

Randomized Trial Assessing the Effectiveness of a Pharmacist-Delivered Program for Smoking Cessation

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As one of the most accessible health professionals in the US healthcare system,¹ pharmacists are in a key position to assist individuals with tobacco-cessation services. Moreover, pharmacists are ideally situated to interact with individuals obtaining medications for smoking-related illnesses.

Pharmacists consider tobacco cessation an important activity and are interested in providing such counseling.^{2,3} Few pharmacists are formally trained to provide tobacco cessation counseling.⁴ However, opportunities for pharmacists to receive such training are increasing,⁵⁻⁷ which has been shown to increase confidence, quality, and provision of counseling.⁴ Automation technology and certification of technicians are freeing pharmacists from traditional dispensing responsibilities.⁸ In addition, updated pharmacy practice laws allowing for collaborative practice agreements with physicians are empowering pharmacists to initiate and modify drug therapy for patients, including tobacco cessation.⁹

Pharmacists in a wide variety of settings have begun to provide direct patient care, including smoking cessation.^{10,11} Although there is growing interest in expanding the pharmacist's role in tobacco treatment, only 15 studies have assessed the effectiveness of pharmacist-delivered tobacco cessation interventions.¹² Five studies were controlled¹³⁻¹⁷ and 10 were uncontrolled.¹⁸⁻²⁷ Fourteen

BACKGROUND: As trained and accessible healthcare professionals, pharmacists are in an ideal position to provide tobacco cessation interventions. Of the 15 studies identified in the literature assessing the effectiveness of tobacco cessation interventions delivered by pharmacists, this is the first randomized controlled trial conducted in the US of a pharmacist-delivered program for smoking cessation using biochemical confirmation.

OBJECTIVE: To assess the effectiveness on smoking cessation of a face-to-face group program conducted by the pharmacist team compared with a brief standard care session delivered by a pharmacist over the telephone.

METHODS: An open-label, prospective, randomized, controlled trial was conducted at a Veterans Health Administration, community-based outpatient clinic in the Rocky Mountain region. Participants were randomly assigned to receive a 3-session face-to-face group program conducted by the pharmacist team or one 5- to 10-minute standard care session delivered by the pharmacist team over the telephone. Participants in both groups were offered either immediate-release bupropion or nicotine patch at no cost. The primary outcome of self-reported abstinence was biochemically confirmed by urinary cotinine at 6 months after the quit date.

RESULTS: One hundred one smokers were randomized from October 3, 2005, to March 30, 2007, with the last 6-month follow-up survey completed on November 6, 2007. Analysis of data was completed in December 2007. Using intent-to-treat procedures, confirmed abstinence rates at the end of 6 months were 28% in the pharmacist-delivered face-to-face treatment group and 11.8% in the standard care telephone session control group ($p < 0.041$).

CONCLUSIONS: This study demonstrates that pharmacists are effective providers of tobacco cessation interventions. Greater utilization of pharmacists in tobacco cessation efforts could have a significant impact on smoking rates, prevention of tobacco-related diseases, and overall improvement in public health across the US.

KEY WORDS: nicotine addiction, pharmacist's role, pharmacy, smoking cessation intervention, tobacco cessation.

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of the studies targeted smoking¹⁴⁻²⁷ and 1 targeted chewing tobacco.¹³ Of 8 studies on smoking interventions conducted in the US, none included a control group^{19-21,23-27} and only 2 used biochemical measures to confirm self-reported cessation.^{19,20} The studies of tobacco interventions deliv-

ered by pharmacists suggest that it is feasible and effective for pharmacists to deliver such interventions.¹² However, rigorously designed studies employing control groups and biochemical verification for smoking cessation have yet to be conducted in the US.

This study assessed the effectiveness on biochemically confirmed reports of smoking cessation of a face-to-face group program conducted by a pharmacist team versus brief telephone assistance delivered by a pharmacist team. Biochemical verification of self-reported cessation is important to establish accuracy for studies using high-intensity interventions, which suffer from inflated quit rates if based on self-report alone.²⁸

Methods

STUDY DESIGN

This prospective, open-label, randomized trial compared the effectiveness on 7-day point prevalence quit rates of a face-to-face 3-session group program conducted by a pharmacist team versus one 5- to 10-minute standard care session delivered by the pharmacist team over the telephone. The intervention team consisted of a licensed clinical pharmacist and advanced pharmacy practice experience (APPE) students. Physicians at one Veterans Affairs (VA) community-based outpatient clinic in the Rocky Mountain region referred patients who smoked to a clinical pharmacist via the electronic computerized patient record system. Participants were randomized from October 3, 2005, to March 30, 2007, with the last 6-month follow-up survey completed on November 6, 2007. Analysis of data was completed in December 2007. Participants in both groups were offered their choice of immediate-release bupropion tablets or nicotine patch. The VA provided medication without cost to participants. At 6 months after the established quit date, self-reported cessation was biochemically confirmed using tests for urinary cotinine. A visit was scheduled within 3 days for the participant to provide a urinary sample at the clinic. Participants in the treatment and control groups set a quit date 10–14 days after the first intervention contact. Those who did not elect to set a quit date were assigned day 12 after the first intervention contact as their quit date. The trial procedures were approved and monitored by the University of Montana institutional review board.

