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Counselor and Stimulus Control Enhancements of a Stage-Matched Expert System Intervention for Smokers in a Managed Care Setting[1]

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Background. **Previous research has demonstrated the efficacy of an interactive expert system intervention for smoking cessation for a general population. The intervention provides individualized feedback that guides participants through the stages of change for cessation. Enhancing the expert system by adding proactive telephone counseling or a stimulus control computer designed to produce nicotine fading could produce preventive programs with greater population impacts.**

Methods. **Four interventions were compared: (a) the interactive expert system intervention; (b) the expert system intervention plus counselor calls; (c) the expert system intervention plus the stimulus control computer; and (d) an assessment only condition. A 4 (intervention) × 4 (occasions) (0,6,12, and 18 months) design was used. Smokers were contacted at home via telephone or mail. The initial subject pool was the 24,178 members of a managed care company. Screening was completed for 19,236 members (79.6%), of whom 4,653 were smokers; 85.3% of the smokers were enrolled.**

Results. **Thirty-eight percent were in the precontemplation stage, 45% in the contemplation stage, and only 17% in the preparation stage. At 18 months, the expert system resulted in 23.2% point prevalence abstinence, which was 33% greater than that of assessment only. The counselor enhancement produced increased cessation at 12 months but not at 18 months. The stimulus control computer produced no improvement, resulting in 20% worse cessation rates than the assessment only condition.**

Conclusions. **The enhanced conditions failed to outperform the expert system alone. The study also demonstrated the ability of the interactive expert system to produce significantly greater cessation in a population of smokers than assessment alone.**

Key Words: **smoking cessation; stages of change; expert systems; telephone counselors; managed care; proactive recruitment.**

INTRODUCTION

Smoking cessation on a population basis requires intervention programs that can impact on total populations of smokers and not just the minority who are prepared to quit. Two previous population-based studies have demonstrated that such programs need to use proactive recruitment procedures, stage-matched materials, and interactive interventions [*1,2*]. The present study assessed the effectiveness of two enhancements of the most effective intervention from previous research, an interactive expert system intervention. The enhancements added proactive telephone counseling in one condition and hand-held stimulus control computers in another.

Impact represents an appropriate method of assessing outcome for intervention studies [*3,4*]. Impact on a population is defined as the efficacy rate (e.g., long-term abstinence) times participation rates. In a previous population-based study, proactive recruitment produced a high participation rate (80%) [*1*]. The study also had a point prevalence efficacy rate of 25%, which is comparable to what is produced by the best interactive programs, e.g., clinics and counseling [*5*], for an impact of $0.80 \times 0.25 = 0.20$, i.e., a reduction of the population smoking rate by 20%. Although clinics and counseling have high efficacy, they produce low impacts, because

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their participation rates are typically only 1 to 5% of eligible populations, resulting in impact rates of 0.0025 to 0.0125. Two additional goals of this research project were to replicate the recruitment rates for a proactively recruited sample and to replicate the previously reported efficacy of the expert system intervention.

In order to increase impact, it is necessary to increase efficacy. This study attempted to enhance the efficacy of one of the most promising population-based treatments, an interactive, stage-matched computer-based expert system. One alternative is to combine the best interventions for population-based cessation with techniques used in clinic-based treatments. Personalized counseling has historically been one of the best treatments for smoking cessation, with efficacy rates of 20 to 30% abstinence at long-term follow-up [*5*]. Telephone counseling has also attracted wide attention as a system for delivery of services for smoking cessation [*6–8*].

Interventions have differed depending on whether the counselor (proactive) or the client (reactive) initiates the counseling calls and the number of calls. The results have been somewhat mixed, with some studies reporting increases in success rates [*8,9*] while others have reported no long-term benefits [*10*]. A recent study treating smokers who were highly prepared to quit reported a clear advantage for a single counseling session over self-help materials (19.8% continuous abstinence vs 14.7%) and a further gain with multiple calls (26.7%) using a proactive approach [*8*].

