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Hypnotherapy is more effective than nicotine replacement therapy for smoking cessation: Results of a randomized controlled trial



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KEYWORDS

Smoking cessation; Hypnosis; Nicotine replacement; Randomized controlled trial; Hospitalization

Summary

Background: The efficacy of pharmacotherapy for smoking cessation is well documented. However, due to relapse rates and side effects, hypnotherapy is gaining attention as an alternative treatment option. The aim of this one-center randomized study was to compare the efficacy of hypnotherapy alone, as well as hypnotherapy with nicotine replacement therapy (NRT), to conventional NRT in patients hospitalized with a cardiac or pulmonary illness.

Methods: We evaluated self-reported and biochemically verified 7-day prevalence smoking abstinence rates at 12 and 26 weeks post-hospitalization. Patients (n=164) were randomized into one of three counseling-based treatment groups: NRT for 30 days (NRT; n=41), a 90-min hypnotherapy session (H; n=39), and NRT with hypnotherapy (HNRT; n=37). Treatment groups were compared to a ''self-quit'' group of 35 patients who refused intervention.

Results: Hypnotherapy patients were more likely than NRT patients to be nonsmokers at 12 weeks (43.9% vs. 28.2%; p = 0.14) and 26 weeks after hospitalization (36.6% vs. 18.0%; p = 0.06). Smoking abstinence rates in the HNRT group were similar to the H group. There was no difference in smoking abstinence rates at 26 weeks between ''self quit'' and participants in any of the treatment groups. In multivariable regression analysis adjusting for diagnosis and demographic characteristics, H and HNRT were over three times more likely than NRT participants to abstain at 26-weeks post-discharge (RR = 3.6; p = 0.03 and RR = 3.2; p = 0.04, respectively).

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Conclusion: Hypnotherapy is more effective than NRT in improving smoking abstinence in patients hospitalized for a smoking-related illness, and could be an asset to post-discharge smoking cessation programs.

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Introduction

Cigarette smoking remains the leading cause of morbidity and mortality in the US, and is well recognized as the most remedial global health hazard. 1-3 Currently 45 million Americans continue to smoke, and about two thirds of smokers have expressed a desire to stop. 4 Smoking cessation programs have been among the most cost-effective measures to improve health and decrease mortality in the general population. 5-7 They have been greatly enhanced by the rapid gains in understanding the psychopharmacology of nicotine, and recognition of nicotine addiction. 8 However, the highly addictive nature of nicotine continues to pose a significant challenge to quitting. 9,10

The process of self-regulation and developing the motivation to stop smoking is complex. Life events may develop that may help motivate patients. Nearly four million smokers are hospitalized each year, and hospitalization for a smoking-related illness ranks high as a "teaching moment" when barriers are reduced and motivational counseling and modalities are accessible, thus enhancing treatment acceptance. 11,12 Most medications for smoking cessation double the odds of achieving abstinence after hospital discharge 13,14; however, the use and acceptance of pharmacotherapy can be limited by common side effects. 15,16

Complementary therapies that supplant the practice of conventional medicine are increasing being sought, and hypnotherapy continues to be viewed with great interest among smokers considering treatment options. 17,18 Through suggestion during intense attention, hypnotherapy may help abstinence by building self-motivation and regulation. 19,20 Although hypnosis has been claimed to be effective, current evidence for its efficacy has been inconclusive. 21,22

We studied the role of hypnotherapy in a behavioral counseling-based smoking cessation program for patients hospitalized with a cardiac or a pulmonary illness and compared it to conventional treatment with nicotine replacement therapy (NRT). We hypothesized that the suggestive powers of hypnosis may encourage behavioral coping mechanisms to further enhance motivation and increase the likelihood of smoking cessation after hospitalization for a smoking-related illness.

Methods

The study was a randomized controlled trial limited to one center. It was conducted at the North Shore Medical Center in Salem, Massachusetts between October 2006 and May 2009. The Institutional Review Board at the North Shore Medical Center and Partners Healthcare organization approved the protocol, and patients provided written consent before participating.

Settings and participants

All current smokers between the ages of 18 and 75 years admitted with a cardiac or pulmonary illness were electronically identified. Patients with a terminal illness, history of substance abuse, or a major psychiatric disorder were excluded. Psychiatric diagnoses were identified from the medical history and included schizophrenia, bipolar and personality disorders. We also excluded patients who were pregnant, patients who could not be followed after hospital discharge due to cognitive or language barriers, and patients who received hypnotherapy or NRT within the past six months (Fig. 1).