SCREENING AND ELIGIBILITY CRITERIA

The flow of participants through the study appears in Figure 1. The patient electronic medical record system was used to identify and exclude patients with a diagnosis of schizophrenia, who require a different approach to help them quit smoking, and those with prior participation in the pharmacy group program. A scripted questionnaire conducted over the telephone was used by the pharmacy

team to screen patients referred to the study. Individuals who planned to leave the area in the next 6 months, used pharmacotherapy for smoking cessation in the last 30 days, or used forms of tobacco other than cigarettes (ie, cigars, pipe tobacco, spit tobacco) in the last 30 days were excluded. Eligible patients smoked one or more cigarettes daily for 7 days, were at least somewhat ready to quit in the next 2 weeks (≥ 4 on a 10-point motivational scale), were willing and capable of attending 3 scheduled sessions at the clinic, and were interested in participating in the study.²⁶ Patients excluded from participating in the trial were treated outside the study.

STUDY ENROLLMENT, RANDOMIZATION, AND BASELINE ASSESSMENT

Following successful completion of the screening procedures, eligible participants were sent copies of an approved consent form along with a self-addressed return envelope. Those who did not return the consent materials were recontacted 2 additional times. Consent forms were collected for all participants invited to participate. Once the signed consent form was received, the participant was sequentially enrolled into the trial and randomized to the treatment or control group by the clinical pharmacist. Randomization codes assigned to each participant were computer generated by the study statistician and stratified by sex in blocks of 6. The pharmacist team conducted a baseline assessment over the telephone, then notified participants of their group assignment. Participants assigned to the face-to-face treatment group were informed of the details regarding the first group session. For participants assigned to the control group, the standard care smoking cessation components were delivered over the telephone.

TREATMENT GROUP

Participants assigned to the treatment group participated in a face-to-face 3-session group program at the clinic delivered by the pharmacist and APPE students. The 6-hour program consisted of 3 in-person sessions (3 hours for session 1, 2 hours for session 2, and 1 hour for session 3) delivered at 2-week intervals over 5 weeks to a small group of smokers that varied in size from 3 to 10 participants per program. Groups were formed about every 3–4 months depending on the number of referrals. The treatment program, adapted from the “Vets Without Cigarettes” program²⁹ developed by the VA Montana Veterans Health Administration, uses multiple theories of behavior change, including the Transtheoretical Model of Change³⁰ and the health belief model.³¹ The program, described previously, used peer support, goal setting, behavioral strategies, and cognitive techniques to elicit and support change.²⁶ Session 1 facilitated preparation to quit by assisting with medica-

tions, establishing a quit date, coping with triggers, and teaching “habit-busting” behavioral strategies that could be applied over the period prior to their quit date. Participants selected a quit date 2–3 days prior to the second session. Session 2 addressed problems associated with the quitting stage immediately following the quit date, such as managing withdrawal symptoms, coping with cravings, managing fear of weight gain, and stress reduction. Session 3 focused on maintenance of change with strategies for prevention of slips and relapses and using a reward system. For follow-up, all participants were instructed to call the clinic for questions or to receive additional support as needed.

CONTROL GROUP

Once the baseline assessment was completed, the pharmacist or APPE student used a structured script to deliver the intervention. Participants received one timed 5- to 10-minute session over the telephone that included all the components of standard care recommended by the Clinical Practice Guidelines³² and practiced within the VA for brief interventions delivered by healthcare providers, referred to as “The 5 A’s”: Ask about tobacco use, Advise to quit, Assess willingness to make a quit attempt, Assist in quit attempt, and Arrange for follow-up. Standard care was delivered over the

telephone similar to telephone quit line services.³³ For follow-up, all participants were instructed to call the clinic for questions or to receive additional support as needed.

STUDY MEDICATION

Participants in both groups were offered their choice of either immediate-release bupropion 100-mg tablets 3 times daily or nicotine patch dosed at 21 mg once daily for 4 weeks, then 14 mg once daily for 2 weeks, then 7 mg once daily for 2 weeks if smoking 10 or more cigarettes daily, or 14 mg once daily for 4 weeks, then 7 mg once daily for 2 weeks if smoking fewer than 10 cigarettes daily, according to VA formulary options and guidelines. Participants receiving bupropion received a 30-day supply plus 2 refills to complete 12 weeks of therapy. Participants receiving nicotine patches received a quantity sufficient to complete 8 weeks of step-down therapy if smoking 10 or more cigarettes daily or 6 weeks if fewer than 10 cigarettes daily. Dosage regimens were similar between groups. Prior to prescribing any medications, the clinical pharmacist reviewed patients’ medical records for contraindications. Contraindications for bupropion included history of seizure disorder, history of eating disorder, use of another form of bupropion, or use of a monoamine oxidase in-

