A Telephone-based Support Program for Over-the-counter Nicotine Patch Users

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Strategies to help the 6.7 million Canadians dependent on tobacco to quit are a critical component of tobacco control.¹ Recent meta-analyses and treatment guidelines indicate that the nicotine patch provides effective treatment for tobacco dependence,²⁻¹¹ doubling the rate of success compared to placebo treatment. Absolute quit rates are in the range of 13% to 18% in clinical trials at 6- to 12-month follow-up, and are enhanced by the addition of behavioural therapy or counselling.^{4,7,11}

The use of nicotine patches in Canada has increased since they became available on an over-the-counter (OTC) basis in June 1998.¹ In this setting, nicotine patches increase quit rates 1.6 to 2.8 times over placebo,¹²⁻¹⁶ but absolute quit rates are lower than for clinical trials, ranging from 5% to 13% at 6-month follow-up. Little is known about the best forms of accompanying behavioural support in the OTC environment.

The Smoking Cessation Clinic at the University of Ottawa Heart Institute (UOHI) has developed Stop Smoking Now! (SSN!), a nurse-managed, telephone-based support program, for OTC users of the Nicotrol (Guelph: Johnson & Johnson-Merck) nicotine patch. This paper provides a preliminary evaluation of the SSN! Program in the OTC setting. It describes characteristics of self-selected par-

ticipants, and self-reported cessation rates at 34-week follow-up.

Program description

The SSN! program is provided at no additional cost to Nicotrol purchasers. Participants register by calling a toll-free number. Background data concerning smoking history, demographic information and expected quit date are collected. A self-help booklet and a series of informational pamphlets are sent via courier, usually arriving within three days of registration. The booklet identifies coping strategies for quitting and remaining smoke-free. Five informational pamphlets, in French and English, are available: managing withdrawal reactions, urges and cravings; dealing with weight gain/increased appetite; stress and negative emotions; developing social support; and handling relapse.

Four telephone calls are made to each participant by trained nurse-counsellors using a scripted intervention adapted with permission from scripts by Orleans et al.¹⁷ Participants are contacted 1, 2, 5 and 10 weeks after their target quit date and offered encouragement, advice and assistance consistent with their reported actions and intentions.

RESULTS

We followed a cohort of 258 people who registered in the SSN! program between June and September 1998. This number represented 5% to 10% of all Nicotrol purchasers during this period (Montreal: Intercontinental Medical Statistics). Because there are only data available concerning the wholesale purchase of Nicotrol by pharmacies, we are unable to provide a precise estimate of the actual number of

TABLE I
Demographic and Smoking History Variables for Program Participants

Variable	Percentage at Registration
Age Group (years)	
≤40	48.1
41+	51.9
Sex	
Male	24.4
Female	75.5
Previous Quit Attempts	
None	35.1
1-2	23.0
3-4	33.8
5+	8.1
Cigarettes Per Day	
1-10	5.2
11-25	73.5
26+	19.8

people who purchased and used Nicotrol during a quit attempt.

Demographic and smoking history variables for program registrants are shown in Table I. Participants were primarily females (75.5%), smoking 11 to 25 cigarettes per day (73.5%). Almost two thirds had made previous attempts to quit smoking.

To determine point-prevalent quit rates (i.e., no smoking in the past 7 days), we reviewed the self-reported smoking status recorded by the telephone counsellors 1, 2, 5 and 10 weeks after the target quit date. Completion rates for the telephone calls were 93.2%, 86.0%, 78.1% and 72.4%, respectively. We also contacted by telephone 205/254 (80.7%) of the participants, an average of 34 weeks (236 days ± 28 days) after their quit date, to determine self-reported smoking status. Participants who could not be contacted were assumed to be smoking.

The overall quit rate, as well as quit rates for participants grouped by demographic and smoking history variables, is shown in Table II. Quit rates 1, 2, 5, 10 and 34 weeks after target quit date were 68.2%, 64.7%, 58.9%, 51.2% and 36.2%, respectively.

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The University of Ottawa Heart Institute Research Corporation has a contract with Johnson&Johnson-Merck to manage the "Stop Smoking Now!" counselling services offered to users of Nicotrol nicotine replacement therapy.

TABLE II
Quit Rates at 34-week Follow-up in All Participants, and Grouped by Demographic and Smoking History Variables

Participant Grouping	n	% Quit (95% CI)
All Participants	258	36.2 (30.3, 42.1)
Age Group (years)		
≤ 40	124	36.8 (28.3, 45.3)
41+	134	34.1 (26.1, 42.1)
Sex		
Males	63	29.0 (17.8, 40.2)
Females	195	38.5 (31.7, 45.3)
Previous Quit Attempts		
None	91	33.3 (23.6, 43.0)
1-2	59	31.4 (19.6, 43.2)
3-4	87	41.3 (31.0, 51.6)
5+	21	33.3 (13.1, 53.5)
Cigarettes Per Day		
1-10	13	60.0 (33.8, 86.2)
11-25	190	36.5 (29.6, 43.4)
26+	51	28.9 (16.5, 41.3)

The perceived helpfulness of various SSN! Program components was evaluated (Table III) using a scale ranging from 1 (not helpful at all) to 5 (very helpful). Participants rated telephone counselling as the most helpful program component, followed by the nicotine patch, self-help booklet, mailed materials and wallet coping card, in descending order of helpfulness.