Nicotine dependence was assessed according to number of cigarettes smoked daily, pack-years of smoking, and prior quit attempts. Hospital discharge summaries were reviewed to determine the diagnosis responsible for the hospital admission. We used a smoking-specific self-efficacy measure via questionnaire to assess patients' sense of the importance of quitting, as well as their confidence in their ability to stop smoking.

Intervention

We randomized participants to one of three treatment groups: NRT only (NRT), hypnotherapy only (H), and a group receiving both hypnotherapy and NRT (HNRT). Treatment modalities are described in detail below. Randomization assignments were performed in permuted blocks of three (ratio 1:1:1) with assignments sequentially numbered, and schedule was maintained independent of the study by the project coordinator. Randomized assignments were concealed from both patients and research staff until patients had signed the informed consent document and were enrolled in the study. Eligible patients who did not wish to receive hypnotherapy or NRT were not randomized, but were observed as a fourth "self-quit" group.

All enrolled patients received self-help materials and counseling during their hospitalization. The self-quit group received the standard counseling given to all admitted patients, and received no further contact until 26 weeks post-hospitalization. Treatment groups receiving hypnotherapy and/or NRT had intensive counseling for 30 min in the hospital and had five follow-up telephone calls with additional counseling at 1, 2, 4, 8, and 12 weeks after hospital discharge. Telephone counseling sessions were standardized and usually lasted 15 min. During these calls, counselors enforced abstinence and assessed NRT adherence. Due to the nature of the intervention conditions, counselors could not be blinded to the modality of intervention.

Nicotine replacement therapy

Patients receiving NRT were given a free one-month supply of nicotine patches with the initial dose based on the number of cigarettes they smoked prior to hospitalization. For

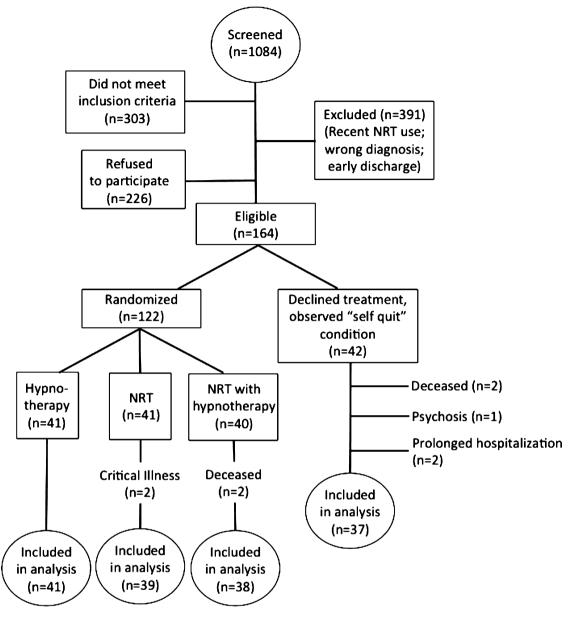


Figure 1 Flow chart showing participant enrollment.

example, patients smoking 10—20 cigarettes a day received a dose of 21 mg/day.²⁴ NRT patients were also given nicotine gum or lozenges to administer as needed to control their cravings and reduce withdrawal symptoms. The quit date was established at one week after discharge, and patients were encouraged to continue the use of NRT for at least two months.

Hypnotherapy

Patients randomized to hypnotherapy received a one time in-person hypnotherapy session within 1–2 weeks of hospital discharge, which consisted of a 90-min individualized session with a certified hypnotist and a tobacco treatment specialist (KP). Sessions began with an interview to assess motives and triggers for smoking. Hypnotherapy was then introduced as a collaborative and positive relationship that

can only happen with the patient consent, and any concerns about power and control were addressed. Through repetitive statements and deep breathing, a state of relaxation and focused attention was achieved. All patients achieved a trance state during hypnosis. Sets of suggestions with visual imagery were then made to emphasize good health and healing and to dissociate pleasant experiences from smoking. Suggestions were also made to create negative affectivity toward nicotine, building of self worth, and urge control to resist smoking. The sessions were individualized to reinforce the patient's main reasons and triggers for wanting to stop smoking. Patients were also trained in selfhypnosis, and a standardized tape for smoking cessation and relaxation was given at the end of the session for continued use at home to reinforce behavior modification and abstinence.