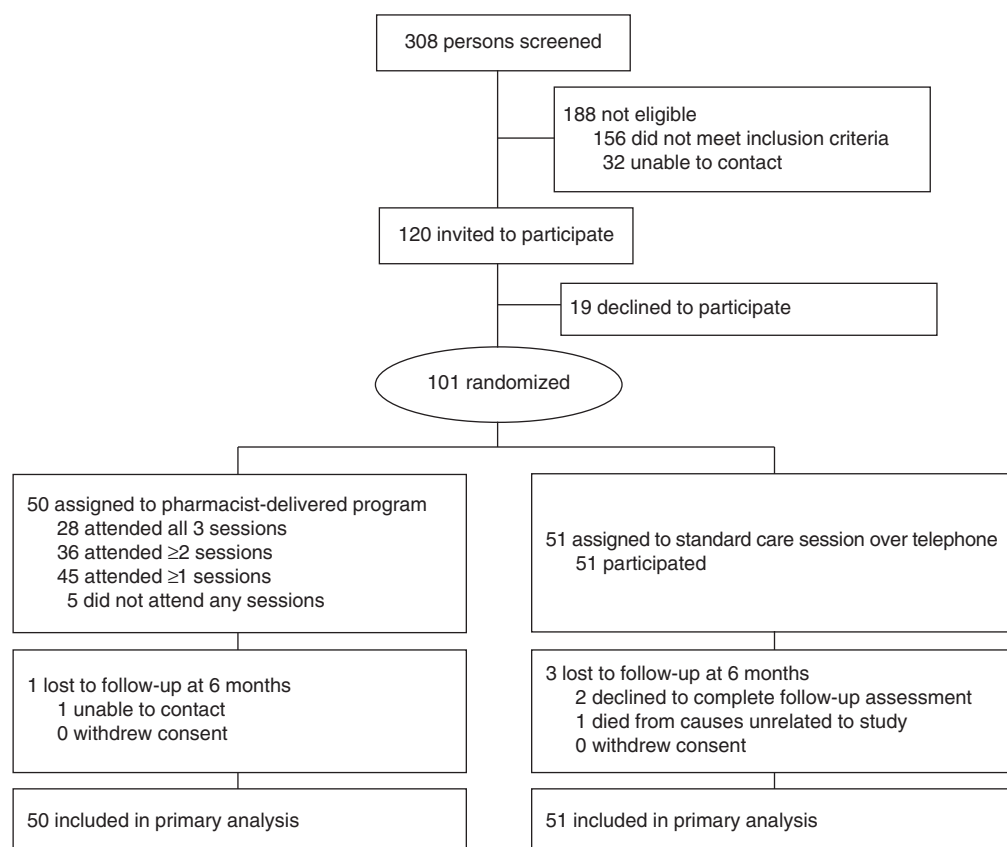


Figure 1. Participant flow through pharmacist-delivered smoking cessation program.

hibitor in the past 14 days. Precautions for nicotine patch included myocardial infarction within the last 2 weeks, serious arrhythmias, and worsening angina pectoris. Study participants who selected drugs received them using the VA medication mail delivery system.

MEASURES

Six months after the quit date, participants were telephoned by a research assistant to complete a brief assessment. Participants who reported not smoking for the previous 7 days—not even a puff—were invited to come into the clinic to provide a sample to test for urinary cotinine.³⁴ Participants invited to provide a urine sample were reimbursed \$20 for their time and travel costs.

The primary outcome variable for the study was biochemically confirmed 7-day point prevalence smoking cessation at 6 months, defined as having smoked no cigarettes—not even a puff—for the previous 7 days. Secondary outcomes included 30-day point prevalence abstinence and continuous abstinence (≥ 6 mo). Thirty-day point prevalence was defined as having smoked no cigarettes—not even a puff—in the last 30 days. Continuous abstinence was defined as no cigarettes—not even a puff—since quit day.

A questionnaire was used to assess for use of other forms of tobacco, nicotine replacement therapies, and exposure to secondhand smoke at the time of the urine test. LabCorp analyzed the urine samples using immunoassay (SolarCare Technologies Corp., Bethlehem, PA). Considering the longest cotinine half-life and typical initial cotinine concentrations, a patient with negative test results can be assumed to have been tobacco-free for a 7-day period.²⁸ Participants with urine cotinine concentrations of 0.3 $\mu\text{g/mL}$ or higher were considered to be smokers.

Sociodemographic information, smoking behaviors, measures of self-efficacy/motivation, and health information were assessed at baseline using survey questions adapted from prior studies.^{35–37} Nicotine dependence was assessed with the 6-item Fagerstrom Test for Nicotine Dependence scale at baseline and at 6 months if still smoking.³⁸ The 4-item Perceived Stress Scale was used at baseline and at 6 months to measure the degree to which situations over the past month were appraised as stressful. Each of 4 items was rated as 0 (none) to 4 (very often); the higher the score, the more perceived stress.³⁹ The 10-item Center for Epidemiologic Studies Short Depression Scale score was measured at baseline and 6 months.⁴⁰ Scores of 10 or higher (range 0–30) indicate the likelihood of clinical depression. Self-efficacy and motivation to quit smoking were each assessed separately, both at baseline and 6 months. Participants were asked, “On a scale of 1 to 10, how motivated/confident are you to quit smoking, with 1 being not at all motivated/confident and 10 being very mo-

tivated/confident?” Once participants reported quitting, phrasing of the items was altered to assess motivation/confidence to stay quit.^{41,42}