A previous traditional clinical trial using reactive recruitment and a sample of convenience of 756 smokers combined counseling with the expert system computer program [*7*]. Contrary to expectations, the expert system plus counseling condition did not outperform the expert system alone condition. At 12-month follow-up, each treatment had produced about 18% abstinence. But at 18-month follow-up, the expert system plus counseling treatment continued to produce 18% point prevalence abstinence while the expert system alone condition was producing 25% abstinence.

The leveling off of the computer plus counseling condition was attributed to two factors: (a) the sudden termination of counseling after four proactive contacts in the first 6 months, and (b) concerns that the counseling protocol may have put too much pressure on smokers who were not prepared to quit. The counseling calls may have produced some social support and social control that, when no longer present, resulted in no further progress. Classic relapse curves following termination of such treatments show no further progress and actually show regression back to smoking in a large percentage of participants [*11*]. This regression or relapse is usually attributed to addiction but may, in part, be due to the sudden termination of treatment, which removes whatever social support and control that clinics and counseling might provide.

These results needed to be replicated in order to determine if they were just a chance finding. Perhaps with an entire population of proactively recruited smokers, proactive counseling might provide additional help that would result in greater efficacy. Based on the research described above, the counseling protocols were improved. Previously, for example, counselors put too much pressure on smokers in the contemplation stage by trying to get them to set a quit date in the next month. In the new protocol, contemplators were given three choices: delaying their first cigarette an additional 30 min; reducing their daily consumption by four cigarettes; or quitting for at least 24 h in the next month. These choices were based on empirical differences that were found between smokers in the contemplation stage and those in the preparation stage [*12*]. In addition to changes suggested by data from this study, the revised protocol also incorporated elements from motivational interviewing [*13*]. A more extensive description of the counseling protocol is provided elsewhere [*14*].

A second enhancement was to provide a more action-oriented intervention that had been effective in a previous clinical trial [*15,16*]. This intervention involved providing a hand-held computer that signaled the smoker when to smoke. Initially, smokers simply record whenever they smoke. After rates and familiarity with the machine are established, the smoker is instructed to smoke when and only when cued by the machine. Over a period of time, the smoking rate is gradually decreased to zero. The principle behind this procedure is to bring smoking under stimulus control. Once smoking was under the computer's stimulus control, the interval between signals to smoke can be increased and the result will be nicotine fading and greater ease in quitting. At the time this study was designed, this treatment was being commercialized successfully as the Lifesign program.

The hypotheses of this study were that (a) both the counseling and the stimulus control computer enhancements of the expert system would result in greater efficacy than the expert system intervention alone, (b) the previously high recruitment rates would be replicated using the proactive recruitment approach in a managed care setting, and (c) the previously reported efficacy for the expert system intervention would be replicated.

METHOD

Sample

The total population of 24,178 adults in four offices of a managed care system was screened for smoking via mail and telephone surveys. Of the 4,653 smokers identified, 3,967, or 85.3%, were recruited. Of this group 1,447 were randomly assigned to one of four groups.

The remaining 2,520 participated in a separate eight-group intervention study designed to test components of the expert system treatment [*2*]. One group, the expert system (ES) intervention condition, was shared between this study and the other study [*2*].

Demographics

The average age of subjects in the study (N = 1,447) was 38.1 (SD = 12.2). The gender composition was 56% female and 44% male. With respect to education, 35% had one year of college or more, 49% had graduated from high school, and 16% had less than a high school education, for a mean education of 12.7 years. The stage distribution of the sample was precontemplation (PC), 37.9%; contemplation (C), 44.8%; and Preparation (PR), 17.3%. This is very comparable to the sample characteristics for the random digit sample used in a previous trial of the ES, where the average age was 40.7, the proportion of females was 55.7%, the average education was 12.7, and the stages distribution was PC, 42.1%; C, 40.3%; and PR, 17.6% [*1,17*]. The stage distribution is also approximately the same as that reported in other large samples [*18*].

Table 1 presents the means and standard deviations for five continuous demographic and smoking history variables for each of the four groups. An analysis of variance was performed on each of the variables to test if there were preexisting differences between the groups. All tests were performed at the 0.01 level because of the size of the sample. Only one of the differences was significant, number of cigarettes smoked per day. Since random assignment was employed and a large number of tests were performed, this significant difference was interpreted as a Type I error. In addition there were no significant differences for gender, marital status, or stage of change at baseline.

