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Résumé

Interventions en cessation tabagique à l'intention des patients hospitalisés et gérées par le personnel infirmier : résultats d'un essai clinique aléatoire

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Cet essai clinique randomisé a été conçu pour évaluer, en cessation tabagique, l'efficacité des interventions intensives comparées aux interventions brèves, chez les patients hospitalisés. La prestation de conseils et la remise de dépliants figurent parmi les interventions brèves. Le counseling au chevet du patient, la remise de documentation à emporter et la prestation d'un couseling par la voie de sept appels téléphoniques à la suite d'un congé d'hôpital et s'échelonnant sur plus de deux mois figurent parmi les interventions intensives. Ces dernières ont généré une abstinence confirmée de 1 an chez 28 % de participants (85/301), alors que ce chiffre se situe à 24 % (76/315) pour les interventions brèves. Le taux d'abstinence était particulièrement élevé chez les patients qui n'ont pas eu recours à la pharmacothérapie (36 %), contrairement à ceux qui ont adopté cette approche (16 %). Tel était le cas aussi chez les patients atteints de maladies cardiovasculaires (40 %), par opposition aux personnes atteintes d'autres maladies (20 %). Puisqu'il s'agissait d'un essai clinique à répétition, des points de repères à des fins de planification ont été proposés : un recrutement de fumeurs identifiés de 12 % à 15 % ; une complétion de plus de 90 % pour les interventions intensives; 15 % d'impersévérance; et une corroboration d'abstinence de 75 %. Les résultats confirment les conclusions chez l'ensemble des patients hospitalisés, y compris celles portant sur l'abstinence absolue et les résultats de traitements anticipés, l'impact des patients atteints de maladies cardiovasculaires sur les résultats, la reproductibilité d'une abstinence élevée dans un système de soins de santé universels, et le besoin de poursuivre d'autres recherches pour éclairer la pratique.

Mots clés : cessation tabagique, interventions brèves, interventions intensives, abstinence, impersévérance

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Nurse Case-Managed Tobacco Cessation Interventions for General Hospital Patients: Results of a Randomized Clinical Trial

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This randomized clinical trial was designed to test the efficacy of intensive versus brief smoking cessation interventions for hospital patients. The interventions included advice and pamphlets for Brief and bedside counselling, take-home materials, and 7 post-discharge telephone counselling calls over 2 months for Intensive. Confirmed 1-year abstinence was 28% for Intensive (85/301) and 24% for Brief (76/315). Abstinence was significantly higher for patients who did not use pharmacotherapy (36%) versus those who did (16%) and for patients with CVD (40%) versus other diagnoses (20%). Because this was a replication trial, benchmarks for planning can be suggested: 12% to 15% recruitment of identified smokers, 90% plus completion for Intensive, 15% drop-out, and 75% abstinence corroboration. The results consolidate findings for general inpatients, including expected absolute abstinence and treatment outcomes, the effect of CVD patients on outcomes, the reproducibility of high abstinence in a universal health-care system, and the need for more research to inform practice.

Keywords: acute care, health promotion, intervention effects, nursing interventions, outcome research and measures, tobacco use

This randomized clinical trial evaluated a nurse case-managed intensive versus brief tobacco cessation intervention for general hospital patients. The Canadian Nurses Association acknowledges the importance of nurses helping patients to quit smoking (Canadian Pharmacists Association, 2001), and the Registered Nurses Association of Ontario (RNAO) (2007), because of the severity of tobacco-related diseases, has developed best practice guidelines for integrating smoking cessation into daily practice. Tobacco use is the primary cause of preventable mortality and morbidity in developed countries: More than 80% of respiratory diseases, 30% of cardiovascular disease (CVD), 85% of lung cancers, 30% of all other cancers, and one in five deaths are directly related to tobacco use (US Department of Health and Human Services, 2004).

Although incorporating tobacco interventions into daily nursing practice can be a challenge (Rice & Stead, 2008), hospitalization provides an opportunity to do so. Saliency of disease often motivates patients to

quit; patients are removed from smoking cues and forced into temporary abstinence, frequently undergoing the worst withdrawal during hospitalization (Emmons & Goldstein, 1992); and the benefits of quitting can be immediate — for instance, decreased risk for intra-operative and post-operative complications (e.g., Møller, Villebro, Pedersen, & Tønnesen, 2002). Cessation can also result in greater risk reduction and cost-effectiveness than other secondary disease-management therapies such as medication (Goldman, Garber, Grover, & Hlatky, 1996) and in decreased utilization of health services compared to patients who do not quit (Wagner, Curry, Grothaus, Saunders, & McBride, 1995).

While there is evidence for the effectiveness of inpatient tobacco interventions, more research is needed (Fiore et al., 2008). The most recent Cochrane review included seven intensive versus brief tobacco intervention trials with general inpatients (Rigotti, Munafo, & Stead, 2008) — two tested pharmacotherapy, two tested behavioural interventions without pharmacotherapy, two tested behavioural interventions with pharmacotherapy, and one was written in Japanese so was not accessible. The pooled effect showed that inpatient contact plus a minimum follow-up of 1 month was significantly more effective than brief interventions with no follow-up. However, five trials were small (fewer than three quitters in the control group in two trials), only one was significant independent of meta-analyses, and none were conducted in a Canadian context.

The significant trial was a nurse case-managed intensive behavioural intervention without pharmacotherapy carried out within California health maintenance organizations (HMOs). It showed high 1-year confirmed abstinence (27% vs. 20% control) and, counter-intuitively, significantly lower abstinence for patients who self-selected to use pharmacotherapy, likely due to higher levels of addiction (Houston Miller, Smith, DeBusk, Sobel, & Taylor, 1997), a finding that has since been replicated with cardiac patients in western Canada (Smith & Burgess, 2009).