Withdrawal symptoms, which included depressed mood, trouble falling asleep, irritability/frustration/anger, anxiety, difficulty concentrating, restlessness, increased appetite/weight gain, and cravings to smoke were assessed at 6 months. Each of 8 symptoms was rated from 0 (none) to 3 (severe).^{35,43} For participants choosing to use medication, adherence was assessed at 6 months using the following statement: “On a scale from 1 to 10, how closely did you follow the recommended dosing schedule, with 1 being not at all and 10 being exactly?”⁴⁴ Study records were used to assess number of program sessions completed by each participant in the treatment group.

DATA MANAGEMENT

Participant data and testing results were recorded in a Microsoft SQL Server 2000 database (Microsoft Corp., Redmond, WA). Data were double-entered and checked for out-of-range values at regular intervals. Internal consistency and validity programs were used to check for data entry errors and duplicates.

STATISTICAL ANALYSIS

For a priori sample size calculations, we assumed a 7-day point prevalence abstinence of 10% for the control group based on previous studies using standard medical care³² and 35% for the intervention group based on our previous pilot study of the pharmacist-delivered intervention.²⁶ The sample size of 100 participants (50 per treatment) would yield 86% power to detect a difference between groups with an α of 0.05. Baseline categorical variables were summarized by frequencies and percentages, and quantitative variables were summarized by mean \pm SD for each treatment regimen. Baseline categorical variables by treatment group were compared using the χ^2 test and the 2-sample *t*-test. χ^2 Tests were used to compare point prevalence smoking cessation and continuous abstinence rates based on intent-to-treat analysis between the treatment and control groups. For the primary outcomes on smoking cessation, all subjects who were lost to follow-up or reporting abstinence at the 6-month post-quit date but failed to return for urine cotinine testing were classified as smokers in the primary analyses. All data analysis was conducted using SAS version 9.0 (Cary, NC).

Results

The results of the participant flow through the study appear in Figure 1. The most common reason for exclusion was inability to attend all 3 sessions (54/188), due to barri-

ers such as cost of transportation, travel distance from outlying areas, and scheduling conflicts associated with work or other activities. Of the 19 eligible patients declining to participate, the most common reasons were that they were not ready to quit or their aversion to groups. There were no differences in age or number of cigarettes smoked per day for those who declined to participate; however, readiness to quit in the next 2 weeks was lower on the 10-point motivational scale ($p = 0.004$).

The baseline characteristics of participants were not significantly different between treatment groups (Table 1). The majority of participants were male (93%), non-Hispanic white (96%), college educated (61%), retired (56%), and married or a member of an unmarried couple (55%). At baseline, 57% of participants considered themselves to be in good-to-excellent health. These characteristics were equally distributed by treatment group ($p > 0.34$).

At 6 months after the quit date, the biochemically confirmed 7-day point prevalence quit rate was 28% (14/50) in the pharmacist-delivered face-to-face treatment group and 11.8% (6/51) in the standard care group ($p < 0.041$) (Table 2). Self-reported quit rates were significantly higher in the treatment group for all time periods. Of the 14 biochemically confirmed quitters in the treatment group, 93% (13/14) attended all 3 counseling sessions. Of participants who attended all 3 sessions, 46% (13/28) were able to maintain continuous abstinence, compared with only 5% (1/22) of those attending 2 sessions or fewer, suggesting the importance of attending all 3 sessions of the program. Of the 23 participants who self-reported abstinence and were invited to provide a urine sample for biochemical verification, 88% (15/17) in the treatment group and 100% (6/6) in the control

group completed the test. Only one participant reporting abstinence in the treatment group and no one in the control group tested positive for urinary cotinine.

Bupropion was chosen by 66% (67/101) of the subjects and nicotine patches were chosen by 25% (25/101) of the subjects. Only 9% (9/101) of the subjects did not select any drug. There was no overall difference by treatment group for type of medication chosen ($p = 0.37$). There was also no significant difference in quit rates for type of medication chosen between treatment groups ($p = 0.41$).

Of the 83 participants who opted to use study medications and were assessed for adherence on the 6-month follow-up survey, 63% (52/83) replied that they followed the recommended dosing schedule exactly. There was an equal distribution between the treatment and control groups among those who followed the recommended dosing schedule ($p = 0.98$).

Patients reported medication problems to the clinical pharmacist. All adverse effects to medications were mild. One patient reported developing dizziness possibly related to nicotine toxicity while wearing the 21-mg patch, requiring a reduction in dosage. One patient discontinued bupropion because of a rash.

At follow-up, participants reported on whether or not they experienced any of 8 withdrawal symptoms commonly associated with smoking cessation. Nearly all (96%) participants reported at least one withdrawal symptom.

