). Such "threat" messages may be limited in motivating smokers to enroll into treatment programs. Theories of behavior change suggest that individuals who believe they are at higher personal risk of developing cancer are more likely to engage in cancer risk-reduction activities (Weinstein, 1998). However, because heightened risk perceptions can lead to avoidance in some circumstances by reducing a person's confidence (i.e., self-efficacy), communicating personal risk information, including genetic information, in counseling or educational contexts has not always produced beneficial results. Several preliminary studies have been conducted to understand the influence of genetic information on personal self-efficacy and intention to engage in healthy behaviors, including quitting smoking (Cappella, Lerman, & Kang, 2006; Cappella et al., 2005). Using large nationally representative samples, these studies have shown that the inference of the genetic basis of nicotine dependence reduces self-efficacy but increases behavioral intention to act in a healthy way. When efficacy information is included in this genetic prime message (i.e., information about medications), the impact of the inference of the genetic prime on self-efficacy is mitigated without reducing intentions to change behavior (Shim, Cappella, & Lerman, in press). These findings converge with more recent theoretical applications of self-regulation theory to behavioral responses to genetic information, which emphasize the role of "if-then" contingency rules in determining the effects of genetic information on behavior (Marteau & Weinman, 2006). Symmetry between genetic information (genetic basis for nicotine dependence and response to treatment) and an intervention (effective medications) is thought to be critical for promoting adaptive behavioral responses (enrollment into a smoking cessation treatment program). The effect of a genetic prime message and efficacy information on actual enrollment in a smoking cessation program, however, has not been tested.

This study tested if adding a genetic prime message concerning nicotine dependence to the typical threat message used to recruit smokers into smoking cessation treatment programs increases enrollment into a smoking cessation program that provided 12-weeks of open-label varenicline and counseling. Varenicline was given since it yields very high cessation rates among FDA-approved medications for nicotine dependence (Aubin et al., 2008; Gonzales et al., 2006). We expected that participants randomized to a threat plus a genetic prime message would be more likely to enroll in the smoking cessation program. This study was designed as a preliminary trial to assess if any meaningful effect on program enrollment could be discerned from this new recruitment message. Increasing the use of proven smoking cessation treatments by augmenting smoking cessation treatment program recruitment messages could have a substantial impact on the rates of smoking in the United

States and on tobacco-related morbidity and mortality. As secondary objectives, we examined the effect of the two recruitment messages on actual smoking cesstion following the treatment program and assessed the effect of race/ethnicity on program enrollment and smoking cessation given results from a prior study (Dahm et al., 2009).

Methods

Participants

Participants for this trial were responding to media advertisements for a smoking cessation program at a large academic institution. Since this trial required use of behavioral and pharmacological treatments, participants were required to meet numerous inclusion and exclusion criteria. Eligible participants were male and female smokers aged 18–65, who reported smoking ≥ 10 cigarettes per day, and who planned to live in the area for the next six months. Participants were excluded if they: 1) were using chewing tobacco; 2) were currently enrolled or planned to enroll in another smoking cessation program in the next six months; 3) planned to use other nicotine substitutes or other smoking cessation treatments in the next six months; 4) had a history of substance abuse and/or were currently receiving treatment for substance abuse (e.g., alcohol, opioids, cocaine, marijuana, or stimulants); 5) reported consuming >25 standard alcoholic drinks per week; 6) were currently using psychotropic medication (e.g., anti-psychotics, anti-depressants, anxiolytics); 7) were currently using medication for chronic pain, anti-coagulants, asthma medication, or any heart medications; 8) were pregnant, planning a pregnancy, or lactating; 9) had a history or a current diagnosis of any Axis 1 psychiatric disorder; 10) were diagnosed with cancer, heart disease, or HIV; 11) had a history of epilepsy or a seizure disorder; 12) had a history or current diagnosis of abnormal heart rhythms and/or tachycardia (>100 beats per minute), chronic obstructive pulmonary disease (COPD) or cardiovascular disease (stroke, angina, coronary heart disease), or had experienced a heart attack in the last six months, or reported uncontrolled hypertension (systolic blood pressure >150 or diastolic blood pressure > 90); and 13) had a history of kidney and/or liver failure (including organ transplant).