Table 1 Comparison of intervention groups (hypnotherapy, hypnotherapy plus nicotine replacement therapy [NRT]) and non-treatment group (Self-Quit) with the NRT-only control group in terms of baseline characteristics and follow-up status.

Characteristic	NRT n = 39 Mean ± SD	Hypnotherapy n = 41 Mean ± SD	Hypnotherapy plus NRT $n = 38$ Mean \pm SD	Self-Quit n=37 Mean ± SD
Age (years)	$\textbf{55.3} \pm \textbf{12.2}$	$\textbf{55.0} \pm \textbf{10.6}$	54.4 ± 8.9	$\textbf{56.0} \pm \textbf{10.7}$
Female (n, %)	18 (46.2%)	25 (61.0%)*	14 (36.8%)	16 (43.2%)
White race (n, %)	32 (82.1%)	38 (92.7%)*	31 (81.6%)	36 (97.3%)*
Years of education	$\textbf{12.6} \pm \textbf{2.0}$	$\textbf{13.0} \pm \textbf{2.0}$	$13.2 \pm 1.8^{*}$	$\textbf{13.2} \pm \textbf{1.9}$
Married or living with someone (n, %)	22 (56.4%)	17 (41.5%)*	17 (44.7%)	17 (46.0%)
Living with a smoker $(n, \%)$	16 (41.0%)	18 (45.0%)	13 (34.2%)	14 (38.9%)
Cardiac diagnosis at enrollment ^a $(n, \%)$	25 (64.1%)	26 (63.4%)	22 (57.9%)	27 (73.0%)
Enrolled in cardiac rehab $(n, \%)$	6 (15.4%)	3 (7.3%)	5 (13.2%)	2 (5.4%)
Average number of cigarettes smoked per day	$\textbf{21.2} \pm \textbf{12.6}$	$\textbf{19.8} \pm \textbf{12.6}$	20.5 ± 9.3	$15.0 \pm 10.0^{\circ}$
Total years as a smoker	$\textbf{34.2} \pm \textbf{14.4}$	$\textbf{36.5} \pm \textbf{12.7}$	34.3 ± 11.7	$\textbf{33.2} \pm \textbf{10.8}$
Number of attempts to quit smoking	$\textbf{3.6} \pm \textbf{4.2}$	$\textbf{4.5} \pm \textbf{5.4}$	$5.6 \pm 6.3^{*}$	$\textbf{4.1} \pm \textbf{3.4}$
Quitting-related self-efficacy: importance scale ^b	$\boldsymbol{9.7\pm0.7}$	$\boldsymbol{9.7\pm0.84}$	$9.3 \pm 1.4^{*}$	$9.4 \pm 1.2^{*}$
Quitting-related self-efficacy: confidence scale ^b	$\textbf{7.6} \pm \textbf{2.1}$	$\textbf{8.2} \pm \textbf{2.1}^*$	$\textbf{7.6} \pm \textbf{2.0}$	$\textbf{8.2} \pm \textbf{1.9}^*$
Lost to follow-up $(n, \%)$	12 (30.8%)	14 (34.2%)	13 (34.2%)	17 (46.0%)

^{*} Tends to differ from NRT control group (p = 0.05 - 0.2); based on ANOVA for continuous variables and chi-square or Fisher's exact test for categorical variables.

Assessment

The primary outcome measure was 7-day prevalence of tobacco abstinence at 26 weeks post-hospitalization, as determined by self-report and verified by urinary cotinine levels (a level of less than 15 ng/ml was considered indicative of abstinence). In participants who failed to provide a urine sample, abstinence was confirmed by contacting a household proxy. Secondary outcomes were self-reported 7-day prevalence of tobacco abstinence from smoking at 12 weeks post-hospitalization for the three treatment groups, comparison of abstinence rates at 26 weeks between intervention groups and self quit group, and the influence of admitting diagnosis (cardiac vs. pulmonary) on abstinence rates at 12 and 26 weeks after discharge.