Discussion

This is the first randomized controlled trial conducted within the US to assess the effectiveness of a pharmacist-delivered program for smoking using biochemical verification. The 28% biochemically confirmed quit rate obtained in this study was higher than quit rates for the only 2 biochemically confirmed randomized controlled trials conducted in the UK and Australia. They reported intent-to-treat quit rates of 14.7%¹⁵ and 18.5%¹⁴ at 6 months. The intensity and components of the group program may account for the difference in quit rates between our study and the other reported studies. In 2 prior uncontrolled studies by our group, using the same intervention, the intent-to-treat self-reported tobacco cessation rates were 34%⁴⁵ and 36.5%,²⁶ which are similar to the self-reported quit rate of 34% obtained in our current study. Furthermore, the high retention at follow-up in our study likely contributed to the higher quit rates. The choice of pharmacotherapy within groups was equivalent.

The primary strength of this study is the compliance with recognized standards in

Table 1. Baseline Characteristics for Treatment and Control Groups^a

Characteristic	Group		p Value
	Pharmacist-Delivered Program (n = 50)	Standard Care (n = 51)	
Age at time of study enrollment (y)	56.7 ± 9.8	55.0 ± 9.5	0.378
Age when began smoking (y)	17.2 ± 5.5	17.3 ± 5.6	0.975
Years of smoking (y)	35.2 ± 12.9	36.2 ± 12.1	0.685
Cigarettes per day (n)	18.9 ± 11.2	20.1 ± 9.3	0.563
Quit attempts (n)	8.7 ± 10.6	7.9 ± 9.5	0.677
FTND score	4.2 ± 2.5	4.4 ± 2.1	0.648
Chronic health conditions (n)	2.4 ± 1.6	2.2 ± 1.5	0.505
PSS-4	4.7 ± 3.9	4.9 ± 3.5	0.785
CESD-10 score	8.9 ± 6.9	8.9 ± 6.7	0.966
Motivation to quit	8.9 ± 1.4	8.5 ± 1.6	0.159
Confidence to quit	7.6 ± 2.3	7.5 ± 2.2	0.860

CESD-10 = 10-Item Center for Epidemiologic Studies Short Depression Scale; FTND = Fagerstrom Test for Nicotine Dependence; PSS-4 = Perceived Stress Scale.
^aMean ± SD.

methodological design for measuring efficacy in tobacco cessation interventions, which include randomized controlled trial, appropriate duration of follow-up, intent-to-treat analysis to account for attrition, and biochemical verification. Moreover, this study was successful in recruitment and retention of participants, which are important prerequisites for conducting a rigorous evaluation of smoking cessation programs. The applicability of this study would have the greatest impact within the VA system, managed care setting, or other similar ambulatory care site where a large number of pharmacists practice and are empowered with an expanded scope of practice that allows for the ability to meet with patients and prescribe tobacco cessation medications. Pharmacists in community practice may need to develop collaborative practice agreements with physicians in the community to be able to prescribe tobacco cessation medications, excluding nicotine gum and patches, which are available over-the-counter, depending on pharmacy practice laws that vary among different states. Also, this study provides some additional evidence on the effectiveness of the immediate-release (versus sustained-release) formulation of bupropion for smoking cessation.^{46,47}

Pharmacists are particularly well-suited to provide tobacco cessation interventions because of immediate accessibility and ability to assist with counseling, initiation of drug therapy, and easy follow-up for support or medication-related problems. Moreover, this study supports the findings reported in the Clinical Practice Guideline³² that there is a strong dose–response relationship between intensity of counseling and cessation success. The more intense the treatment intervention in length or number of treatment sessions delivered, the greater the rate of smoking cessation. While intensive pharmacist interventions may have a greater impact on abstinence rates, these interventions may

have limited ability to reach certain smokers, such as those who were ineligible for this study because of inability to attend the group program. For example, tobacco users may not be interested or may lack availability, accessibility, or ability to afford an intensive group program.

This study has a number of limitations. The standard care model delivered via the telephone to the control group was used to determine whether the additional time and effort required for the proposed intervention would result in significantly better outcomes compared with brief interventions delivered by healthcare providers. Therefore, one limitation of this design is that the delivery time and attention differed significantly between the treatment and control groups. It is not possible to generalize the study findings to all smokers in the general population because study participants were predominantly white, male, and middle-aged. While the reproducibility of this study in different patient populations is unknown, research suggests that both men and women and different racial and ethnic minorities may benefit from similar smoking cessation interventions as delivered in this study.³² While one strength of the study is the long (6 mo) follow-up period, the delay between treatment and the follow-up assessments could have introduced error in participants' recall of distal events, such as their accurate use of medication and withdrawal symptoms. Since the same pharmacist team delivered the intervention in both conditions, it is possible that their knowledge of the study hypothesis could have influenced the study outcome. Detailed protocols and checklists for steps to complete at each contact point helped systematize the intervention delivery and minimize this concern. The screening process selected for individuals who had the time, availability, and transportation to attend the group program, which could have been a possible source of bias.

Despite these limitations, the study provides a rigorous evaluation of an effective pharmacist-delivered tobacco cessation intervention. Ultimately, this intervention could serve as a model for widespread and effective use of pharmacists as providers of tobacco-cessation services, especially within the VA and similar ambulatory care settings. Additionally, establishing effectiveness of pharmacist-delivered tobacco cessation services could provide justification for compensation by third-party payers. Most importantly, greater use of pharmacists in tobacco cessation efforts could have a significant impact on smoking rates, prevention of tobacco-related disease, and improvement in public health across the US.