Intervention Conditions.

Assessment only. Smokers in the assessment only condition were assessed on the complete battery of assessment instruments (see below) on four occasions (0, 6, 12, and 18 months).

Expert system intervention. The interactive ES is described elsewhere [*14,19*]. This group received three individualized computer feedback reports and a set of stage-matched self-help manuals. After completion of the assessment on the 14 variables of the transtheoretical model, scores were compared to those of relevant reference groups, any previous assessments available, and a series of decision rules to determine which intervention materials were most appropriate for that individual. The intervention materials were assembled into a 2- to 3-page, single-spaced feedback report, which was divided into four sections: (a) a description of the subjects' current and previous stage of change, their pros and cons of quitting, and feedback when necessary about their underevaluating the pros and overevaluating the cons of quitting; (b) feedback on their use of up to six change processes, which describes how they compare normatively on each process with self-changers who were most successful in progressing to the next stage and how they compare ipsatively with their previous assessment; (c) a description of tempting situations with feedback on how to enhance their self-efficacy in their most tempting situations; and (d) a section on strategies for taking small steps to progress to the next stage, such as having those in the contemplation stage delay their first cigarette each day by an extra 30 min as a method of modeling smokers in the preparation stage. The feedback reports also referred participants to sections of the stage-matched self-help manuals that were most relevant to their individual progress. The

TABLE 1

Means and Standard Deviations for Four Treatment Groups at Baseline on Five Demographic and Smoking History Variables[a]

		Treatment group			
Variable		Assesment only (AS) (N = 359)	Expert system (ES) (N = 368)	ES plus counselors (ES + CO) (N = 359)	ES plus lifesign computer (ES + SC) (N = 366)
Cigarettes per day[a]	*M*	20.1	18.9	19.0	21.7
	(SD)	(11.7)	(11.8)	(11.5)	(13.3)
Education	*M*	12.7	12.6	12.7	12.6
	(SD)	(2.4)	(2.2)	(2.3)	(2.5)
Time to first cigarette	*M*	57.2	68.2	57.6	57.1
	(SD)	(96.8)	(106.2)	(86.4)	(98.1)
Number 24 h quit att./year	*M*	1.9	2.0	1.9	1.8
	(SD)	(2.6)	(2.7)	(2.5)	(2.6)
Age	*M*	38.7	38.5	38.9	38.0
	(SD)	(11.6)	(12.2)	(12.4)	(12.1)

[a] $P < 0.01$; all other differences are not significant ($P > 0.01$).

three reports were delivered at baseline and at 3 and 6 months. The 3-month report required an additional assessment that is not one of the four assessments performed on all subjects for outcome evaluation purposes.

Expert system plus counseling. This group received all of the components of the expert system treatment in addition to three proactive counselor calls at 0, 3, and 6 months. The counseling protocol was based on the expert system report with the counselors interacting with each participant about the most important parts of each report. Details of this protocol are described in detail elsewhere [*14*]. In the previous protocol, a *fourth* call was included for which no interactive report was available. The counselors found it very difficult to effectively counsel under this condition, particularly with smokers in the precontemplation and contemplation stages. Typically these smokers were not aware of any progression or regression that had occurred since the last call and had little to talk about. When the report is available, however, there is a richness of changes to discuss, such as an increase in the cons of smoking, an improvement on particular processes of change, or progress across one or more stages of change.

Expert system plus stimulus control computers. Besides the ES reports, smokers in this condition who were originally in the contemplation and preparation stage were also mailed the Lifesign computers and instruction materials. Smokers originally in the precontemplation stage were not mailed the Lifesign computers because they were not ready to use such an action-oriented intervention. If these smokers progressed to contemplation or preparation over the next 6 months, they were then sent Lifesign materials.

