Is telephone counselling a useful addition to physician advice and nicotine replacement therapy in helping patients to stop smoking? A randomized controlled trial

Evidence

Études

Robert D. Reid, PhD, MBA; Andrew Pipe, MD; William A. Dafoe, MD

From the Prevention and Rehabilitation Centre and Smoking Cessation Clinic, University of Ottawa Heart Institute, Ottawa Ont.

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Abstract

Background: The authors evaluated the incremental efficacy of telephone counselling by a nurse in addition to physician advice and nicotine replacement therapy in helping patients to stop smoking.

Methods: The trial was conducted at the University of Ottawa Heart Institute. A total of 396 volunteers who smoked 15 or more cigarettes daily were randomly assigned to either of 2 groups: usual care (control group) and usual care plus telephone counselling (intervention group); the groups were stratified by sex and degree of nicotine dependence. Usual care involved the receipt of physician advice on 3 occasions, self-help materials and 12 weeks of nicotine replacement therapy. Telephone counselling was provided by a nurse at 2, 6 and 13 weeks after the target quit date. Point-prevalent quit rates were determined at 52 weeks after the target quit date.

Results: The point-prevalent quit rates at 52 weeks did not differ significantly between the control and intervention groups (24.1% v. 23.4% respectively). The quit rates did not differ significantly at the secondary measurement points of 4, 12 and 26 weeks.

Interpretation: Brief physician assistance, along with nicotine replacement therapy, can help well-motivated smokers to quit. Three additional sessions of telephone counselling by a nurse were ineffective in increasing quit rates. This form of assistance may be useful in the absence of physician advice or when self-selected by patients.

Smoking cessation remains a critical public health challenge. It would increase life expectancy by 2.6–4.4 years among Canadian male smokers and by 2.6–3.7 years among Canadian female smokers,[1] and it is one of the most cost-effective of all current health care interventions.[2]

Interventions by physicians are an important approach to smoking cessation. Ritvo and colleagues[3] identified 3 key strategies for successful physician-assisted interventions: physician advice and support, nicotine replacement therapy and cognitive-behavioural counselling. In one important study of physician assistance without nicotine replacement therapy that reported 1-year quit rates, the biochemically validated quit rates were between 10% and 15%.[4] Even in the absence of adjunctive counselling, nicotine replacement therapy is a highly effective aid to smoking cessation, doubling or tripling quit rates over placebo treatment.[5–9] In studies comparing active and placebo nicotine patches with physician advice, but no adjunctive counselling, validated quit rates at 1 year ranged from 17%[10] to 25%.[11] Validated 1-year quit rates as high as 27.5% have been reported among patients receiving active nicotine patches, physician assistance and intensive face-to-face counselling by a nurse.[12] In general, higher rates are associated with patients who are more motivated to quit, who receive extensive face-to-face counselling and who use nicotine replacement therapy. Because there is strong evidence of the benefits of nicotine

replacement therapy and physician assistance, these elements are the foundation against which other adjunctive treatments are tested.[3]

By increasing the accessibility, convenience and flexibility of smoking cessation interventions, particularly for people living in remote areas, proactive telephone counselling by trained counsellors is a form of adjunctive assistance that shows promise. It has been demonstrated to be effective as an adjunct to multicomponent hospital-initiated programs[13–16] (increasing quit rates from 20%–21% to 27%–31%) or when used by motivated smokers using self-quitting strategies[17,18] (increasing quit rates from 5%–16% to 10%–23%). Lichtenstein and colleagues[19] found that most randomized trials of proactive telephone counselling showed significant short-term (3 to 6 month) effects; several also found long-term differences between intervention and control conditions.[13,16–18]

The present study is the first to evaluate the incremental benefit of telephone counselling by nurses in addition to the relatively powerful intervention of physician advice, nicotine replacement therapy and self-help material. Orleans and colleagues[17] found a relative increase of 64% in 1-year quit rates (from 14% to 23%) when telephone counselling was added to self-help materials and social support instruction.[17] In our study, the addition of 3 telephone counselling sessions was intended to double the number of treatment sessions patients received and the time they spent addressing smoking-related issues. A priori, we calculated that a 15% improvement in absolute quit rates was necessary to justify the additional patient and program costs of telephone counselling.