Analysis

Characteristics of the study population were described by reporting the means and standard deviations (SD) for the continuous covariates and frequencies and percentages for each level of categorical covariates. We reported the means and SDs of continuous covariates by treatment group and by smoking cessation status at 12 and 26 weeks post-hospitalization, and used ANOVA to assess whether differences in means between categories were statistically significant. For categorical covariates, we calculated the *p*-value for differences by treatment group and smoking cessation status using the chi-square test or Fisher's Exact test for tables with small cell frequencies.

We conducted outcome analyses as intention-to-treat, and considered participants who were not reached at follow up to be continuing smokers. We evaluated associations between treatment group and smoking cessation status using

unadjusted and multivariable logistic regression, with the smoking cessation variables as the dependent variables. We considered covariates that were associated with intervention group status or smoking cessation status at p < 0.20 for inclusion in our final multivariable models. We conducted analyses with and without each of these covariates, and included in the final multivariable model any variable whose removal resulted in at least a 10% change in the beta coefficient for the smoking cessation status variable. We performed all statistical analyses using SAS software version SAS 9.2 (©2011 SAS Institute Inc., Cary, NC).

Results

A total of 164 patients admitted with a cardiac or a pulmonary diagnosis fulfilled inclusion criteria, and were enrolled in this study (Fig. 1). Of these, 122 patients were randomized to a treatment group (NRT, H, HNRT), and 42 patients declined treatment with NRT or hypnotherapy and were included in an observed "self quit" group. Of those randomized to a treatment condition, 33.9% were lost to follow-up by the 26-week time point (Table 1). There was no statistically significant difference in baseline demographic variables among groups (Table 1). Participants were predominantly middle aged and white, and 48% were female. Smoking history was similar among the groups. A cardiac diagnosis was the primary cause on admission in 59.8% of patients. Ischemic heart disease accounted for 86.5% of these admissions, and there was evidence for myocardial injury in 33.7% of cardiac patients. Exacerbation of chronic airway obstruction or pneumonia accounted for 80% of pulmonary admissions.

Self-efficacy related to smoking cessation was high in all groups at baseline, and did not differ based on type of diagnosis at hospitalization (i.e., cardiac vs. pulmonary; data not

^a Remaining patients had a pulmonary diagnosis at enrollment.

^b Scale range: 0–10, with a score of 10 indicating high self-efficacy.

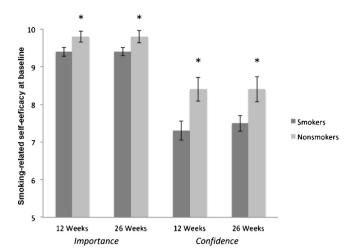


Figure 2 Comparison of average smoking-related self-efficacy (i.e., perceived importance of and confidence in ability to stop smoking) at baseline by smoking status at follow-up (12 and 26 weeks) with standard errors.

shown). However, smoking-related self-efficacy at baseline was associated with smoking abstinence at follow-up, such that smoking abstainers at both follow-up time points had reported higher self-efficacy in terms of both importance and confidence at baseline (p < 0.05 for all comparisons; Fig. 2).

Compared to the NRT group, patients receiving hypnotherapy were more likely to abstain from smoking at 12 and 26 weeks after hospitalization. At 12 weeks, 43.9% of patients in hypnotherapy group were self-reported nonsmokers compared to 28.2% of patients that received NRT (p=0.14; Table 2). Smoking abstinence rates were somewhat attenuated at 26 weeks post-discharge in these groups (H: 36.6% vs. NRT: 18%; p=0.06). Smoking abstinence rates in the group receiving hypnotherapy plus NRT were similar to those observed in those receiving hypnotherapy alone (Table 2).

In multivariable analysis, participants in both intervention conditions (i.e., H and HNRT) were over three times more likely than NRT group participants to have quit smoking based on the cotinine-verified 26-week smoking assessment

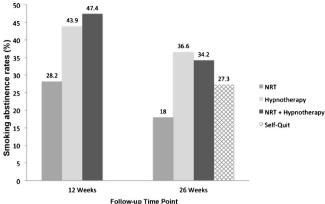


Figure 3 Comparison of smoking abstinence rates at follow-up time points by intervention status.

(RR = 3.6, 95%CI: 1.1—11.4; and RR = 3.2, 95%CI: 1.04—9.7, respectively; Table 2). Multivariable results based on the self-reported 12-week data were similar to those based on the 26-week data for the HNRT condition participants (RR = 3.4; 95%CI: 1.2—10.0), and were attenuated for participants in the hypnotherapy condition (RR = 2.2; 95%CI: 0.8-6.2).