Measures. A battery of measures were given at preintervention and at 6, l2, and 18 months. Most of the measures were process measures used to generate the interactive progress reports. These measures included the 10 processes of change [*20*]; the pros and cons, or decisional balance [*21*], and situational temptations [*22*]. All measures have been shown to demonstrate adequate reliability and validity in previous smoking cessation studies. Cross-sectional differences on these measures between the groups representing the stages of change are reported elsewhere [*12,17,23,24*], as are longitudinal differences over a 2-year period [*25*].

Point prevalence abstinence. This is a self-report measure of subjects who have not smoked for at least 24 h at each follow-up [*26*]. It is used as the primary outcome measure in this study for several reasons. First, it is a measure sensitive to change over time and it represents the individuals who are in the action (A) and maintenance (M) stage at any follow-up point. With stage-matched interventions, delayed action effects are expected because it takes time for smokers to progress through the stages before taking action. In a previous study [*7*], for example, stage-matched manuals produced results comparable to those of the action-oriented manuals for the first 12 months. At l8 months, however, the stage-matched manuals were producing l8% abstinence compared to 11% of the action-oriented manuals. Second, 24-h abstinence is one of the common outcome measures reported in the literature and is consistent with other point prevalence measures such as 7-day abstinence, thus allowing for considerable cross-study comparisons. Outcomes using 7-day, 30-day, and 6-month abstinence rates are also presented for comparison purposes.

Cotinine validation. Cotinine assessments had become the standard for validating self-report measures of cessation. A detailed case for why cotinine validation procedures are inappropriate for studies like this is presented elsewhere [*26*]. Problems with cotinine validation include very low rates of false reporting (typically less than 2% of subjects falsely report having quit), an inability to validate prolonged abstinence, and an inability to demonstrate differential rates of false reporting between treatment groups unless 15,000–20,000 subjects are treated. The 1990 Surgeon General's report [*27*] concluded that such validation should no longer be considered necessary in most studies of smoking cessation. A recent report from four large-scale clinical trials and a meta-analysis provide further empirical support for this position [*28,29*].

Procedures. The entire adult population of 24,178 subscribers in the Rhode Island and Southeastern Massachusetts region of a managed care system was screened for smoking via mail and telephone surveys. The subscribers were first sent a letter introducing the surveys on the letterhead of the managed care organization. Informed consent materials for the phone survey were contained in that letter. Two weeks later, a screening questionnaire that assessed and staged participants on 15 different behavioral risk factors, including smoking, was mailed. Subscribers who did not respond by mail were surveyed by telephone after 2 weeks; 49.5% responded by mail and 50.5% responded by phone. The 1,447 identified smokers in the current study were then mailed the full battery of smoking related measures, along with informed consent materials for the intervention study. After 2 weeks, those who did not respond by mail were assessed by telephone and a verbal informed consent was obtained; 50.5% responded by mail and 49.5% responded by phone. All information for the study was completely confidential, including that from the health care provider. A written version of the informed consent was then mailed. Written informed consent forms were to be signed and returned. Follow-up assessments by mail or telephone occurred every

6 months. Intervention mailings and counselor calls occurred every 3 months. This recruitment procedure was shared with another study [*2*].

RESULTS

Overview

The data were analyzed as a 4 (intervention groups) × 4 (occasions) ANOVA on the untransformed proportions followed by a series of planned comparisons [*30,31*]. The four groups are (a) assessment only (AS), (b) ES intervention, (c) ES plus counseling (ES + CO), and (d) ES plus stimulus control computers (ES + SC). Table 2 presents the 24-h, 7-day, 30-day, and 6-month abstinence rates for each of the four groups on the four occasions and significant differences between the groups on 24-h point prevalence abstinence at each follow-up assessment ($P < 0.05$).