Methods

The study was conducted at the University of Ottawa Heart Institute. We recruited volunteer smokers through radio advertisements. People aged 18 years or more were eligible if they smoked 15 or more cigarettes daily during the past year and were interested in quitting smoking within 30 days. We excluded people who had recent or severe heart disease, variant angina or active and untreated arrhythmias, women who were pregnant or lactating, people who had alcohol dependence or a history of drug abuse, people with a coexisting psychiatric illness and people with biochemical evidence of kidney or liver dysfunction.

At a screening session potential participants received advice on the importance of smoking cessation and were asked to provide informed consent. A detailed medical and smoking history was taken, blood was drawn for basic evaluation of hematological and blood chemistry values, and a study physician completed a standardized medical examination.

Before assignment to a study group, participants were stratified by sex and degree of nicotine dependence (high or low) to ensure that the 2 groups were balanced with regard to these factors. Highly dependent smokers were defined as those with a Fagerstrom Tolerance Questionnaire score of 7 or greater.[20] This questionnaire is a widely used 8-item test of nicotine dependence.[20–23]

We randomly assigned the volunteers to either usual care (control group) or usual care plus telephone counselling (intervention group) using a random numbers table. Group assignment was revealed by a study coordinator after the screening session and medical assessment.

Usual care involved the receipt of nicotine replacement therapy, self-help material and advice from 1 of 3 study physicians, who had participated in a 4-hour training session in accordance with the program "Guide Your Patients to a Smoke-Free Future."[24] The study physicians were blind to the treatment allocation of participants. Physician visits occurred about 2 weeks before the target quit date, and 4 and 12 weeks after the date. Each visit was limited to 15 minutes. At the first visit the physician reinforced the decision to quit, helped to set a target quit date and explained the proper use of the nicotine patch. Participants received, at no cost, a 12-week supply of nicotine patches, each patch to be worn for 16 hours daily: a 15-mg patch used for the first 8 weeks, a 10-mg patch for the next 2 weeks and a 5-mg patch for the final 2 weeks. The physician also provided a self-help booklet. During the second and third visits the physician provided follow-up advice in accordance with the program "Guide Your Patients to a Smoke-Free Future."

In addition to the usual care, participants in the intervention group also received telephone counselling 2, 6 and 13 weeks after the target quit date. Calls were made by trained nurse-counsellors using a scripted intervention adapted with permission from scripts by Orleans and colleagues.[17]

Participants received mailed questionnaires 4, 12, 26 and 52 weeks after their target quit date. If the questionnaire was not returned within 14 days, a second copy was delivered by courier. Failure to return the second copy prompted a call from the study coordinator, and participants completed the questionnaire by telephone. Participants unable to be contacted and surveyed within a 4-week window were considered to be smoking.

Follow-up questionnaires and interviews began with a reminder that subjects might be asked for a breath sample for validation of smoking status, creating a "bogus pipeline."[25] All participants who reported abstinence were asked to provide a breath sample for carbon monoxide (CO) determination. CO, with a half-life of less than 8 hours, can validate self-reports of not having smoked in the past 24 to 48 hours.[26]

The dependent variable of primary interest was the point prevalent abstinence rate at 52 weeks after the target quit date. Abstinence was defined as patient self-report of no smoking (not even a puff) in the preceding 7 days.[27] Smoking status was determined 4, 12, 26 and 52 weeks after the target quit date. A CO level of 9 ppm or less in a breath sample was considered confirmatory for nonsmoking.[28]

All eligible participants, regardless of compliance with the protocol, were included in the analysis. The sample size was calculated to detect an absolute difference in quit rates of 15% between the 2 groups ($\alpha = 0.05$, $\beta = 0.20$), and the size was increased by 10% in anticipation of attrition during the study period. Baseline characteristics between groups were compared using 2-tailed independent-group *t*-tests for continuous variables and χ^2 tests for categorical variables. For the primary analysis, the χ^2 test was used to compare the 52-week point prevalent quit rates between the 2 groups. A secondary analysis of quit rates was completed using sex and degree of nicotine dependence as stratification variables. Abstinence rates at 4, 12 and 26 weeks after the target quit date were also compared.

The Research Ethics Committee of the Ottawa Hospital — Civic Campus approved the study protocol.

Results

A total of 453 people responded to the radio advertise-

ments, and 408 (90.1%) attended the screening session. Twelve (2.9%) were excluded because of abnormal results of liver and kidney function tests, alcohol dependence or a history of drug abuse. The remaining 396 participants were randomly allocated to the control group (n = 199) and the intervention group (n = 197) (Fig. 1). The baseline characteristics of the subjects did not differ significantly between the 2 groups (Table 1).