Based on the principle that replication is the cornerstone of good science, the present trial was designed to replicate the significant HMO trial in Canadian hospitals to see if the high cessation rates and intervention effect would generalize. The Canadian system was expected to have lower average socio-economic status (SES) than HMOs because the HMO system serves those who are employed or can afford private health-care insurance whereas Canadian hospitals serve the full spectrum of SES due to equal access to care through a single-tier universal health-care system. Since smoking is higher and cessation is lower among lower SES, whether measured as education, income, or wealth (Chapman, Fiscella, & Kawachi, 2010), it was not evident that the HMO findings

would replicate. The only other intensive behavioural intervention trial (besides the HMO trial) resulted in low, non-significant outcomes (10% vs. 9%) (Hennrikus et al., 2005).

The HMO intervention, Staying Free, originated with post-myocardial infarction (MI) patients (Taylor, Houston Miller, Killen, & DeBusk, 1990). Nurses were enlisted as case managers due to their clinical experience and their integrated role in the health-care system (DeBusk et al., 1994). The intervention, initiated during hospitalization and followed up post-discharge by telephone, is front-end loaded — the initial session is the longest and most calls are in the first few weeks to capture the most critical time for preventing relapse (Taylor et al., 1990). The intervention is based on increasing self-efficacy to remain abstinent, and efficacy has remained the primary predictor in Staying Free trials (Smith & Burgess, 2009; Smith, Kraemer, Houston Miller, Taylor, & DeBusk, 1999). The focus on Bandura's (1986) self-efficacy originated with the researchers' finding in cardiac rehabilitation that efficacy was a better predictor of behaviour than past performance (Taylor, Bandura, Ewart, Houston Miller, & DeBusk, 1985). Staying Free has been tested as part of a multiple-risk-factor intervention (DeBusk et al., 1994) and has been implemented in nursing practice with self-reported abstinence identical to that found in the HMO trial (Smith, Reilly, Houston Miller, DeBusk, & Taylor, 2002). It is the only inpatient intervention awarded the US Congressionally-Based Top Tier Evidence Standard (Coalition for Evidence-Based Policy, 2010).

The hypotheses in the present trial were based on the HMO trial. We hypothesized that: (1) a nurse case-managed intensive intervention would increase abstinence significantly over a brief intervention with general inpatients, (2) absolute rates would be similar to the HMO rates (≥ 20%), and (3) self-selected pharmacotherapy users would have significantly higher addiction and lower abstinence. A prediction equation was used to test the effects of the significant HMO predictors and efficacy on abstinence.

A secondary question, designed to consolidate findings from the literature, explored whether diagnoses of CVD or MI affected absolute cessation rates for the study. In meta-analyses (Rigotti et al., 2008), abstinence is high for CVD and MI patients and comparatively low for general inpatients. All general inpatient trials have included CVD patients, but only Houston Miller et al. (1997) report cessation rates for CVD and other diagnoses separately. The findings suggest that programs that enrol larger proportions of CVD patients should be expected to have higher cessation rates overall, which might help to explain the wide variability in abstinence for general patient trials.

For program planning, we tracked recruitment, treatment fidelity, drop-out, and abstinence corroboration in an attempt to set benchmarks to address gaps in the literature. Only one general inpatient trial (Hennrikus et al., 2005) has reported intervention fidelity. It is also the only study to report recruitment based on all identified smokers, not only eligible smokers, but the data were incomplete. Since both drop-out and abstinence corroboration are used in calculating abstinence but both have varied widely, a replication trial, such as the present one, can address benchmarking of these issues more directly than a one-off trial.

Methods

Design

This randomized clinical trial, conducted in three community hospitals in southern Ontario, tested two nurse case-managed inpatient smoking cessation interventions — Intensive and Brief. To isolate the treatment effect, all participants were administered Brief before randomization. Patients were not blinded to treatment. A computerized random number generator was used to select random permuted blocks of 10 patients for randomization to treatment, which was stratified by hospital and by age (less than 45 years, 45 plus years) because the study was originally designed for patients aged 45 plus — the HMO study showed that older patients were more likely to quit (Smith et al., 1999). Two weeks into recruitment, low numbers of older smokers resulted in our extending eligibility to 18 plus years. Power calculations were based on the HMO trial wave 1 (Taylor et al., 1996). Assuming a base rate of 20% 1-year confirmed abstinence, 293 patients per group would provide 80% power ($p < .05$) to find a 10% absolute difference. The base rate could be as low as 9% and the trial would still have 80% power ($p < .05$) to detect an 8% absolute difference. The study received ethics clearance from the hospitals and the researchers' institutional review board.

Sample

Eligibility criteria were identical to those in the Houston Miller et al. (1997) trial: 18 plus years, tobacco use in the last 30 days, minimum 36-hour stay, telephone access in the telephone-exchange area, and willingness to be randomized and to quit (all intensive intervention trials except Hennrikus et al. [2005] have selected on intention to quit). Exclusion criteria were: enrolled in another cessation trial, pregnant, medically complicated (e.g., palliative, unstable), institutionalized, unable to speak English/communication difficulties, substance abuse, and psychiatric history.

Case Managers

Two part-time recruitment nurses and one part-time intervention nurse were hired by the investigators for each hospital. Training included 1 week of education, role-playing and shadowing, four conference calls with an HMO nurse during the first 2 months, and semi-monthly case-review meetings throughout recruitment.

Brief Intervention

Brief (5 minutes) included cessation advice personalized to patients' medical conditions and review of two take-home pamphlets (a community resources pamphlet and the Canadian Cancer Society's *How to Quit*). Attending physicians, blind to treatment condition, were prompted by a note in patients' charts to provide a message personalized to patients' medical condition (for the script, see Smith et al. [2002]).