We screened 262 individuals for this trial; 132 were ineligible and 130 were eligible and randomized (62 to threat-only; 68 to threat plus genetic prime). Five randomized participants (two in threat-only and three in threat plus genetic prime) withdrew their verbal consent and were removed from the study sample. The remaining 125 eligible and consenting participants were scheduled for an enrollment visit (history and physical) for an open-label smoking cessation treatment program involving counseling and varenicline for 12 weeks. The characteristics of the study sample are presented in Table 1.

Procedures

All procedures for this study were approved by the site Institutional Review Board. Participants responding to media advertisements for a free smoking cessation program were screened by telephone for interest and eligibility. Callers were informed about a study to assess the effects of different messages about smoking and health on enrollment and response to treatment and the study procedures and requirements were explained. Those who were interested in the study were assessed for eligibility by telephone. Those who were

eligible provided verbal informed consent to enroll in the study and completed a baseline survey. Participants were then randomly selected for a threat-only or a threat plus genetic prime recruitment message. The respective message was presented to the participant at this time and they were scheduled for an in-person history and physical session within the following two weeks. At this visit, the study procedures were again reviewed, interested participants signed an informed consent and HIPAA form, and final eligibility was confirmed. Participants were then scheduled for the first counseling session of the smoking cessation program for the following week, which is when smoking cessation treatment began; attendance at this first treatment session was the primary outcome variable for this study.

The Recruitment Messages

The Threat-Only Message—This message contains basic information about the harms associated with smoking and the availability of smoking cessation treatments. The message was read verbatim to participants randomized to this condition: “This year, like most years, more than 400,000 Americans will die prematurely because they smoke cigarettes. In fact, the number of people who die from smoking each year outnumbers those who die from HIV/AIDS, illegal drug use, alcohol use, motor vehicle accidents, suicides, and murders combined. Smoking is responsible for: 80% of all lung cancer deaths; 20% of all cancer deaths; cancers of the mouth, bladder, kidney, stomach, and cervix, among others; chronic obstructive pulmonary disease (COPD), which is chronic bronchitis and emphysema that causes trouble breathing because of lung damage; and increased heart rate and blood pressure which increases your risk for heart disease, heart attack, and stroke; health problems among children exposed to second-hand smoke, including sudden infant death syndrome, and childhood respiratory illness, such as bronchitis, colds, pneumonia, and asthma. On average, people who smoke cigarettes die 14 years earlier than nonsmokers. People who continue to smoke cumulatively add to the health damage they have already suffered by smoking. Research indicates that your attempt to quit smoking will be more likely to succeed if you use counseling and approved medications. Getting help from a professional is more effective than trying to quit on your own. If you stop smoking, it can improve your health immediately. We hope to see you for your next visit.”

The Threat Plus Genetic Prime Message—Based on research conducted previously by the present study team (e.g., Cappella et al., 2005; 2006), a novel recruitment message that involved priming smokers about the genetic basis of nicotine dependence was developed. Participants randomized to this condition received the threat message and the following: “Whether a person gets hooked on cigarettes, how much they smoke, and how hard it is to quit is determined, in part, by genes he or she has inherited. Variations in genes that people inherit can affect the levels of brain chemicals called neurotransmitters. Differences in levels of neurotransmitters, in turn, have been shown by scientists to influence smoking habits. Dopamine is one of these brain chemicals that helps regulate reward or pleasure-seeking behavior. Researchers have connected the risk for nicotine dependence and how well smokers respond to treatments for nicotine dependence with variations in genes in the dopamine reward pathway. Scientists have also found that genetic differences influence how medications are metabolized, or broken-down, in the body. These

genetic differences between smokers also appear to play an important role in a person's ability to quit smoking with a particular medication."

The Smoking Cessation Program

All participants received 12 weeks of varenicline, according to approved FDA labeling, and six sessions of behavioral smoking cessation counseling with a trained counselor. Participants initiated varenicline with 0.5mg once per day for day 1 to day 3, then 0.5mg twice a day for day 4 to day 7, and then 1.0mg twice per day from day 8 to day 84. Varenicline was selected since it produces very high cessation rates among the available FDA-approved smoking cessation medications (Aubin et al., 2008; Gonzales et al., 2006; Jorenby et al., 2006). Counseling was included since it is considered an integral component of effective smoking cessation treatment and can improve the efficacy of medications (Fiore et al., 2000; 2008). The counseling program was a structured and manual-based counseling intervention modeled on accepted guidelines for smoking cessation treatment (Fiore et al., 2008). The intervention is designed to enhance awareness of the harmful effects of smoking, assist the person in developing skills to quit and avoid relapse, and instruct the smoker on medication use (see Schnoll et al., 2010). All counseling sessions were provided in-person.