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Table 2. Point Prevalence and Continuous Abstinence Rates Based on Intent-to-Treat Analysis

PP/CA Rate	Group		p Value
	Pharmacist-Delivered Program, ^a n (%)	Standard Care, ^b n (%)	
Cotinine-confirmed 7-day PP	14 (28.0)	6 (11.8)	0.041
Self-reported			
1-day PP	20 (40.0)	8 (15.7)	0.006
7-day PP	17 (34.0)	6 (11.8)	0.008
30-day PP	16 (32.0)	6 (11.8)	0.014
6-mo CA	14 (28.0)	6 (11.8)	0.041

CA = continuous abstinence; PP = point prevalence.

^an = 50.

^bn = 51.

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References

- Gunderson SK, Cultice JM, Knapp K. How many pharmacists are in our future? The Bureau of Health Professions Projects Supply to 2020. www.hhs.gov/pharmacy/phpharm/howmany.html (accessed 2008 Sept 10).
- Margolis JA, Meshack AF, McAlister AL, Boye-Doe H, Simpson L, Hu S. Smoking cessation activities by pharmacists in East Texas. *J Am Pharm Assoc* 2002;42:508-9.
- Harris KJ, Noonan CW, Dent LA. Tobacco treatment practices of pharmacists in a frontier state. Poster presented at: Fourteenth Scientific Sessions, Society for Research on Nicotine and Tobacco Annual Meeting, Portland, OR, 2008.
- Hudmon KS, Prokhorov AV, Corelli RL. Tobacco cessation counseling: pharmacists' opinions and practices. *Patient Educ Couns* 2006;61:152-60.
- Hudmon KS, Corelli RL, Chung E, et al. Development and implementation of a tobacco cessation training program for students in the health professions. *J Cancer Educ* 2003;18:142-9.
- Hudmon KS, Kroon LA, Corelli RL, et al. Training future pharmacists at a minority educational institution: evaluation of the Rx for change tobacco cessation training program. *Cancer Epidemiol Biomarkers Prev* 2004;13:477-81.
- Rx for change: clinician-assisted tobacco cessation. <http://rxforchange.ucsf.edu/> (accessed 2008 Sept 4).
- White paper on pharmacy technicians 2002: needed changes can no longer wait. *J Am Pharm Assoc* 2003;43:93-104.
- Ferro LA, Marcrom RE, Garrelts L, et al. Collaborative practice agreements between pharmacists and physicians. *J Am Pharm Assoc* 1998;38:655-64.
- Delaware Pharmacists Society. Smoking cessation program. www.deparmacy.net/smokingcessation/index.htm (accessed 2008 Sept 10).
- Hudmon KS. Pharmacists for tobacco cessation. San Francisco: Rx for Change, February 2005.
- Dent LA, Harris KJ, Noonan CW. Tobacco interventions delivered by pharmacists: a summary and systematic review. *Pharmacotherapy* 2007;27:1040-51.
- Howard-Pitney B, Killen JD, Fortmann SP. Quitting chew: results from a randomized trial using nicotine patches. *Exp Clin Psychopharmacol* 1999;7:362-71.
- Maguire TA, McElroy JC, Drummond A. A randomized controlled trial of a smoking cessation intervention based in community pharmacies. *Addiction* 2001;96:325-31.
- Vial RJ, Jones TE, Ruffin RE, Gilbert AL. Smoking cessation program using nicotine patches: linking hospital to the community. *J Pharm Prac Res* 2002;32:57-62.
- Sonderskov J, Olsen J, Sabroe S, Meillier L, Overvad K. Nicotine patches in smoking cessation: a randomized trial among over-the-counter customers in Denmark. *Am J Epidemiol* 1997;145:309-18.
- Sinclair HK, Bond CM, Lennox AS, Silcock J, Winfield AJ, Donnan PT. Training pharmacists and pharmacy assistants in the stage-of-change model of smoking cessation: a randomised controlled trial in Scotland. *Tob Control* 1998;7:253-61.
- Carroll P, Rois R, Sarson D, Flynn J. A community pharmacy-based program using transdermal nicotine replacement therapy—actions and outcomes. *Aust Pharmacist* 2000;19:51-5.
- Roth MT, Westman EC. Use of bupropion SR in a pharmacist-managed outpatient smoking-cessation program. *Pharmacotherapy* 2001;21:636-41.
- Zillich AJ, Ryan M, Adams A, Yeager B, Farris K. Effectiveness of a pharmacist-based smoking-cessation program and its impact on quality of life. *Pharmacotherapy* 2002;22:759-65.
- Smith MD, McGhan WF, Lauger G. Pharmacist counseling and outcomes of smoking cessation. *Am Pharm* 1995;NS35:20-9.
- Isacson D, Bingeors C, Ribohn M. Quit smoking at the pharmacy—an evaluation of a smoking cessation programme in Sweden. *J Soc Administrative Pharm* 1998;15:164-73.
- Doescher MP, Whinston MA, Goo A, Cummings D, Huntington J, Saver BG. Pilot study of enhanced tobacco-cessation services coverage for low-income smokers. *Nicotine Tob Res* 2002;4(suppl 1):S19-24.
- Kennedy DT, Giles JT, Chang ZG, Small RE, Edwards JH. Results of a smoking cessation clinic in community pharmacy practice. *J Am Pharm Assoc* 2002;42:51-6.