TABLE 2

Point Prevalence Abstinence Rates on Four Measures for Four Treatment Groups across Four Occasions

Intervention	Occasion		
	6 Months*	12 Months**	18 Months***
Part I: 24-h point prevalent abstinence			
Assessment only	12.1	14.4	17.5
Expert system intervention	16.6	20.6	23.2
Expert system + counselor	18.2	25.6	23.2
Expert system + lifesign	11.3	14.1	14.6
Part II: 7-Day point prevalent abstinence			
Assessment only	11.8	13.5	17.1
Expert system intervention	15.1	19.4	22.9
Expert system + counselor	16.7	24.7	23.2
Expert system + lifesign	10.3	13.4	13.9
Part III: 30-Day prolonged abstinence			
Assessment only	8.3	12.3	14.7
Expert system intervention	12.3	17.9	21.4
Expert system + counselor	15.2	24.2	21.9
Expert system + lifesign	8.6	11.5	11.9
Part IV: 6-Month prolonged abstinence			
Assessment only	—	4.4	6.4
Expert system	—	7.9	11.2
Expert system + counselor	—	8.5	12.3
Expert system + lifesign	—	7.1	6.9

* Significant differences ($P < 0.05$): ES, ES + CO > AS, ES + SC (except for 6-month prolonged abstinence measure where measure is undefined).

** Significant differences ($P < 0.05$): ES + CO > ES > AS, ES + SC (except for 6-month prolonged abstinence where ES, ES + CO, ES + SC > AS).

*** Significant differences ($P < 0.05$): ES, ES + CO > AS > ES + SC (except for 6-month prolonged abstinence where ES, ES + CO > AS, ES + SC).

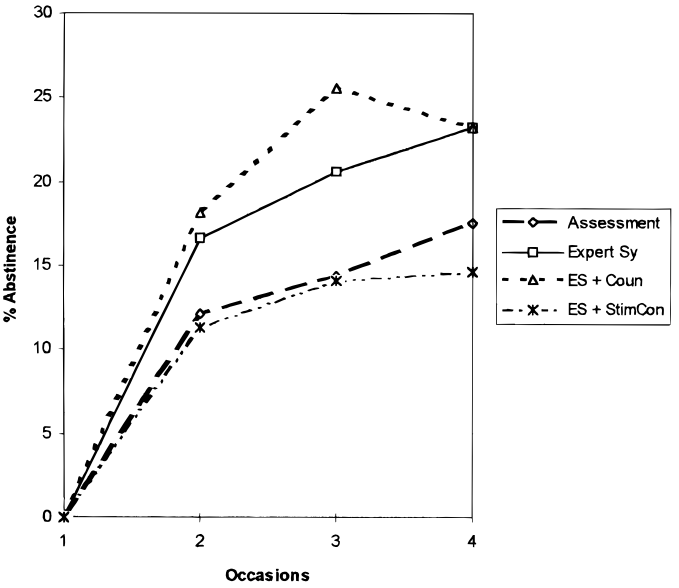

FIG. 1. Comparison of assessment only, expert system, expert system plus counselor calls, and expert system plus stimulus control computer interventions across four occasions (0, 6, 12, and 18 months).

Expert system vs assessment only. Figure 1 illustrates the point prevalence abstinence rates at 0, 6, 12, and 18 months for the group of smokers receiving the ES intervention and the group of smokers receiving the AS. The smoking cessation rates are significantly higher for the ES condition at each time point (4.5 at 6 months, 6.2 at 12 months, and 5.7 at 18 months). The difference is almost 33% at 18 months. This result essentially replicates a difference of the same magnitude between these two conditions as that reported previously on a representative sample [*1*].

Expert system vs expert system plus counseling. Figure 1 compares point prevalence abstinence rates at 0, 6, 12, and 18 months for groups of smokers receiving the ES alone vs the ES + CO. What is striking is that at 12 months the counseling condition is significantly outperforming the ES alone (25.6 vs 20.6%). But at 18 months, both treatments are producing the exact same abstinence rates (23.2%).

Expert system vs expert system plus stimulus control computers. Figure 1 also compares the abstinence rates for groups receiving the ES alone vs the ES + SC. Here the most striking results are that the ES alone condition is producing significantly more abstinence at each follow-up than the enhanced computer condition (16.6 vs 11.3%; 20.6 vs 14.1%; and 23.2 vs 14.6%). Furthermore the Lifesign treatment was the only one producing significantly less abstinence at 18 months than the proactive AS condition (14.6 vs 17.5%). Although the sample was inadequate for a subgroup analysis by stage, it should be noted that the Lifesign condition

produced the lowest point prevalence cessation rates within both the contemplation and the preparation groups.