Intensive Intervention

Inhospital education included risks of smoking, benefits of quitting, withdrawal, weight gain, urges, smoke-free homes, and take-home materials (relapse-prevention video, workbook, and relaxation tape from the American Heart Association). Counselling focused on increasing self-efficacy to remain abstinent, which was operationalized in the intervention using Marlatt and Gordon's (1985) relapse-prevention model. The model maintains that smoking (behaviour) is situation-specific so it is vital to develop strategies that increase self-efficacy to remain smoke-free in specific situations. The strategies need to be personally relevant and not standardized, because what works for one person will not necessarily work for another. Patients rated their self-efficacy to remain abstinent in 14 situations identified as high risk for smoking (Baer, Holt, & Lichtenstein, 1986) and worked with the intervention nurse to develop cognitive, behavioural, and social-support strategies to remain abstinent in situations for which confidence was less than 70%. Post-discharge telephone counselling (5–10 minutes/call), scheduled for 2, 7, 14, 21, 30, 45, and 60 days, focused on relapse prevention and/or quitting after a relapse. Pharmacotherapy was not provided.

Procedure

All patients admitted to participating hospitals over a 16-month period (November 1998–February 2000) were asked by admitting clerks if they had used tobacco in the month prior. Recruitment nurses received a daily census that included smoking status to allow for efficient identification of smokers and review of charts for eligibility. They approached patients once medically stabilized, described the study, obtained informed

Table 1 *Baseline Characteristics of Randomized Patients*

Category	Intensive Counselling *N* = 309	Brief Counselling *N* = 334
Males: number (%)	148 (48)	169 (51)
Age (years): *M* ± *SD (range)*	49 ± 14 (18–83)	49 ± 14 (18–81)
≥ 45 years: *n* (%)	194 (63)	204 (61)
Caucasian: *n* (%)	293 (96)	320 (96)
Education (≤ high school): *n* (%)	232 (75)	238 (71)
Employed: *n* (%)	180 (58)	210 (63)
Married/common law: *n* (%)	196 (63)	218 (65)
Cigarettes/day: *M* ± *SD [mode] (range)*	20 ± 12 [25] (1–75)	20 ± 12 [25] (1–100)
Addiction: *M* ± *SD (range)*	13 ± 4 (5–25)	13 ± 4 (5–25)
Quit at least 1 week within last year: *n* (%)	75 (24)	77 (23)
Smoked during hospitalization: *n* (%)	21 (7)	31 (9)
Depression: *M* ± *SD (range)*	2 ± 2 (0–8)	2 ± 2 (0–8)
Confidence to quit: *M* ± *SD (range)*	73% ± 23 (0–100)	68% ± 24 (0–100)
Intention; *M* ± *SD (range)*	6 ± 1 (1–7)	6 ± 1 (3–7)
Definitely intend to quit: *n* (%)	174 (57)	191 (58)
Lives with smokers: *n*/*N* (%)	164/274 (60)	155/296 (52)
No smoking bans at home: *n*/*N* (%)	132/301 (44)	152/326 (47)
Drinks/week: *M* ± *SD [median, mode](range)* [a]	8 ± 8 [6, 2] (1–36)	7 ± 7 [5, 2] (1–50)
Hospital stay (days); *M* ± *SD (range)*	6 ± 6 (1–68)	6 ± 6 (1–71)

[a] Drinks/week applies to drinkers only: *n* = 146 Intensive; *n* = 159 Brief.
Note: Unless stated, fewer than five were missing from the denominators for any analysis.

consent, collected baseline measures, provided Brief, opened the randomization envelope, and informed patients of their group assignment. Intervention nurses provided the inhospital and post-discharge Intensive. Research assistants, blind to treatment conditions, telephoned participants 3, 6, and 12 months post-discharge to assess smoking status; calls were recorded as missed after 25 attempts.

Measures

The Houston Miller et al. (1997) measures were used. These included demographics, hospital stay, and smoking history (Table 1). Published scales included a modified Fagerstrom Tolerance Questionnaire (*range* = 5 [low addiction] to 25 [high addiction]) with test-retest reliability of .71 to .90 (Killen, Fortmann, Newman, & Varady, 1990); confidence to quit (0% to 100%) with established discriminate validity to distinguish successful quitters from non-quitters (Smith et al., 1999); and depressed mood in the last month (*range* = 0 [not at all] to 8 [severely]), which has established discriminate validity and has correlated highly with the Beck Depression Inventory short form (r = .70; King, Taylor, Haskell, & DeBusk, 1989). Smoking status was self-reported 7-day point prevalence at 3, 6, and 12 months post-discharge (not even a puff for the last 7 days; Ossip-Klein, Parker, Bigelow, Curry, & Kirkland, 1986) and confirmed at 1 year (saliva cotinine less than 15 ng/mL or proxy-confirmation). Receipt of physician advice was measured at 3 months, use of adjunct resources at 6 and 12 months, and use of pharmacotherapy at 3, 6, and 12 months.