Measures

Demographics—Standard questionnaires were administered to collect demographic information, including age, gender, and race/ethnicity.

Tobacco and Alcohol Use—Participants indicated their current smoking rate and current number of alcoholic drinks consumed per day. For trial eligibility, participants were asked about use of smokeless tobacco and current or planned use of smoking cessation treatments.

Medical History—Medical history was ascertained. A urine drug screen and pregnancy test was completed. Breath alcohol content and blood pressure were assessed.

Psychiatric History—Lifetime prevalence of Axis 1 psychiatric diagnoses was determined using the MINI International Neuropsychiatric Interview (MINI; Shehan et al., 1998). The MINI was administered by a trained technician to assess exclusion criteria. A subset of MINI interviews were audio-taped to ensure that the administration was consistent for all participants.

Smoking Cessation Program Enrollment—Enrollment into the smoking cessation program was measured by determining attendance at the first smoking cessation counseling session since this is when treatment began and this variable included only participants who were eligible following the in-person history and physical session (12 participants, 6 from each group, were deemed ineligible for the cessation program at the history and physical session and, thus, were excluded from analyses regarding enrollment at the first smoking cessation counseling session). Previous studies have defined enrollment into smoking cessation treatment programs in this manner (Dahm et al., 2009; Schnoll et al., 2004; Gariti et al., 2008).

Smoking Cessation—Smoking cessation at the end of treatment was measured using 7-day point prevalence abstinence, biochemically-confirmed, which is the most widely reported outcome in smoking cessation clinical trials (Fiore et al., 2008). Abstinence was defined as self-report of no smoking for seven days prior to the end of treatment (week 13) and confirmation with breath carbon monoxide (≤ 10ppm; Benowitz et al., 2002). Participants were assumed to be smoking if they were lost to follow-up, failed to provide a carbon monoxide sample, or had carbon monoxide levels > 10ppm (Benowitz et al., 2002).

Statistical Analyses

Participant baseline characteristics (e.g., gender, cigarettes per day) were compared across threat-only and threat plus genetic prime groups using analysis of variance (ANOVA) and chi-square tests. Logistic regression was used to evaluate prediction models for smoking cessation program enrollment (attendance at the first smoking cessation program session) and smoking cessation at the end of treatment. The effect of the recruitment message (threat-only vs. threat plus genetic prime) on these outcomes was evaluated controlling for variables (i.e., covariates) related to smoking behavior and cessation program enrollment: age, gender, race/ethnicity, and continuous measures of cigarettes per day and alcoholic drinks per day (see CDC, 2009; Dahm et al., 2009; Hymowitz et al., 1991; Schnoll et al., 2007). Chi-square was used to examine the relationship between race/ethnicity and enrollment and smoking cessation.

Results

Sample Characteristics

As shown in Table 1, 49% of the sample was female and about 58% were self-identified racial/ethnic minorities (African American, Asian, and multi-racial), including 52% African American. Participants were about 44 years of age, smoked about 19 cigarettes per day, and drank 2.3 alcoholic drinks per day. There were no significant differences between the recruitment message groups on these baseline characteristics.

Recruitment Message and Smoking Cessation Program Enrollment

Overall, 45.1% of participants (51/113) attended the first counseling session of the smoking cessation program (Table 2). The regression model for predicting enrollment at this visit based on the recruitment message, controlling for covariates, is shown in Table 3. A significantly greater proportion of participants in the threat plus genetic prime message condition (51.7%; 31/60) attended this session, vs. participants in the threat-only condition (37.7%; 20/53, $p = .03$; see Table 2). In addition, within this regression model, self-identified Caucasian participants were more likely to attend the first counseling session, vs. self-identified racial/ethnic minority participants (57% vs. 36%, $p = .01$) and participants who attended this session reported smoking fewer cigarettes per day, on average, at baseline ($M = 17.96$), vs. participants who did not attend this session ($M = 19.81$, $p = .04$). Parenthetically, the findings were similar when enrollment was defined as attendance at the initial history and physical session (results not shown). In addition, while the present study did not have adequate power to examine interaction effects, descriptive analyses indicated that, while there was a higher rate of enrollment at the first counseling session for

Caucasians who received the threat and genetic prime message, vs. Caucasians who received the threat-only message (74% vs. 57%; $\chi^2[1] = 5.1$, $p = .03$), there was no significant difference between ethnic/racial minority participants who received the threat and genetic prime message, vs. ethnic/racial minority participants who received the threat-only message (33% vs. 38%; $\chi^2[1] = .14$, $p = .46$).