Participation rates were tracked throughout the study (Table 2). Participants were provided with a total of 84 patches each and, on average, returned 18.8 (standard deviation [SD] 15.7) unused patches at the 12-week visit. Participants who were abstinent at the 12-week visit returned fewer unused patches than those who were smoking (4.3 v. 22.5 patches, $p < 0.01$). The participation rates did not differ significantly between the 2 groups for any of the common intervention components. The completion rates for the telephone counselling sessions are listed in Table 2.

One-year follow-up data was obtained for 337 (85.1%) of the participants. Of the 94 subjects who reported not smoking at 52 weeks, 71 (75.5%) provided breath samples for CO measurement. The proportion of subjects who provided breath samples did not differ significantly between the 2 groups. Measurement of CO verified self-reported abstinence in 70 (98.6%) of the 71.

Of the 59 subjects (14.9%) who withdrew from the trial, 6 dropped out during treatment, 4 changed address and could not be located through directory assistance, and 49 could not be contacted during the follow-up period. The withdrawal rate did not differ significantly between the control and intervention groups (14.6% v. 15.2%).

The point-prevalent quit rates in the 2 groups are shown in Table 3. We used self-reported smoking status in the primary analysis because (a) bogus pipeline procedures were used to maximize the veracity of self-reports, (b) CO monitoring cannot validate 7-day abstinence given the short half-life of CO, (c) people fail to return for validation for reasons other than deception, usually nuisance and social pressures,[28] (d) the proportion of participants who provided breath samples for CO measurement did not differ significantly between the 2 groups, (e) validation procedures identified only one discrepancy with self-reported smoking status, and (f) adjustment of the abstinence rates for validation did not affect conclusions about the efficacy of the interventions.

The overall quit rates at 4, 12, 26 and 52 weeks were 45.9%, 36.1%, 28.5% and 23.8% respectively. The quit rates did not differ significantly between the 2 groups at 52 weeks (24.1% in the usual care group and 23.4% in the intervention group), nor did they differ at the secondary outcome points of 4, 12 and 26 weeks.

When stratified by sex and level of nicotine dependence, the quit rate at 52 weeks was 27.6% among men with low dependence and 25.6% among men with high dependence; the corresponding rates among women were 25.0% and 19.3%. The quit rates did not differ significantly between the 2 groups in any of the strata.

Interpretation

This trial demonstrated that the addition of 3 telephone counselling sessions with a nurse were ineffective in increasing quit rates beyond the 52-week rate of 23.7% achieved with brief physician advice and nicotine replacement therapy. The overall 1-year quit rate we observed is similar to that in previous studies of nicotine replacement therapy in combination with various behavioural interventions.[11,29–31] For comparison purposes, it has been estimated that about 6% of people involved in smoking cessation studies could be expected to quit smoking without any intervention.[32]