Statistical Analyses

Baseline characteristics were compared using chi-square and t tests. Type I errors for multiple baseline and subgroup analyses were controlled using Bonferroni adjustment ($p < .01$). Mantel-Haenszel test of homogeneity of effects determined whether the data could be pooled across the stratification variables for outcome analyses. The interventions as a whole, but not the components, were tested for their effects on abstinence, with group differences analyzed using odds ratios (OR) with 95% confidence intervals (CI); logistic regression was used for subgroup analyses to test interactions between the grouping variable and treatment. To prevent over-fitting the prediction equation, we used hierarchical versus stepwise regression, a criterion of 15 quitters/predictor, and included only variables with less than 10% missing data and tolerance greater than 0.80 with other variables to minimize multicollinarity (Babyak, 2004). Entry steps were as follows: (1) treatment and the significant HMO predictors (Smith et al., 1999) — efficacy, age, addiction, depressed mood, and drinks/week; (2) MI versus other diagnoses, given that MI studies have

the highest abstinence rates (Rigotti et al., 2008); and (3) four additional variables with previous predictive validity — education (Chapman et al., 2010), gender (Croghan et al., 2009), previous-year quit 7 plus days (Pierce, Gilpin, & Farkas, 1998), and home smoking bans (Messer, Mills, White, & Pierce, 2008).

Results

Smoking prevalence was 19% — 33% for less than 45 years (2,030/6,123) and 15% for 45 plus years (3,116/20,847). Of the smokers, 12% enrolled, 25% refused, and 62% were ineligible (Figure 1), some for multiple reasons (456). Of the reasons for ineligibility, 42% were medically related: complicated (915), substance abuse (401), psychiatric (177), obstetric (45); 41% were short admissions/missed (1,495); and 17% for other reasons — outside calling area (195), communication difficulty (151), already enrolled (136), institutionalized or transferred (66), psychosocial (26), no phone (25), other (38). There were no between-group differences at baseline (Table 1) or lost to follow-up (Figure 1). Patients lost to follow-up had significantly higher depression (2.9 ± 2.8 vs. 2.4 ± 1.89) and lower confidence (64% ± 22% vs. 71% ± 24%); fewer were married (48/94 vs. 349/522); and fewer definitely intended to quit (38/94 vs. 308/517).

Treatment Fidelity

All 643 participants received Brief prior to randomization. At 3 months, 55% reported receiving physician advice (Brief 146/270; Intensive 140/253), which varied significantly by disease but not by treatment: CVD 76% (111/146), pulmonary 64% (37/58), other internal medicine 61% (74/121), orthopedic 43% (17/40), surgery 35% (26/75), cancer 33% (9/27), gynecology 21% (12/56).

In Intensive, 305 received bedside counselling, which averaged 36 minutes (± 20, *range* = 5–165) excluding video-viewing and 48 minutes (± 24, *range* 5–183) including video; two declined and two were missing data. Almost all received the workbook (97%), audiotape (96%), and video (95%), and 96% received at least one post-discharge phone call, with the average number of calls being six (± 2; Figure 1). By the end of Intensive treatment, 20 patients were lost to follow-up. Scores on the 14-item efficacy counselling questionnaire (*mean* = 66% ± 18%) correlated significantly with baseline efficacy ($r = 0.405$, $p < .001$).

Abstinence

Mantel-Haenszel tests of homogeneity of effects were non-significant, indicating that data from the hospitals and age categories could reasonably be pooled for analyses. Intensive had significantly higher abstinence

Figure 1 ***Patient Enrolment, Allocation, Intervention Completion, and Follow-up***