- Huntzinger PE. SMOKED: a pharmacist-monitored tobacco cessation program. *Mil Med* 2002;167:1001-5.
- Dent LA, Scott JG, Lewis E. Pharmacist-managed tobacco cessation program in Veterans Health Administration community-based outpatient clinic. *J Am Pharm Assoc* 2004;44:700-14.
- Roth MT, Andrus MR, Westman EC. Outcomes from an outpatient smoking-cessation clinic. *Pharmacotherapy* 2005;25:279-88.
- Society for Research on Nicotine and Tobacco. Biochemical verification of tobacco use and cessation. *Nicotine Tob Res* 2002;4:149-59.
- Veterans Health Administration. Montana Regional Healthcare System. Vets Without Cigarettes Smoking Cessation Program. 2000.
- Prochaska JO, Velicer WF. The transtheoretical model of health behavior change. *Am J Health Promot* 1997;12:38-48.
- Glanz K, Rimer BK, Lewis FM, eds. Health behavior and health education. 3rd ed. San Francisco: John Wiley & Sons, Inc., 2002.
- Fiore MC, Jaén CR, Baker TB, et al. Treating tobacco use and dependence: 2008 update. Clinical practice guideline. Rockville, MD: US Department of Health and Human Services, Public Health Service, May 2008.
- 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;11:243-57.
- Hughes JR, Keely JP, Niaura RS, Ossip-Klein DJ, Richmond RL, Swan GE. Measures of abstinence in clinical trials: issues and recommendations. *Nicotine Tob Res* 2003;5:13-25.
- Ahluwalia JS, Harris KJ, Catley D, Okuyemi KS, Mayo MS. Sustained-release bupropion for smoking cessation in African Americans: a randomized controlled trial. *JAMA* 2002;288:468-74.
- Harris KJ, Grobe J, McCarter K, et al. Smoking while in college: baseline analysis from a longitudinal survey. Presented at: Eighth Scientific Meeting of the Society for Research on Nicotine and Tobacco, Savannah, GA, Feb 22, 2002.
- Harris KJ, Okuyemi KS, Catley D, Mayo MS, Ge B, Ahluwalia JS. Predictors of smoking cessation among African-Americans enrolled in a randomized controlled trial of bupropion. *Prev Med* 2004;38:498-502.
- Heatherton TF, Kozlowski LT, Frecker RC, Fagerstrom KO. The Fagerstrom test for nicotine dependence: a revision of the Fagerstrom tolerance questionnaire. *Br J Addict* 1991;86:1119-27.
- Cohen S, Kamarck T, Mermelstein R. A global measure of perceived stress. *J Health Soc Behav* 1983;24:385-96.
- Andresen EM, Malmgren JA, Carter WB, Patrick DL. Screening for depression in well older adults: evaluation of a short form of the CES-D (Center for Epidemiologic Studies Depression Scale). *Am J Prev Med* 1994;10:77-84.
- Miller WR, Rollnick S. Motivational interviewing: preparing people for change. 2nd ed. New York, NY: The Guilford Press, 2002.
- Boardman T, Catley D, Mayo MS, Ahluwalia JS. Self-efficacy and motivation to quit during participation in a smoking cessation program. *Int J Behav Med* 2005;12:266-72.
- Hughes JR, Hatsukami D. Signs and symptoms of tobacco withdrawal. *Arch Gen Psychiatry* 1986;43:289-94.
- Hudman KS, Hemberger KK, Corelli RL, Kroon LA, Prokhorov AV. The role of the pharmacist in smoking cessation counseling: perceptions of nonprescription nicotine replacement therapy users. *J Am Pharm Assoc* 2003;43:573-82.

45. Dent LA, Carter JT. Motivating tobacco users to quit: an effective pharmacist-managed program. Presented at: Spring Practice and Research Forum, American College of Clinical Pharmacy Spring Meeting, Myrtle Beach, SC, Apr 12, 2005.
46. Ferry LH, Burchette RJ. Efficacy of bupropion for smoking cessation in nondepressed smokers (abstract). *J Addict Dis* 1994;13:249.
47. Hughes JR, Stead LF, Lancaster T. Antidepressants for smoking cessation. *Cochrane Database Syst Rev* 2007;(1):CD000031. DOI: 10.1002/14651858.CD000031.pub3

Ensayo Randomizado para Evaluar la Efectividad de un Programa Farmacéutico para la Supresión del Hábito Tabáquico

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EXTRACTO

INTRODUCCION: Los farmacéuticos, como profesionales sanitarios entrenados y accesibles, están en una posición ideal para realizar intervenciones para la supresión del hábito tabáquico. De los 15 estudios identificados en la literatura valorando la efectividad de las intervenciones para la supresión del hábito tabáquico suministrada por farmacéuticos, este es el primer estudio randomizado controlado de un programa sobre tabaco facilitado por un farmacéutico realizado en Estados Unidos y utilizando confirmación bioquímica.