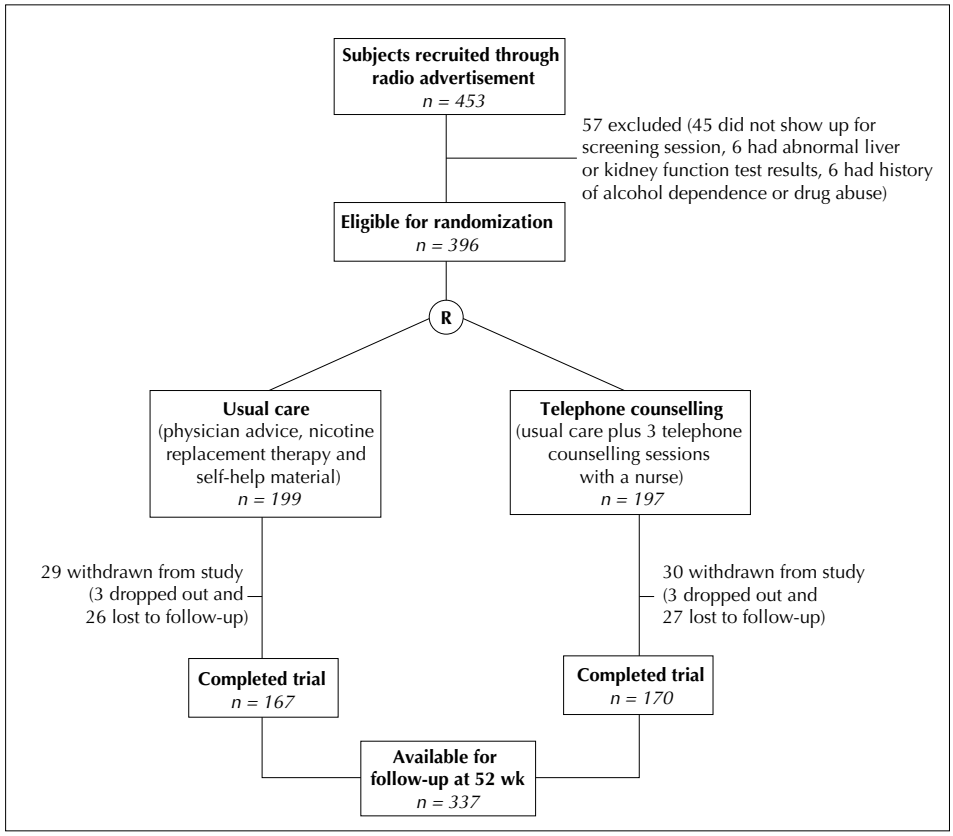

Fig. 1: Flow of study participants through selection and treatment protocols and follow-up. R = randomization.

It would be premature to conclude that telephone counselling is ineffective. The extensive physician-based intervention produced a relatively impressive quit rate in the control group. Telephone counselling may benefit smokers who are receiving less structured care (e.g., as an adjunct to self-administered nicotine replacement therapy) or who self-select this form of assistance. In a pilot study involving 123 subjects who self-selected telephone counselling as an adjunct to nicotine replacement therapy and physician assistance, we found that the self-reported quit rate (not biochemically validated) at 1 year was 44.7% (unpublished data). The telephone counselling protocol was the same as that used in the present study.

Prochaska and DiClemente[33] identified a continuum of stages preceding successful behaviour change.[33] One reason for the lack of effect of telephone counselling in our study may be that the participants were especially prepared to quit. Other studies have involved participants at various levels of motivation and preparation to quit. Curry and associates[34] found that outreach telephone counselling had its biggest impact over the long term on smokers who were initially least motivated to quit. In our study more than 80% of the participants were at the optimal stage of preparation for quitting according to the continuum described by Prochaska and DiClemente. Also, our participants were likely more motivated than average smokers identified in the course of regular visits to their primary care physician because they were recruited through radio advertisements that required them to initiate contact.

The schedule of telephone counselling may be important. DeBusk and colleagues[13] evaluated a multicomponent home-based smoking cessation program for patients after acute myocardial infarction that included nurse-initiated telephone follow-up at 2, 7, 21 and 90 days after discharge. The intervention produced 1-year quit rates of 70%, versus 53% for usual care. Zhu and associates[18] found that a schedule providing 5 telephone counselling sessions over 30 days was effective. The critical period for delivering counselling services may be during the first 1 to 2 weeks. Further studies may determine whether a changes in the script or timing of calls could yield different results.

Our findings support the notion that a well-conducted brief intervention by physicians, supported by nicotine replacement therapy and self-help material, can have a beneficial impact on the smoking behaviour of relatively heavy smokers. Training of physicians in these techniques should continue. Additional research may determine whether telephone counselling benefits smokers receiving less than optimal or no assistance from their physician.

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Table 1: Characteristics of volunteers participating in smoking cessation study

Characteristic	Control group* *n = 199*	Intervention group† *n = 197*
Mean age at study entry (and SD), yr	37.5 (7.9)	38.4 (8.2)
% male	52.3	52.8
Mean no. of cigarettes smoked daily (and SD)	22.8 (6.9)	24.2 (8.5)
Mean no. of years smoking (and SD)	21.3 (8.1)	21.9 (8.2)
Mean FTQ score (and SD)	7.1 (1.7)	7.2 (1.9)
% with FTQ score ≥ 7	65.2	69.0
Mean no. of quit attempts in past year	1.4 (2.0)	1.6 (2.0)

Note: SD = standard deviation, FTQ = Fagerstrom Tolerance Questionnaire.[20]
*Participants received usual care (physician advice, nicotine replacement therapy and self-help material).
†Participants received usual care plus telephone counselling sessions with a nurse.

Table 2: Completion rates for components of the smoking cessation intervention

Component	Completion rate, % Control group	Intervention group
Screening and assessment	100.0	100.0
Physician counselling*		
First visit	100.0	100.0
Second visit	89.9	90.9
Third visit	87.9	85.8
Use of nicotine patch for 12 wk	79.9	76.1
Telephone counselling†		
First call	–	95.9
Second call	–	87.8
Third call	–	79.2

*The first visit was 2 weeks before the target quit date, the second visit was 4 weeks after target quit date, and the third visit was 12 weeks after target quit date.
†The nurse made the first call 2 weeks after, the second call 6 weeks after and the third call 13 weeks after the target quit date.