Recruitment

In a previous study on 4,144 smokers recruited through a random digit dialing procedure [*1*], proactive procedures were able to recruit 80% of the eligible smokers. In the present study of 4,653 smokers of a managed care system, the same procedures produced a comparable percentage (85.3%).

Retention

Table 3 presents the participation rates for the four groups. The reason for missing data was classified into one of two categories: Lost to Follow-up or Refused. The classification Lost to Follow-up included those subjects who could not be contacted either by mail or by phone. The classification Refused included those subjects who declined further participation in the study. A detailed analysis of the attrition rates from three clinical trials, including this one, is provided elsewhere [*32*]. For this study, the analyses indicated that there were no significant ($P > 0.05$) differences between the groups and the effect sizes were extremely small (6 months, $\eta^2 = 0.0034$; 12 months, $\eta^2 = 0.0020$; 18 months, $\eta^2 = 0.0021$). This result is consistent with all analyses of Lost to Follow-up differences in the other two clinical trials [*32*]. Lost to Follow-up seems to be a random variable related to *duration* only and not to smoking status.

In contrast to the Lost to Follow-up analysis, the comparison of Refused rates between the interactive and noninteractive conditions found significant differences (6 months ($\chi^2(3, N = 1{,}447) = 38.255$, $\eta^2 = 0.0269$; 12 months ($\chi^2(3, N = 1{,}447) = 32.496$, $\eta^2 = 0.0210$; 18 months ($\chi^2(3, N = 1{,}447) = 40.461$, $\eta^2 = 0.0273$).

TABLE 3

Final Sample Sizes at Baseline and Three Follow-up Occasions

Intervention condition	*N*	Follow-up occasion		
		6 months	12 months	18 months
Assessment only	350	305 (36; 9)[a]	277 (52; 21)	252 (71; 26)
Expert system[b]	362	278 (54; 29)	281 (70; 38)	251 (82; 55)
ES + counselor[c]	361	253 (54; 54)	223 (67; 69)	203 (70; 86)
ES + lifesign[b]	374	302 (47; 25)	269 (68; 37)	261 (67; 46)

[a] First entry is remaining sample size. In parentheses, the first number is Lost to Follow-up and second number is Refused. Other minor causes of missing data (i.e., death) are not included.

[b] Subjects received an additional phone contact at 3 months.

[c] Subjects received an assessment phone contact at 3 months and counselor calls.

However, the four conditions are not strictly comparable. Subjects in the three intervention conditions received one or more additional calls. At 3 months, smokers in the ES, ES + CO, and ES+ SC conditions received an additional assessment for purposes of generating the ES progress report. Subjects in the ES + CO condition also received additional contacts from the counselor.

This result is consistent with all analyses of Refused differences in two previous clinical trials [*32*], which concluded that the percentage who refused to continue to participate was a function of the number of contacts. Additional contacts increased the number of refusals. If the Refusal rates between the interactive and noninteractive conditions are compared by the number of contacts, there were no significant differences ($P > 0.05$) at one contact, two contacts, three contacts, or four contacts. Refused to participate seems to be a random variable related to *number of contacts* only and not to smoking status.

In order to determine the optimum procedure for this study, a number of key variables were investigated to determine if they were related to the pattern of missing data. Seven demographic or smoking history variables assessed at baseline were related to retention. No significant differences ($P > 0.01$) were found on six of the seven variables, including cigarettes per day, number of years smoking, number of 24-h quits in the past year, time to first cigarette, age, and gender. There was a significant difference with respect to education ($t(1436) = 3.30$, $P < 0.001$). Subjects who were missing had a slightly lower mean education level (12.4 years) than those who were retained (12.8). This difference represents a very small effect size ($\eta^2 = 0.01$) and could be spurious. Alternatively, it could represent a small but real tendency for lower-education-level smokers to find some of the materials too difficult. The reading level of the print materials was 6th to 7th grade. Stage of change and smoking status were not related to retention at any assessment occasion ($P > 0.01$). On the basis of this analysis, a complete analysis was selected to report in detail since it is the most widely employed procedure [*33*] and the strong assumptions of the method were supported.