DISCUSSION

The OTC users in this study achieved a high long-term cessation rate of 36.2% at 8-month follow-up. In comparison, it is estimated that only 2.5% to 5.0% of smokers who quit on their own remain abstinent for one year.^{18,19} An important limitation to the generalizability of these results is the fact that participants self-selected the program; similar results can only be expected in people choosing this form of assistance. Participants likely represented a particularly motivated subset of OTC patch users.

These quit rates were also higher than the 5% to 13% 6-month rates previously reported in the OTC setting.¹²⁻¹⁵ Only one trial has reported data over longer-term follow-up. Winchell et al.¹⁶ observed a one-year continuous abstinence rate (i.e., no smoking after the quit date) of 8%.

There were a disproportionate number of female registrants in the SSN! program in comparison to the general population of adult smokers, and women in the program were more likely to quit than men. The National Population Health Survey (NPHS) found that, in 1996/97, females comprised 46% of all current smokers.²⁰ The NPHS also found that there was virtually no difference in the percentage of male

and female daily smokers who say they are considering quitting smoking within 6 months. There is no clear evidence suggesting gender differences in the effectiveness of smoking cessation interventions.⁴ However, to our knowledge, this is one of few studies to report a trend toward higher quit rates for women than men (38.5% vs. 29%).

A limitation of the present study was the lack of biochemical validation of smoking status. Because participants were from all provinces, we were not able to verify the smoking status reported during the telephone follow-up.

While this study provides preliminary evidence of a positive effect of the program and the usefulness of various program components, our ability to draw firm conclusions is limited by the lack of a control group. Future research will incorporate the use of a control group, biochemical validation of outcomes, and measurement of a wider range of predictors.

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REFERENCES

1. Reid R, Coyle D, Papadakis S, Boucher K. Nicotine Replacement Therapies in Smoking Cessation: Ottawa: Canadian Council on Tobacco Control, May 1999.
2. Hughes JR, Goldstein MG, Hurt RD, Shiffman S. Recent advances in the pharmacotherapy of smoking. *JAMA* 1999;281(1):72-76.
3. Hughes JR, Fiester S, Goldstein MG, et al. American Psychiatric Association practice guideline for the treatment of patients with nicotine dependence. *Am J Psychiatry* 1996;153(suppl):S1-S31.

TABLE III
Perceived Helpfulness of Various Program Components

Program Component	Mean Score (and SD)*
Nicotine Patch	4.0 (1.2)
Self-Help Booklet	4.0 (1.1)
Telephone Counselling	4.3 (1.0)
Mailed Materials	3.8 (1.1)
Wallet Coping Card	2.5 (1.6)

* 5-point scale: 1=not helpful at all; 5=very helpful

4. Agency for Health Care Policy and Research Smoking Cessation Guideline Panel. Clinical Practice Guideline Number 18: Smoking Cessation. U.S. Department of Health and Human Services, April 1996. Report No.: AHCPR Publication No. 96-0692.
5. Henningfield J. Nicotine medications for smoking cessation. *New Engl J Med* 1995;333:1196-201.
6. Jorenby D, Keehn D, Fiore M. Comparative efficacy and tolerability of nicotine replacement therapies. *CNS Drugs* 1995;3(3):227-36.
7. Fiore MC, Smith SS, Jorenby DE, Baker TB. The effectiveness of the nicotine patch for smoking cessation. A meta-analysis. *JAMA* 1994;271(24):1940-47.
8. Law M, Tang J. An analysis of the effectiveness of interventions intended to help people stop smoking. *Arch Intern Med* 1995;155:1933-41.
9. Li-Wan A. Transdermal nicotine in smoking cessation. A meta-analysis. *Eur J Clin Pharmacol* 1993;45(6):519-28.
10. Shiffman S, Mason K, Henningfield J. Tobacco dependence treatments: Review and prospectus. *Annu Rev Public Health* 1998;19:335-58.
11. Silagy C, Mant D, Fowler G, Lancaster T. Nicotine replacement therapy for smoking cessation (Cochrane Review). The Cochrane Library, Issue 1 ed. Oxford: Update Software, 1999.
12. Sonderskov J, Olsen J, Sabroe S, Meillier L. Nicotine patches in smoking cessation. *Am J Epidemiol* 1997;145:309-18.
13. Leischow S, Muramoto M, Cook G, et al. OTC nicotine patch: Effectiveness alone and with brief physician intervention. *Am J Health Behav* 1999;23(1):61-69.
14. Leishow SJ, Castellini S, Merikle E. The efficacy of the nicotine patch as an over-the-counter medication. *J Addict Dis* 1997;16:140.
15. Hays JT, Croghan IT, Offord KP, et al. Over-the-counter (OTC) transdermal patch therapy. *J Addict Dis* 1997;16:136.
16. Winchell CJ, Wright C, Burke L, et al. Long-term abstinence in users of OTC nicotine replacement. *Clin Pharmacol Ther* 1997;61:191.
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. Cohen S, Lichtenstein E, Prochaska JO. Debunking myths about self-quitting: Evidence from 10 prospective studies of persons who attempted to quit smoking by themselves. *Am Psychol* 1989;44:1355-65.
19. Hughes J, Gulliver S, Fenwick J, et al. Smoking cessation among self-quitters. *Health Psychol* 1992;11(5):331-34.
20. Health Canada. National Population Health Survey Highlights: Smoking Behaviour of Canadians. Health Canada, January 1999.

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