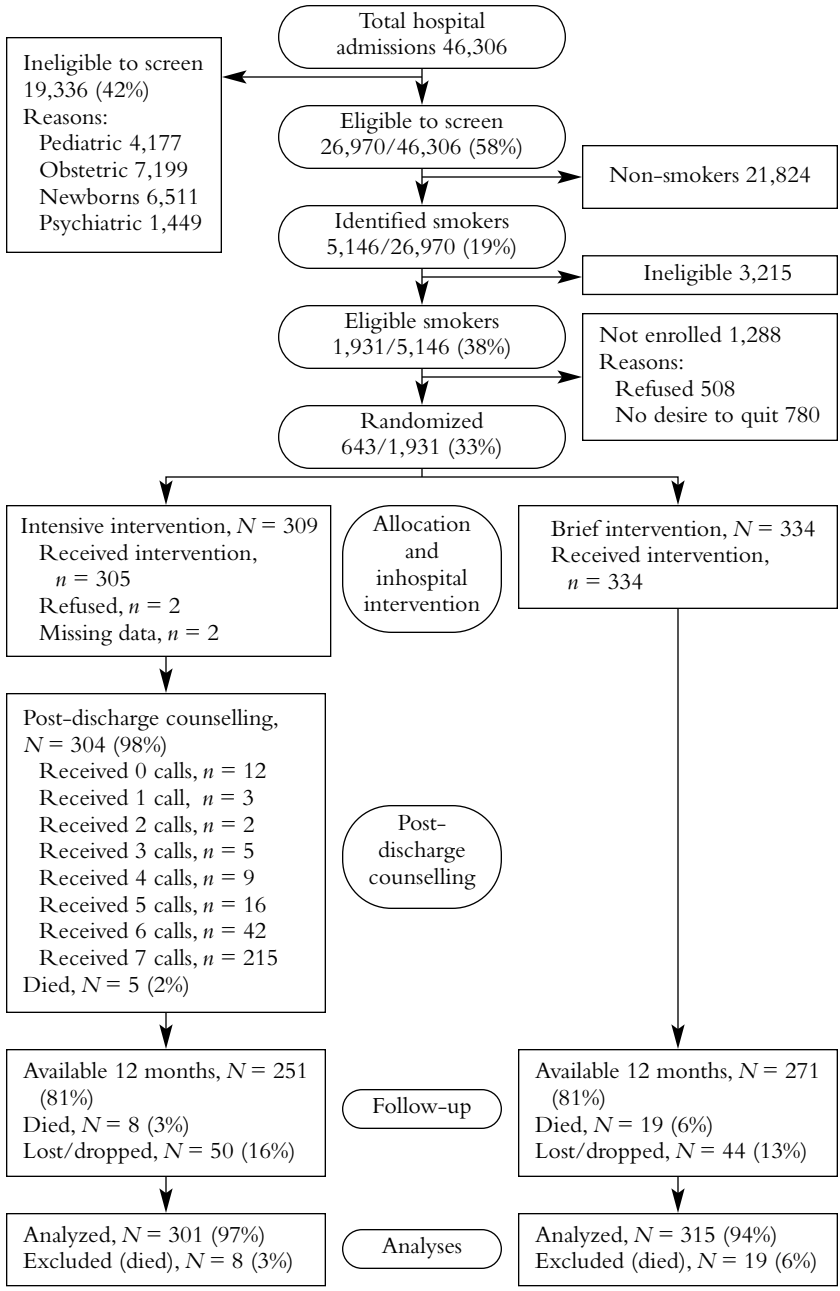

Table 2 ***Tobacco Abstinence by Treatment***

	Intensive Counselling		Brief Counselling				
	n/N	**(%)**	***n/N***	**(%)**	**% Diff**	**OR**	**95% CI**
3-month self-report	124/301	(41)	104/315	(33)	8	1.42	1.02–1.97
6-month self-report	103/301	(34)	98/315	(31)	3	1.15	0.82–1.61
12-month self-report	108/301	(36)	105/315	(33)	3	1.12	0.80–1.56
12-month confirmed	85/301	(28)	76/315	(24)	4	1.24	0.86–1.77
Excluding patients not available for follow-up (n = *522)*							
12-month self-report	108/251	(43)	105/271	(39)	4	1.19	0.84–1.69
12-month confirmed	85/251	(34)	76/271	(28)	6	1.31	0.90–1.91
12-month confirmed abstinence by discharge diagnosis							
Cardiovascular (CVD)	39/92	(42)	33/88	(37)	5	1.23	0.68–2.23
MI	20/42	(48)	20/51	(39)	9	1.41	0.62–3.22
Other IHD	9/23	(39)	4/18	(22)	17	2.25	0.56–9.05
Other CVD	10/27	(37)	9/19	(47)	-10	0.65	0.20–2.15
Pulmonary	9/37	(24)	10/34	(29)	-5	0.77	0.27–2.21
Other internal medicine	9/64	(14)	11/76	(14)	0	0.97	0.37–2.50
Cancer	6/19	(32)	3/15	(20)	12	1.85	0.38–9.08
Orthopedic	6/21	(29)	4/24	(17)	12	2.0	0.48–8.37
Gynecology	6/26	(23)	8/40	(20)	3	1.20	0.36–3.97
Non-cardiac surgery	10/42	(24)	7/38	(18)	6	1.38	0.47–4.09

OR = odds ratio; CI = confidence interval

Note: CVD rates include MI, other IHD, and other CVD. The trial does not have sufficient power to statistically test subgroups by diagnosis but data are presented here to compare with those of other studies and for use in meta-analyses. Caution should be used when comparing cessation rates by diagnosis expressed as a percentage, because a one-unit change in a numerator can vary widely across diagnoses in terms of percentage due to differences in denominators.

than Brief at 3 months and marginally higher abstinence at 6 and 12 months (Table 2).

Pharmacotherapy

Twenty-six percent of patients self-selected to use pharmacotherapy (Brief 62/250, Intensive 68/240) — bupropion (72), patch (22), gum (14), bupropion and patch or gum (18), patch and gum (2), and not specified (2); 26% in each group were missing data (46 not reached at any follow-up, 80 missing at least one follow-up). Pharmacotherapy users had significantly lower 1-year confirmed abstinence (21/130, 16%) than non-users (129/360, 36%; OR = 2.92, 95%, CI = 1.7–4.89); there were no significant treatment or treatment by pharmacotherapy interaction effects. The only significant baseline differences between users and non-users were as follows: users had higher addiction (14.6 ± 4 vs. 12.8 ± 4), users smoked more cigarettes/day (23 ± 12 vs. 18 ± 11), and more users had previously used pharmacotherapy (87/130 vs. 120/360).

Medical Condition

Abstinence for CVD patients (72/180, 40%) was significantly higher than for non-CVD patients (89/436, 20%; OR = 2.59, 95% CI = 1.77–3.78); there were no significant treatment or treatment by disease interaction effects. More CVD patients were male (116/180 vs. 181/436), definitely intended to quit (125/179 vs. 221/432), and received physician advice (116/152 vs. 170/371), and they were significantly older (55 ± 11 vs. 46 ± 14), had higher confidence (75% ± 24% vs. 68% ± 23%), and smoked more cigarettes/day (23 ± 14 vs. 18 ± 11).

Predictors of 1-Year Confirmed Abstinence

Patients missing data on any of the predictor variables were excluded from the regression analysis (45/616). Regression step 2 was significant but step 3 was not, indicating that step 2 was the better model. All steps 1 and 2 variables except treatment were significant: efficacy (OR = 1.02, 95%, CI = 1.01–1.03), age (OR = 1.02, 95%, CI = 1.002–1.031), addiction (OR = 0.94, 95%, CI = 0.90–0.99), depressed mood (OR = 0.89, 95% CI = 0.81–0.97), drinks/week (OR = 1.03, 95% CI = 1.00-1.06), and MI (OR = 2.22, 95% CI = 1.34–3.70).