Table 3: Self-reported abstinence from smoking at follow-up, by sex and degree of nicotine dependence

Group	Follow-up; abstinence rate, % (and 95% CI) 4 wk	12 wk	26 wk	52 wk
Men with low nicotine dependence				
Control (n = 41)	61.0	43.9	43.9	34.1 (19.6–48.6)
Intervention (n = 38)	47.4	36.8	31.6	21.1 (8.1–34.1)
Women with low nicotine dependence				
Control (n = 31)	54.8	41.9	29.0	22.6 (7.9–37.3)
Intervention (n = 22)	59.1	45.5	27.3	27.3 (8.7–45.9)
Men with high nicotine dependence				
Control (n = 63)	38.1	31.7	28.6	23.8 (13.3–34.3)
Intervention (n = 66)	45.5	34.8	27.3	27.3 (16.6–38.0)
Women with high nicotine dependence				
Control (n = 64)	42.2	35.9	21.9	18.8 (9.2–28.4)
Intervention (n = 71)	38.0	29.6	23.9	19.7 (10.4–29.0)
All				
Control (n = 199)	46.7	37.2	30.2	24.1 (18.2–30.0)
Intervention (n = 197)	45.2	35.0	26.9	23.4 (17.5–29.3)

Note: CI = confidence interval.

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Competing interests: The University of Ottawa Heart Institute Research Corporation has a contract with Johnson & Johnson–Merck Consumer Pharmaceuticals to manage the "Stop Smoking Now!" telephone counselling service offered to users of Nicotrol NRT. The authors received a grant from Johnson & Johnson–Merck to conduct a pilot study before the clinical trial; no payment was received from the company for the clinical trial or its analysis and write-up. Dr. Pipe has received speaker fees from Hoechst Marion Roussell and Glaxo Wellcome.