Recruitment Message and Smoking Cessation

Overall, at the end of the smoking cessation treatment program, 66.7% of participants (34/51) were confirmed to have quit smoking (see Table 2). The regression model for predicting smoking cessation based on the recruitment message, controlling for covariates, is shown in Table 4. The quit rates across the recruitment message arms were not significantly different (65% vs. 67.7%). Within this model, participants who were self-identified as Caucasian were more likely to quit smoking, vs. those who self-identified as racial/ethnic minority participants (78.6% vs. 52.2%, $p = .03$).

Discussion

Most smokers who try to quit smoking do not use approved and recommended smoking cessation treatment programs in their quit attempts. Unfortunately, trying to quit in this fashion has a significantly lower probability of success. One potential reason for this lack of utilization of formal smoking cessation treatment programs is the reliance on basic recruitment messages that typically focus on the adverse health effects of smoking. Theories of behavior change (Marteau & Weinman, 2006; Weinstein, 1998) and studies of behavior change intentions (Cappella et al., 2006; Cappella et al., 2005) suggest that augmenting smoking cessation treatment program recruitment messages with information about genetic information may increase program enrollment rates. In this preliminary study, we detected evidence that enrollment into a smoking cessation treatment program could be enhanced by incorporating information about genetic aspects of nicotine dependence and response to treatments. To our knowledge, this is the first study to demonstrate a meaningful increase in actual (vs. intended) smoking cessation program enrollment from this novel recruitment message. While there was no effect of the novel recruitment message on quit rates at the end of treatment, given the relatively small sample size and preliminary nature of this study, the results support previous studies that have associated the presentation of genetic information on nicotine dependence to smokers and intentions to quit smoking (Cappella et al., 2006; Cappella et al., 2005).

While the results from this study are consistent with previous findings suggesting that genetic information can increase intentions to engage in healthy behaviors, the mechanisms for the effect remain unclear. One possibility is that smokers are well aware of the typical threats to their health from tobacco but the genetic considerations are novel and, as a result, persuaisve beyond the well known arguments about disease susceptibility. A second possibility is that genetic threats simply pile on top of ordinary threats from smoking, in effect adding to the overall sense of concern. What is not seen here is a depression of healthy choices that would be associated with a sense of fatalism about genetic influences on nicotine dependence and the ability to quit smoking. The current study cannot distinguish

among these potential pathways of influence; subsequent research will need to test these processes among other candidates.

Our results also suggested that future research designed to address rates of enrollment into smoking cessation treatment programs need to address issues that may undermine interest in treatment programs among smokers from racial/ethnic minority groups. We found lower rates of enrollment and smoking cessation for smokers that self-identified as racial/ethnic minorities, compared to smokers who self-identified as Caucasian. In addition, the results suggest that the genetic prime message may have had less of an influence on enrollment into a smoking cessation program among self-identified ethnic/racial minority smokers. These findings converge with previous studies which have shown that, compared to Caucasians, African Americans are less likely to seek treatment for smoking cessation (Zhu et al., 2001), use nicotine replacement therapies (Fu et al., 2008), or enroll in smoking cessation clinical trials (Dahm et al., 2009). Participation of ethnic/racial minorities in formal smoking cessation treatment programs may be influenced by concerns surrounding participating in research (Yerger et al., 2008). Indeed, previously, we found that worry about potential treatment-related side effects were significantly higher among African Americans undergoing screening for a smoking cessation trial, compared to Caucasians (Dahm et al., 2009). Likewise, African American smokers report lower trust of physician/scientists and lower endorsement of the need for formal treatments for nicotine dependence, and greater concern over the addictive nature and safety of smoking cessation treatments (Yerger et al., 2008). Thus, future studies of recruitment messages for smoking cessation treatment programs should consider unique concerns among racial/ethnic minority smokers which undermine enrollment into treatment programs.