Discussion

This nurse case-managed smoking cessation intervention trial conducted within the Canadian health-care system provided a rigorous replication of Houston Miller et al.'s (1997) HMO trial. Despite a substantially lower SES than in the HMO trial, abstinence for both Brief and Intensive was

higher than 20%, as expected. Intensive achieved the predicted abstinence rate but was not significantly higher than Brief, which was unprecedentedly high, thereby lessening the difference between treatments. Other findings consistent with the findings of the HMO trial include significantly lower abstinence among self-selected pharmacotherapy users, which was half that of non-users; significantly higher abstinence among CVD patients, which was double that of non-CVD patients; and the same predictors as the HMO trial, with a diagnosis of MI improving prediction. Abstinence corroboration and proportion of CVD patients were the same as found in the HMO trial, allowing for equitable comparison between trials.

The treatment difference and absolute abstinence rates provide important insights. The smaller than expected (4%) treatment difference ironically highlights what might be realistic for general inpatients. It is identical to the weighted average difference for the other two intensive behavioural trials (Hennrikus et al., 2005; Houston Miller et al., 1997) and higher than the weighted average difference that was significant for all intensive general inpatient trials in the most recent meta-analysis (Rigotti et al., 2008), suggesting that with this trial added to the collective, intensive interventions will remain evidence-based practice. This trial also showed that it is possible to reproduce the high HMO rates and achieve high cessation rates for both Intensive and Brief, even with a lower SES population in a different health-care system. The only other intensive behavioural trials were at odds — one reported high abstinence for both groups and the other low. The present trial increases the weighted average abstinence for behavioural interventions to 22% for Intensive and 18% for Brief. This would require 1,236 patients/group for future research to have sufficient power to find a significant difference (one-sided test); larger samples would be required for more complex designs.

The outcomes stratified by medical condition contribute further by showing that the proportion of CVD and MI patients will positively affect both absolute rates and treatment differences, thereby highlighting the importance of stratifying randomization and analyses by CVD to avoid confounding results. The stratified analyses showed that cessation among non-CVD patients in both groups was identical to that in the HMO trial, which is the only other general inpatient trial to tease out the effect of CVD outcomes on overall cessation (Houston Miller et al., 1997). With these two identical outcomes and no other data available, a provisional benchmark for non-cardiac abstinence can be suggested (22% Intensive, 19% Brief). The stratification analyses also elucidated that the source of the high Brief abstinence relative to the HMO trial was due to CVD patients, among whom abstinence for both treatments was higher

than in the HMO trial and abstinence for Brief was oddly high among non-IHD (ischemic heart disease) patients with reversed treatment outcomes. The non-IHD subgroup, although small, did affect overall CVD Brief rates and decreased the CVD treatment difference. These findings suggest that while the overall high Brief abstinence is compelling, it was related only to CVD and should be interpreted with caution.

Intensive performed as expected even though the treatment difference was not significant. There is no empirical evidence that Intensive rates can go higher — along with the HMO trial (Houston Miller et al., 1997) and one other trial, these are the highest reported for general inpatients (see Rigotti et al., 2008). There are also no empirically based suggestions for how to improve Intensive. It included more than 1 month of post-discharge follow-up, the only identifiable successful ingredient in inpatient interventions (Rigotti et al., 2008), and self-efficacy, the basis of the intervention, was a significant predictor of cessation. In meta-analyses with general populations there is no evidence that specific techniques or increased contact beyond what Intensive included can enhance cessation further — only varenicline and nicotine patch plus bupropion and extended-use patch plus gum/inhaler have surpassed Intensive's 28% abstinence (Fiore et al., 2008).

Self-selected use of pharmacotherapy was consistent with that in the HMO trial (Houston Miller et al., 1997) but lower than that for the general population (Shiffman, Brockwell, Pillitteri, & Gitchell, 2008). Among users, abstinence was significantly lower than among non-users and addiction was higher, consistent not only with two inpatient trials — the HMO trial and a cardiac trial (Smith & Burgess, 2009) — but with a review of self-selected use in the general population (Walsh, 2008). Although these findings seem counter-intuitive, as meta-analyses show a benefit for pharmacotherapy (Fiore et al., 2008), cessation with pharmacotherapy tends to be high in drug trials and low under "real world" self-selection conditions, in part due to medication non-compliance, which is related to lower cessation (Walsh, 2008). Clinical implications include ensuring that recommended dosages and durations are followed, and for persistent difficulties, such as repeated relapse and breakthrough withdrawal symptoms, higher-dose nicotine replacement therapy, combination therapies, and extended-use pharmacotherapy are recommended (Fiore et al., 2008). The development of standardized compliance measures would be beneficial in future studies (Walsh, 2008).

Program planning benchmarks based on the three intensive behavioural trials can now be suggested: 12% to 15% recruitment of identified smokers (consistent with Hennrikus et al., 2005), 15% dropout (average of the HMO trial and Hennrikus et al., 2005), and 75% abstinence corroboration (consistent with the HMO trial). Of note, recruitment was

much higher than the less than 1% of estimated smokers in the general population recruited through radio and newspapers for a smokers' helpline study with this intervention (Smith et al., 2004), thereby highlighting the receptivity of inpatients to interventions. Age distributions, however, will affect the absolute number recruited: Smoking prevalence was lower in this study than in the general population because the majority of hospitalized patients were older and their smoking rate was fittingly half that of younger patients.

We need further research specifically to inform decision-making in practice. Inpatient trials have all used a "centralized" approach — that is, full-time case managers hired by researchers to provide the interventions. Comparative evidence is needed for the "decentralized" guideline approach, which recommends that all staff nurses provide at least Brief interventions to their own patients (e.g., RNAO, 2007). Even though centralized Brief in research is consistent time-wise with guideline decentralized recommendations, it is likely not equivalent because patients are engaged for an additional 10 to 20 minutes for baseline data collection and there is more accountability when only one nurse is providing the intervention. Possible studies include: (a) centralized Brief versus staff nurse Brief, to see how Brief works in practice; (b) similarly, centralized Intensive versus staff nurse Brief; and (c) staff nurse Brief versus staff nurse Intensive (Brief with follow-up to a community resource — e.g., quit line). Needed also is translational research on adoption, implementation, and maintenance of programs in practice that includes process outcomes (e.g., fidelity and enrolment) and costs (e.g., training, utilization, and cost-benefit).