References

1. Grover SA, Gray DK, Joseph L, Abrahamowicz M, Coupal L. Life expectancy following dietary modification or smoking cessation. Estimating the benefits of a prudent lifestyle. *Arch Intern Med* 1994;154(15):1697-704.
2. Tsevat J. Impact and cost-effectiveness of smoking interventions [review]. *Am J Med* 1992;93(1A):43S-47S.
3. Ritvo PG, Irvine MJ, Lindsay EA, Kraetschmer N, Blair N, Shnek ZM. A critical review of research related to family physician-assisted smoking cessation interventions. *Cancer Prev Control* 1997;1(4):289-303.
4. Kottke TE, Solberg LI, Brekke ML, Conn SA, Maxwell P, Brekke MJ. A controlled trial to integrate smoking cessation advice into primary care practice: doctors helping smokers. *J Fam Pract* 1992;34:701-8.
5. Gourlay S. The pros and cons of transdermal nicotine therapy. *Med J Aust* 1994;160(3):152-9.
6. Fiore MC, Smith SS, Jorenby DE, Baker TB. The effectiveness of the nicotine patch for smoking cessation. A meta-analysis. *JAMA* 1994;271(24):1940-7.
7. Po ALW. Transdermal nicotine in smoking cessation: a meta-analysis. *Eur J Clin Pharmacol* 1993;45:519-28.
8. Silagy C, Mant D, Fowler G, Lodge M. Meta-analysis on efficacy of nicotine replacement therapies in smoking cessation. *Lancet* 1994;343:139-42.
9. Tang JL, Law M, Wald N. How effective is nicotine replacement therapy in helping people to stop smoking? *BMJ* 1994;308:21-6.
10. Tonnesen P, Norregaard J, Simonsen K, Sawe U. A double-blind trial of a 16-hour transdermal nicotine patch in smoking cessation. *N Engl J Med* 1991;325:311-5.
11. Sachs DPL, Sawe U, Leischew SJ. Effectiveness of 16-hour transdermal nicotine patch in a medical practice setting, without intensive group counseling. *Arch Intern Med* 1993;153:1881-90.
12. Hurt RD, Dale LC, Fredrickson PA, Caldwell CC, Lee GA, Offord KP, et al. Nicotine patch therapy for smoking cessation combined with physician advice and nurse follow-up. One-year outcome and percentage of nicotine replacement. *JAMA* 1994;271(8):595-600.
13. DeBusk RF, Miller NH, Superko HR, Dennis CA, Thomas RJ, Lew HT, et al. A case-management system for coronary risk factor modification after acute myocardial infarction. *Ann Intern Med* 1994;120(9):721-9.
14. Ockene J, Kristeller JL, Goldberg R, Ockene I, Merriam P, Barrett S, et al. Smoking cessation and severity of disease: the Coronary Artery Smoking Intervention Study. *Health Psychol* 1992;11(2):119-26.
15. Stevens VJ, Glasgow RE, Hollis JF, Lichtenstein E, Vogt TM. A smoking cessation intervention for hospital patients. *Med Care* 1993;31(1):65-72.
16. Taylor CB, Houston-Miller N, Killen JD, DeBusk RF. Smoking cessation after acute myocardial infarction: effects of a nurse-managed intervention. *Ann Intern Med* 1990;113:118-23.
17. Orleans CT, Shoenbach VJ, Wagner EH. Self-help quit smoking interventions: effects of self-help materials, social support instructions, and telephone counseling. *J Consult Clin Psychol* 1991;59(3):439-48.
18. Zhu SH, Stretch V, Balbanais M, Rosbrook B, Sadler G, Pierce J. Telephone counseling for smoking cessation: effects of single-session and multiple-session interventions. *J Consult Clin Psychol* 1996;64(1):202-11.
19. Lichtenstein E, Glasgow RE, Lando HA, Ossip-Klein DJ, Boles SM. Telephone counseling for smoking cessation: rationales and meta-analytic review of evidence. *Health Educ Res* 1996;11(2):243-57.
20. Fagerstrom KO, Schneider NG. Measuring nicotine dependence: a review of the Fagerstrom Tolerance Questionnaire. *J Behav Med* 1989;12(2):159-82.
21. Fagerstrom KO. Measuring degree of physical dependence on tobacco smoking with reference to individualization of treatment. *Addict Behav* 1978;3:235-41.
22. Fagerstrom KO. Physical dependence on nicotine as a determinant of success in smoking cessation. *World Smoking Health* 1980;5:22-3.
23. Fagerstrom KO. Towards better diagnosis and more individual treatment of tobacco dependence. *Br J Addict* 1991;86(5):543-7.
24. Canadian Council on Smoking and Health. *Guide Your Patients to a Smoke-Free Future*. Ottawa: The Council; 1996.
25. Roese NJ, Jamieson DW. Twenty years of bogus pipeline research: a critical review and meta-analysis. *Psychol Bull* 1993;114(2):363-75.
26. Benowitz N. The use of biological fluid samples in assessing tobacco smoke consumption. *NIDA Res Monogr* 1983;48:6-26.
27. Ossip-Klein DJ, Bigelow G, Parker SR, Curry S, Hall S, Kirkland S. Classification and assessment of smoking behavior. *Health Psychol* 1986;5(Suppl):3-11.
28. Velicer WF, Prochaska JO, Rossi JS, Snow MG. Assessing outcome in smoking cessation studies. *Psychol Bull* 1992;111(1):23-41.
29. Transdermal Nicotine Study Group. Transdermal nicotine for smoking cessation. Six-month results from two multicenter controlled trials. *JAMA* 1991; 266:3133-8.
30. Jorenby DE, Smith SS, Fiore MC, Hurt RD, Offord KP, Croghan IT, et al. Varying nicotine patch dose and type of smoking cessation counseling. *JAMA* 1995;274(17):1347-52.
31. Fiore MC, Kenford SL, Jorenby DE, Wetter DW, Smith SS, Baker TB. Two studies of the clinical effectiveness of the nicotine patch with different counseling treatments. *Chest* 1994;105(2):524-33.
32. Viswesvaran C, Schmidt FL. A meta-analytic comparison of the effectiveness of smoking cessation methods. *J Appl Psychol* 1992;77(4):554-61.
33. Prochaska JO, DiClemente CC. Stages of change in the modification of problem behaviors. *Prog Behav Modif* 1992;28:183-218.
34. Curry SJ, McBride C, Grothaus LC, Louie D, Wagner EH. A randomized trial of self-help materials, personalized feedback, and telephone counseling with nonvolunteer smokers. *J Consult Clin Psychol* 1995;63(6):1005-14.

Reprint requests to: *Dr. Robert D. Reid, Prevention and Rehabilitation Centre, University of Ottawa Heart Institute, 40 Ruskin St., Ottawa ON K1Y 4W7; breid@ottawaheart.ca*