The data were also analyzed employing five alternative missing data procedures [*34*]. The results for the point prevalence abstinence rates are reported in Table 4. Results for the other three outcome measures followed the same pattern. The set of predictor variables employed included stage of change, 24-h quit in the past year, time to first cigarette, cigarettes per day in the last week, gender, weight, education, and age. The five methods employed are Complete Case analysis, Listwise Deletion, EM Estimation, Regression Estimation, and Intention to Treat analysis. Complete Case

TABLE 4

Point Prevalence Abstinence Rates for Four Treatment Groups at 6, 12, and 18 Months for Five Missing Data Procedures

Treatment group	Procedure	Assessment		
		6 months	12 months	18 months
Assessment only	Complete case	12.1	14.4	17.5
	Listwise	12.3	15.0	18.4
	EM	12.3	14.2	17.3
	Regression	12.5	15.2	18.2
	Intention to treat	10.6	11.4	12.6
Expert system intervention	Complete case	16.5	20.6	23.2
	Listwise	16.3	20.2	22.3
	EM	16.5	19.1	22.3
	Regression	16.3	20.2	22.7
	Intention to treat	12.7	14.4	14.4
Expert system + counselor	Complete case	18.2	25.6	23.2
	Listwise	18.9	27.3	24.2
	EM	18.1	26.3	23.7
	Regression	19.8	28.5	25.1
	Intention to treat	12.7	15.8	13.0
Expert system + lifesign	Complete case	11.3	14.1	14.6
	Listwise	11.5	14.3	14.6
	EM	11.4	14.1	14.8
	Regression	11.3	14.0	14.4
	Intention to treat	9.1	10.2	10.2

Note. Baseline predictors used: 24-h quit in the past year, time to first cigarette, cigarettes per day in past week, gender, weight, education, age, and stage membership.

analysis employs all subjects for whom data were available at the final assessment, regardless of what other data may be missing. Listwise Deletion employs only subjects for whom complete data are available on all occasions. For example, if 18-month status is unknown, 24-month status will also be treated as missing. The EM algorithm assumes a distribution for the partially missing data and makes inferences based on the likelihood under that distribution. The "missing" data are substituted with the expectations. The Regression method computes multiple linear regression estimates. If data are missing completely at random (MCAR), Complete Case, Listwise, EM, and Regression techniques will give consistent and unbiased estimates. EM and Regression estimation will still provide good estimates if the data are conditionally missing at random (MAR). Intention to Treat analysis is an ad hoc procedure that assigns all missing cases the status of smoker. Four of the five procedures produce extremely similar results for this study. The Intention to Treat analysis, as expected, produced an extreme distortion.

DISCUSSION

This study attempted to improve the effectiveness of an interactive ES for population smoking cessation by adding proactive telephone counseling and a Stimulus Control nicotine fading computer. However, the enhanced conditions failed to outperform the ES alone. This study did succeed in replicating high recruitment rates in a managed care population of smokers. The study also demonstrated the ability of the interactive ES to produce significantly greater cessation in a population of smokers than AS.

Recruitment and Retention of a Population of Smokers

In a managed care population of 4,653 smokers, proactive recruitment procedures produced an 85.3% recruitment rate. These results basically replicated the 80% recruitment rates generated using similar proactive procedures in a representative sample of 4,144 smokers [*1*]. However, that study involved a random digit dial procedure with no previously existing connection between the intervention group and the smoker. In this case, the interviewer was identified as having a connection with the health maintenance organization. This connection could be responsible for the slightly higher recruitment rate for the present study.

Expert System Intervention Applied to a Population of Smokers

The comparison between the ES intervention condition and the AS condition demonstrated the effectiveness of this intervention. The ES intervention group was better than the AS group at each follow-up point. At the 18-month follow-up, the ES intervention group was almost 33% better. This result essentially replicates the results of the random digit dial study [*1*].

When group composition is taken into account, i.e., that approximately 80% of the smokers were in precontemplation or contemplation at the beginning of the study, the results are also very similar to those for a reactively recruited sample [*7*].