The major limitation of the trial is the lack of generalizability to subgroups that were excluded, such as patients with short admissions and patients hospitalized for substance abuse and/or psychiatric co-morbidities for whom it is difficult to design interventions that take into account various cognitive and social deficits (Esterberg & Compton, 2005). Also, the patients were English-speaking and predominately Caucasian; it is not clear how the interventions would work in different cultural settings, such as in hospitals with large Francophone or Aboriginal populations.

The results from this trial help to consolidate research findings for inpatient cessation interventions but present somewhat of a paradox for practice. As noted, although the treatment difference was not significant, this trial will increase the weighted average treatment difference for general inpatients in meta-analyses and thus Intensive will continue to be supported as evidence-based practice. There are various ways to fund Intensive and there are "how to" resources to help hospitals with implementation (Smith & Taylor, 2006). Brief might also be an appealing option in these times of cost constraint. Although it is lacking inpatient

meta-analytic evidence, Brief is recommended by clinical practice guidelines as the minimum for nursing practice (RNAO, 2007). Decentralized Brief, however, is not a panacea — training must be ongoing and can be complex in large hospitals; there is often staff resistance and lack of accountability; it is difficult to measure outcomes; and it still requires funds from the operating budget and some form of central organization (Smith & Taylor, 2006).

In conclusion, this trial contributes to evidence-based nurse case-managed prevention interventions in Canada. It is the third smoking cessation trial to test an intensive behavioural intervention without pharmacotherapy, and the first to do so in Canada. Because this was a replication study, we were able to address important issues needed to consolidate research findings that have not been directly addressed — absolute cessation rates, expected treatment differences, the effect of CVD patients on overall outcomes, replicability in universal health care, benchmarks for planning, and the need for research that informs practice. The consistency in design and outcomes with the HMO trial adds to the confidence with which the interpretations were made and will add value to inpatient meta-analyses by decreasing heterogeneity.

Despite the growing evidence base, inpatient cessation interventions in Canada are not mandated by policy or needed for accreditation, so decisions to implement them will come down to organizational values and how decisions are made about the allocation of finite health-care dollars. The benefits of prevention in clinical practice are often in the future and are easier to overlook in the short term when immediate, acute-care needs are straining resources. The MI that did not happen because someone quit smoking is not easy to measure but the costs to prevent it are, and the cost savings from cessation ultimately get passed on to the ministry of health and not necessarily to the hospital: The bed that is not filled with the prevented MI will be filled by another. Nonetheless, studies like the present one are important for the development of evidence and to continue to challenge researchers and practitioners to find ways to incorporate prevention that will ultimately reduce health-care costs and benefit patients, clinical practice, and society.

References

Babyak, M. A. (2004). What you see may not be what you get: A brief, nontechnical introduction to overfitting in regression-type models. *Psychosomatic Medicine, 66,* 411–421.

Baer, J. S., Holt, C. S., & Lichtenstein, E. (1986). Self-efficacy and smoking re-examined: Construct validity and clinical utility. *Journal of Consulting and Clinical Psychology, 54*(6), 846–852.

Bandura, A. (1986). *Social foundations of thought and action: A social cognitive theory.* Englewood Cliffs, NJ: Prentice-Hall.

Canadian Pharmacists Association. (2001). *Joint statement on smoking cessation tobacco — The role of health professionals in smoking cessation.* Retrieved May 17, 2010, from http://www.pharmacists.ca/content/about_cpha/who_we_are/policy_position/pdf/SmokingCessationStatement-Final.pdf.

Chapman, B., Fiscella, K., & Kwachi, I. (2010). Education and smoking: Confounding or effect modification by phenotypic personality traits? *Annals of Behavioral Medicine, 3,* 237–248.

Coalition for Evidence-Based Policy. (2010). *Top Tier Evidence Initiative: Evidence summary for the Staying Free smoking cessation program.* Retrieved October 7, 2010, from http://toptierevidence.org/wordpress/?page_id=507.

Croghan, I. T., Ebbert, J. O., Hurt, R. D., Hays, J. T., Dale, L. C., Warner, N., et al. (2009). Gender differences among smokers receiving interventions for tobacco dependence in a medical setting. *Addictive Behaviors, 34*(1), 61–67.

DeBusk, R. F., Houston Miller, N., Superko, R., Dennis, C., Thomas, R. J., Lew, H. T., et al. (1994). A case management system for coronary risk factor modification following acute myocardial infarction. *Annals of Internal Medicine, 120,* 721–729.

Emmons, K. M., & Goldstein, M. G. (1992). Smokers who are hospitalized: A window of opportunity for cessation interventions. *Preventive Medicine, 21,* 262–269.

Esterberg, M. L., & Compton, M. T. (2005). Smoking behavior in persons with a schizophrenia-spectrum disorder: A qualitative investigation of the transtheoretical model. *Social Science and Medicine, 61*(2), 293–303.

Fiore, M. C., Jaén C. R., Baker, T. B., Bailey, W. C., Benowitz, N. L., Curry, S. J., et al. (2008). *Treating tobacco use and dependence: 2008 update.* Clinical Practice Guideline. Rockville, MD: Public Health Service, US Department of Health and Human Services.

Goldman, L., Garber, A. M., Grover, S. A., & Hlatky, M. (1996). Taskforce 6: Cost-effectiveness of assessment and management of risk factors. *Journal of the American College of Cardiology, 27,* 1020–1030.