OBJETIVOS: Se realizó un ensayo abierto, prospectivo, randomizado controlado, para valorar la efectividad de un programa grupal face-to-face comparado con una breve sesión telefónica estándar para abandonar el hábito tabáquico facilitada por un farmacéutico. El primer resultado de auto declaración de abstinencia fue confirmado químicamente por una cotinina urinaria a los 6 meses de la fecha del abandono.

MÉTODOS: El estudio se realizó en la Veterans Health Administration, Community-Based Outpatient Clinic en la región del Rocky Mountain. Los participantes fueron asignados aleatoriamente para recibir un programa grupal de 3 sesiones face-to-face o una sesión telefónica estándar de 5 a 10 minutos facilitada por un equipo farmacéutico. A los participantes en ambos grupos se les ofreció indistintamente bupropion LI (liberación inmediata) tabletas o parches de nicotina sin coste. A los 6 meses, los participantes que autonotificaron abstinencia se les ofreció volver a la clínica para realizar una prueba de cotinina urinaria.

RESULTADOS: Se randomizaron 101 fumadores desde el 3 de Octubre del 2005 al 30 de Marzo del 2007, con los últimos seis meses de seguimiento completados el 6 de Noviembre del 2007. El análisis de los datos se completo en Diciembre del 2007. Utilizando los procedimientos por intención de tratar, los niveles de abstinencia confirmados al final de los seis meses fueron del 28% en el tratamiento farmacéutico grupal y de un 11.8% en el grupo control de tratamiento estándar ($p < 0.041$).

CONCLUSIONES: Este estudio demuestra que las intervenciones farmacéuticas sobre supresión del hábito tabáquico son efectivas. Una mayor utilización de los recursos farmacéuticos en las intervenciones para el abandono del hábito tabáquico pueden tener un impacto considerable en los niveles de tabaquismo, en la prevención de las enfermedades relacionadas con el tabaco, y una mejora global en la salud pública en los Estados Unidos.

Traducido por Corinne Zara Yahni

Effectiveness of a Pharmacist-Delivered Smoking Cessation Program

Essai Randomisé Évaluant l'Efficacité d'un Programme de Cessation du Tabagisme Géré par un Pharmacien

LA Dent, KJ Harris, et CW Noonan

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RÉSUMÉ

HISTORIQUE: Le pharmacien, un professionnel de la santé bien formé et accessible, est en position idéale pour offrir des interventions dans le cadre de la cessation du tabagisme. Des 15 études publiées dans la littérature médicale et évaluant l'efficacité des interventions liées à la cessation du tabagisme faites par des pharmaciens, cette étude américaine est la première randomisée et contrôlée dont l'objet est un programme de cessation du tabagisme impliquant des pharmaciens et utilisant une confirmation biochimique.

OBJECTIF: Une étude ouverte, prospective, randomisée, et contrôlée a été menée afin d'évaluer l'efficacité d'un programme de groupe de type face à face (groupe de soin standard) comparé à une brève session visant à cesser le tabagisme faite par un pharmacien, et ce, par téléphone. La mesure de résultat primaire était l'abstinence rapportée par le sujet lui-même; cette abstinence était confirmée par la mesure urinaire de la cotinine 6 mois après la date d'arrêt du tabagisme.

MÉTHODOLOGIE: L'étude a été conduite dans une clinique externe communautaire de la Veterans Health Administration dans la région des Montagnes rocheuses. Les participants étaient assignés de façon aléatoire à un programme de 3 sessions de thérapie de groupe ou à une session téléphonique de 5 à 10 minutes faite par une équipe de pharmaciens. Les participants dans les 2 groupes pouvaient recevoir gratuitement des comprimés à libération immédiate de bupropion ou des timbres de nicotine. À 6 mois, les participants qui affirmaient leur abstinence ont été invités à venir à la clinique afin de mesurer la cotinine urinaire.

RÉSULTATS: Les fumeurs 101 fumeurs ont été randomisés du 3 octobre 2005 au 30 mars 2007; le dernier suivi après 6 mois a été complété le 6 novembre 2007. L'analyse des données a été complétée en décembre 2007. En utilisant la méthode intention de traitement, les taux d'abstinence confirmés après 6 mois étaient de 28% dans le groupe de traitement de l'équipe de pharmaciens et de 11.8% dans le groupe contrôle de soin standard ($p < 0.041$).

CONCLUSIONS: Cette étude montre que les pharmaciens sont des professionnels efficaces lors d'interventions pour cesser le tabagisme. Une plus grande utilisation des pharmaciens dans les efforts afin de contrer le tabagisme pourrait avoir un impact significatif sur la prévalence du tabagisme, la prévention des maladies liées au tabagisme, et sur l'amélioration globale de la santé publique aux États-Unis.

Traduit par Denyse Demers