Participants randomized to the hypnotherapy group tended to have higher smoking abstinence rates at 12 and 26 weeks of follow-up compared to those randomized to the NRT control group (p = 0.14 and p = 0.06, respectively; Fig. 3). Similarly, participants randomized to the "NRT plus hypnotherapy" group tended to have higher smoking abstinence rates at 12 and 26 weeks of follow-up compared to those randomized to the NRT control group (p = 0.08 and p = 0.10, respectively). There was no difference in smoking abstinence rates at 26 weeks between participants in the observed "self quit" group and participants in any of the three treatment groups (p-values range from 0.34 to 0.50). Patients who quit "cold Turkey" had abstinence rates of 27.0% at 26 weeks, compared to 18.0% in the NRT group (p=0.34), 36.6% in the H group (p=0.37) and 34.2% in the HNRT group (p = 0.50).

While pre-hospitalization smoking rates did not differ based on admitting diagnosis at hospitalization (18.8 \pm 1.1

Table 2 Unadjusted and multivariable relative risks^a for associations between intervention group and smoking status at 12 and 26 weeks follow up.

	Quit rate in NRT control group	Quit rate in intervention group	Unadjusted relative risk	Multivariable relative risk			
	n (%)	n (%)	(95% CI)	(95% CI)			
NRT vs. hypnotherapy							
Model 1: Quit at 12 weeks	11 (28.2%)	18 (43.9%)	2.0 (0.8, 5.1)	2.2 ^b (0.8, 6.2)			
Model 2: Quit at 26 weeks	7 (18.0%)	15 (36.6%)	2.6 (0.9, 7.4)	3.6 ^c (1.1, 11.4)			
NRT vs. NRT plus hypnotherapy							
Model 1: Quit at 12 weeks	11 (28.2%)	18 (47.4%)	2.3 (0.9, 5.9)	3.4 ^d (1.2, 10.0)			
Model 2: Quit at 26 weeks	7 (18.0%)	13 (34.2%)	2.4 (0.8, 6.8)	3.2 ^d (1.04, 9.7)			

- ^a Models reflect quit rates in the intervention group relative to quit rates in the control group.
- ^b Adjusted for gender, marital status, diagnosis at enrollment (cardiac vs. pulmonary).
- ^c Adjusted for race (white vs. other), diagnosis at enrollment (cardiac vs. pulmonary).
- ^d Adjusted for quitting-related self-efficacy (importance scale), diagnosis at enrollment (cardiac vs. pulmonary).

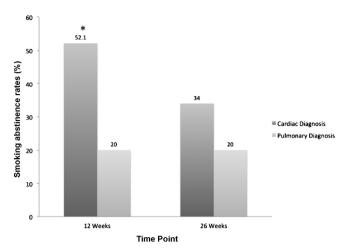


Figure 4 Comparison of smoking status at follow-up time points by diagnosis status (cardiac vs. pulmonary).

cigarettes per day among patients with a cardiac diagnosis vs. 19.9 ± 1.5 among patients with a pulmonary diagnosis, p = 0.54), smoking abstinence rates post-discharge did differ by admitting diagnosis. Smoking abstinence were significantly higher at 12-weeks post-hospitalization in participants admitted with a cardiac diagnosis as compared to those admitted with a pulmonary diagnosis (52.1% vs. 20.0%; p < 0.001; Fig. 4), such that patients admitted with a cardiac diagnosis were over four times more likely to abstain from smoking at 12 weeks than patients admitted with a pulmonary diagnosis (OR = 4.3, 95%CI: 1.8-10.3). This association persisted following adjustment for attendance at a cardiac rehabilitation program (OR = 3.6, 95%CI: 1.5-8.8). Although not significantly different, verified smoking cessation rates at 26 weeks post-hospitalization also tended to be higher in cardiac patients as compared to pulmonary patients (34.1% vs. 20.0%; p = 0.07).

Discussion

This study provides evidence that hypnotherapy is more effective than traditional pharmacotherapy with NRT in enhancing behavioral modification and increasing smoking abstinence rates following discharge in patients hospitalized with a cardiac or pulmonary illness. When compared to patients receiving treatment with NRT with counseling, patients receiving hypnotherapy with counseling were more likely to be nonsmokers at 26 weeks post-hospitalization. Our data also shows that combining NRT and hypnotherapy treatments did not further enhance the smoking cessation rates achieved with hypnotherapy alone.