These findings should be viewed in the context of study limitations. First, this trial was designed to be the first step toward developing this novel recruitment message for smoking cessation treatment programs. As such, the sample size was relatively small, which limited statistical power. The sample size also prevented formal evaluation of potential moderators of the effect of the recruitment message to determine if the novel recruitment message had a greater effect for specific sub-groups of smokers. Second, the present study did not evaluate potential mediators of the effect of the recruitment message and, thus, explaining how the novel message influences outcomes remains unclear. Third, this study did not examine message comprehension and, given the complexity of genetic information, future studies should measure the degree to which the study population understands the content of the genetic prime message. Finally, the present sample, like many smoking cessation clinical trials, was relatively healthy, having been screened for psychiatric and medical conditions. Thus, future studies of this novel recruitment message should use a large enough sample to have adequate statistical power and to allow for sub-group analyses and include formal analytic procedures to evaluate mediators of treatment effects. Further, future studies could evaluate the effects of this novel recruitment message among clinical populations such as smokers with depression or with cancer.

Nevertheless, the findings from this preliminary study suggest that a simple, affordable, and transportable recruitment message can have measurable and meaningful beneficial effects on the willingness of smokers to enroll in a smoking cessation program. By simply augmenting

a recruitment message to emphasize the influence of genes on nicotine dependence and the ability to quit smoking, a greater proportion of smokers attended the smoking cessation treatment program. While the results in this study may seem modest, if translated onto a population level, the effects of this novel recruitment message could have a substantial public health impact. A subsequent, adequately-powered clinical trial appears warranted to fully determine the efficacy of this novel recruitment strategy for increasing use of, and response to, smoking cessation treatment programs.

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Table 1

Sample Characteristics and Differences between Recruitment Message Groups

Characteristic	Threat-only (n = 59)	Threat Plus Genetic Prime (n = 66)	Overall (n = 125)
Sex (% Female)	47.5	50.0	48.8
Age (Mean, SD)	43.9 (8.9)	43.1 (11.4)	43.5 (10.3)
Race (% Caucasian)	49.2	34.8	41.6
Cigarettes Per Day (Mean, SD)	17.8 (6.7)	20.0 (7.8)	18.9 (7.4)
Alcoholic Drinks Per Day (Mean, SD)	2.3 (3.2)	2.2 (3.0)	2.3 (3.1)

Note. There were no significant differences between threat-only and threat plus genetic prime participants.

Table 2

Rates of Enrollment and Cessation Across Threat and Threat Plus Genetic Prime Message Groups

Outcome	Threat (n, %)	Threat Plus Genetic Prime (n, %)	Overall (n, %)
Enrollment Rate (First Smoking Cessation Session)	20/53 (37.7)	31/60 (51.7)	51/113 (45.1)
Quit Rate (End of Treatment)	13/20 (65.0)	21/31 (67.7)	34/51 (66.7)

Table 3

Logistic Regression Predicting Enrollment (First Cessation Counseling Session)

Variable	OR	95% CI	p
Age	.98	.94 – 1.02	.26
Sex[a]	.81	.36 – 1.84	.62
Race[b]	3.02	1.28 – 7.13	.01
Cigarettes Per Day	1.07	1.00 – 1.14	.04
Alcohol Drinks Per Day	.88	.77 – 1.01	.08
Recruitment Message[c]	2.54	1.09 – 5.90	.03

Note. OR = Odds Ratio; CI = Confidence Interval; p = Probability;

[a] Female = 0 and Male = 1;

[b] Ethnic/Racial Minority = 0 and Caucasian = 1;

[c] Threat-only = 0 and Threat plus genetic prime = 1.

Table 4

Logistic Regression Predicting Smoking Cessation

Variable	OR	95% CI	p
Age	.98	.92 – 1.04	.47
Sex[a]	1.86	.47 – 7.34	.38
Race[b]	.19	.05 – .82	.03
Cigarettes Per Day	.91	.80 – 1.03	.14
Alcohol Drinks Per Day	1.03	.82 – 1.29	.80
Recruitment Message[c]	.69	.18 – 2.75	.60

Note. OR = Odds Ratio; CI = Confidence Interval; p = Probability;

[a] Female = 0 and Male = 1;

[b] Ethnic/Racial Minority = 0 and Caucasian = 1;

[c] Threat-only = 0 and Threat plus genetic prime = 1.