Hennrikus, D. J., Lando, H. A., McCarty, M. C., Klevan, D., Holtan, N., Huebsch, J. A., et al. (2005). The TEAM project: The effectiveness of smoking cessation intervention with hospital patients. *Preventive Medicine, 40,* 249–258.

Houston Miller, N., Smith, P. M., DeBusk, R. F., Sobel, D. S., & Taylor, C. B. (1997). Smoking cessation in hospitalized patients: Results of a randomized trial. *Archives of Internal Medicine, 157,* 409–415.

Killen, J. D., Fortmann, S. P., Newman, B., & Varady A. (1990). Evaluation of a treatment approach combining nicotine gum with self-guided behavioural treatments for smoking relapse prevention. *Journal of Consulting and Clinical Psychology, 58,* 85–92.

King, A. C., Taylor, C. B., Haskell, W. L., & DeBusk, R. F. (1989). Influence of regular exercise on psychological health: A randomized controlled trial of healthy, middle-aged adults. *Health Psychology, 8,* 305–324.

Marlatt, G. A., & Gordon, J. R. (Eds.). (1985). *Relapse prevention: Maintenance strategies in the treatment of addictive behaviors*. New York: Guilford.

Messer, K., Mills, A. L., White, M. M., & Pierce, J. P. (2008). The effect of smoke-free homes on smoking behavior in the US. *American Journal of Preventive Medicine, 35*(3), 210–216.

Møller, A. M., Villebro, N., Pedersen, T., & Tønnesen, H. (2002). Effect of preoperative smoking intervention on postoperative complications: A randomized clinical trial. *Lancet, 359*(9301), 114–117.

Ossip-Klein, D., Parker, S., Bigelow, G., Curry, S., & Kirkland, S. (1986). Classification and assessment of smoking behavior. *Health Psychology, 5*(Suppl), 3–11.

Pierce, J. P., Gilpin, E. A., & Farkas, A. J. (1998). Can strategies used by statewide tobacco control programs help smokers make progress in quitting? *Cancer Epidemiology, Biomarkers and Prevention, 459,* 459–464.

Registered Nurses Association of Ontario. (2007). *Integrating smoking cessation into daily nursing practice.* Retrieved May 17, 2010, from http://www.rnao.org/bestpractices/PDF/BPG_smoking_cessation.pdf.

Rice, V. H., & Stead, L. F. (2008). Nursing interventions for smoking cessation. *Cochrane Database of Systematic Reviews,* Issue 1, Art. CD001188.

Rigotti, N. A., Munafo, M. R., & Stead, L. F. (2008). Smoking cessation for hospitalized smokers: A systematic review. *Archives of Internal Medicine, 168*(18), 1950–1960.

Shiffman, S., Brockwell, S. E., Pillitteri, J. L., & Gitchell, J. G. (2008). Use of smoking-cessation treatments in the United States. *American Journal of Preventive Medicine, 34*(2), 102–111.

Smith, P. M., & Burgess, E. (2009). Smoking cessation initiated during hospital stay for patients with coronary artery disease: A randomized controlled trial. *Canadian Medical Association Journal*, *180*(13), 1297–1303.

Smith, P. M., Cameron, R., McDonald, P., Kawash, B., Madill, C., & Brown, K. S. (2004). Structuring telephone counselling for population-based smoking cessation. *American Journal of Health Behavior, 28,* 231–241.

Smith, P. M., Kraemer, H. C., Houston Miller, N., Taylor, C. B., & DeBusk R. F. (1999). In-hospital smoking cessation programs: Who responds, who doesn't? *Journal of Consulting and Clinical Psychology, 67*(1), 19–27.

Smith, P. M., Reilly, K. R., Houston Miller, N., DeBusk, R. F., & Taylor, C. B. (2002). Application of a nurse-managed inpatient smoking cessation program. *Nicotine and Tobacco Research, 4,* 211–222.

Smith, P. M., & Taylor, C. B. (2006). *Implementing an inpatient smoking cessation program.* Mahwah, NJ: Lawrence Erlbaum.

Taylor, C. B., Bandura, A., Ewart, C. K., Houston Miller, N., & DeBusk, R. F. (1985). Exercise testing to enhance wives' confidence in their husbands'

cardiac capability soon after clinically-uncomplicated acute myocardial infarction. *American Journal of Cardiology, 55*(6), 635–638.

Taylor, C. B., Houston Miller, N., Herman, S., Smith, P. M., Sobel, D., Fisher, L., et al. (1996). A nurse-managed smoking cessation program for hospitalized smokers. *American Journal of Public Health, 86,* 1557–1560.

Taylor, C. B., Houston Miller, N., Killen, J. D., & DeBusk, R. F. (1990). Smoking cessation after acute myocardial infarction: Effects of a nurse-managed intervention. *Annals of Internal Medicine, 113,* 118–123.

US Department of Health and Human Services. (2004). *The health consequences of smoking: A report of the Surgeon General*. Atlanta: Centers for Disease Control and Prevention, National Centre for Chronic Disease Prevention and Health Promotion. Office on Smoking and Health. Retrieved May 5, 2010, from http://www.cdc.gov/tobacco/data_statistics/sgr/2004.

Wagner, E. H., Curry, S. J., Grothaus, L., Saunders, K. W., & McBride, C. M. (1995). The impact of smoking and quitting on health care use. *Archives of Internal Medicine, 155,* 1789–1795.

Walsh, R. A. (2008). Over-the-counter nicotine replacement therapy: A methodological review of the evidence supporting its effectiveness. *Drug and Alcohol Review, 27,* 529–547.

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