Hypnosis is a highly individualized mind—body interaction with focused attention and a key suggestion phase that could reinforce a healthy and smoke-free state. ^{18,24,25} While it is not clear how hypnosis facilitates responsiveness to behavior change, it is possible that the beneficial effects of hypnotherapy can be attributed to increased self-confidence and motivation to weaken the desire to smoke. ¹⁸ The altered state of consciousness, which individuals allow themselves to enter, may allow proper and effective suggestions for smoking abstinence to be given. In a study by

Pederson et al.²⁶, hypnosis was shown to be more effective than a simple relaxation session when no suggestions for smoking abstinence were given. Hypnotherapy has also been shown to be a powerful adjunct tool to cognitive behavioral therapy,²⁷ and is of clinical benefit to some patients with bronchial asthma, irritable bowel syndrome and cancer.^{28,29}

However, issues associated with designing blinded and randomized controlled studies have been a major limitation to confirming the efficacy of hypnotherapy for smoking cessation,²¹ and heterogeneous methodology has made it difficult to compare results of existing studies. The few existing randomized controlled trials suggest some usefulness for hypnotherapy in promoting smoking abstinence. Carmody et al. compared hypnotherapy with psychological treatments in 256 subjects, with NRT provided to all participants.³⁰ Abstinence rates at 12 months were higher in the hypnotherapy group, but there was no difference in validated abstinence. Elkin et al. found that intensive hypnotherapy was superior to smokers receiving self-help material, but the number of participants was very small.³¹ However, in a study of 168 smokers, Rabkin et al. found hypnotherapy to be comparable to behavioral treatment and health education, but the hypnotherapy session was brief.³²

Our study also shows that the nature of illness at the time of admission may influence abstinence rates after discharge, such that despite having similar smoking rates prior to hospitalization, patients admitted with a cardiac diagnosis were more likely to have guit smoking at 12 weeks follow up as compared to patients admitted with a pulmonary illness. This association persisted after adjustment for attendance at a cardiac rehabilitation program. Our data also add to evidence from previous studies that hospitalization is an opportune time for intervention to modify behavior. 11,12 This may be due to the fact that patients are more likely to relate their smoking to the hospital admission and thus are more motivated to stop smoking.33 This was evident in the comparable abstinence rates noted at 26 weeks in the "self quit" group when compared to treatment groups, and the high scores on the smoking cessation importance and confidence scales in all groups in our study.

Our analysis is somewhat limited by the fact that comparing two vastly different modalities such as hypnosis and pharmacotherapy represents a randomization challenge, as participants and interventionists cannot be blinded to treatment conditions. We conducted an "intention-to-treat" analysis to address the potential for unplanned crossover and poor treatment adherence, such that differences in smoking cessation rates observed in this analysis may be underestimated. However, we were able to observe a significant difference between groups despite this limitation. Another limitation of this analysis is that participants in this study may differ from participants who declined to participate, and so may not represent the source population or the general public as a whole. However, we did compare an observed "self-quit" group who refused randomization to patients randomized to a treatment condition, and observed no difference between the groups in terms of baseline characteristics.

In conclusion, hypnotherapy combined with counseling appears to be more effective than NRT combined with counseling for improving short-term smoking cessation rates among patients admitted to the hospital for a

smoking-related illness. While encouraging, our results on hypnotherapy were specific to this highly motivated population. The enhanced motivation effect of the smoking-related admission may be short lived, ³⁴ and given the chronic and relapsing nature of nicotine dependence, ³⁵ there may be an important role for ambulatory physicians and specialists to extend this teaching moment and maintain enhanced motivation after hospital discharge. ^{36,37,38} Given the general interest in hypnotherapy, a desire by the patient to use this modality for smoking cessation should not be discouraged. However, further research in diverse populations is needed to confirm the efficacy of hypnotherapy before it can be recommended as mainstream therapy for smoking cessation.

Funding

This work was supported by the Norman H. Read Charitable Trust Foundation.

Authorship statement

All authors had access to the data and had a role in writing the manuscript.

Conflict of interest statement

No authors have any conflict of interest to declare.

Acknowledgments

The authors would like to thank Dr. Susan Regan for her help with data collection. This work was supported by the Norman H. Read Charitable Trust Foundation.

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