The AS group produced higher cessation rates than would be expected. The cessation rate at 18 months was 17.5%. Given a typical secular trend, it would be expected that the cessation rate would be 6–7% a year for a representative sample of smokers [*27,35*] or approximately 9% for the 18-month period. The observed rate in this sample was almost double what would be expected based on secular rates.

One possible explanation is that this sample was unusual in some way. However, there is no evidence from the demographics to support this hypothesis. A second explanation is that the secular quit rates were elevated during this period. However, national trends during this period indicated that no unusual differences in quit rates occurred. Furthermore, a similar result was also observed in a previous study, which included an AS condition [*1*]. An alternative explanation is that the proactive assessment is an active ingredient in the AS condition. The assessment package involves questions about the different cognitive and behavioral processes that have been identified as critical in quitting smoking. Subjects are asked how often they use the different processes and they are asked to evaluate the relative importance of the pros and cons of smoking. Furthermore, at each assessment, they are informed that they will be contacted 6 months in the future to follow-up on how they are doing on each of these variables. This type of assessment could activate cognitions and behaviors related to quitting smoking, especially in a proactively recruited sample not otherwise expecting an active intervention. Unfortunately, the design of this study did not permit an evaluation of this hypothesis. A minimal assessment control group would be required.

Failure of the Enhancements

Two potential enhancements were tested, the addition of telephone counselors and the addition of a credit-card-size computer that operated on stimulus control and nicotine fading principles. Of these, the ES + CO condition produced the most promising results. At 12-month follow-up the counselor enhancement produced five percentage points greater abstinence, an amount that is often viewed as clinically significant. But at 18 months, the counselor condition declined from 25.6 to 23.2%, while the ES alone condition had increased from 20.6 to 23.2%. This pattern is similar to that reported previously from a reactively recruited clinical trial [*7*] in which the ES alone increased abstinence rates from 12 to 18 months, while the counselor condition showed no further improvement.

This pattern of no further improvement or even a decline over time for the counselor condition may be due to sudden termination of the counseling relationship after the 6-month contact. Benefits following the 6-month assessment contact would still show up at the 12-month assessment since the last counselor call occurred after the 6-month assessment. But after the participants were on their own, the absence of social support and social control following termination of counseling may result in either a leveling off or a decline in efficacy. To counter the possible negative effects of relatively sudden termination future research should explore the possible benefits of fading counseling by spacing the contacts at increasingly greater intervals.

The second enhancement, a small computer designed to assist in fading was clearly a failure, resulting in worse rather than better efficacy at each follow-up when compared to the ES alone. Why did this previously effective treatment hurt rather than enhance efficacy? Previous research on this action-oriented intervention was done with reactively recruited samples of convenience that were recruited implicitly or explicitly because they were ready to quit smoking. In the present study an entire population of smokers was proactively recruited whether they were prepared to quit or not, and only 18% were prepared. This action-oriented intervention, then, was not matched to the stage of readiness for the majority of smokers. These results underscore the potential perils of applying action-oriented interventions to an entire population of smokers, even in conjunction with a stage-matched program. Population cessation programs require interventions that are adequately matched to the needs of an entire population of smokers and not just the relatively small minority who are prepared to quit.

The results for the two enhanced conditions support the conclusion that more is not necessarily better. Having twice as many contacts (three counselor calls and three mailed reports vs three reports alone) was no more effective at 18 months (23.2 vs 23.2%). Similarly, adding a relatively expensive hand-held stimulus control computer was no more effective and, in fact, was less effective. From a population health perspective, research that shows that more is not necessarily better is important because of the considerable costs incurred when treating entire populations. Finding the least intensive and least expensive treatments that can produce comparable impacts is one of the critical needs for developing programs based on a population health paradigm.

Future Directions

Unfortunately, the two enhancements included in this study failed to further enhance efficacy, a critical means of increasing impacts. In the psychotherapy and

behavior therapy literature, it has typically been impossible to demonstrate that a combination of therapies are more effective than a single established treatment that has already been shown to be effective [*36*]. In the smoking literature, it has been rare to find either single treatments or combinations of treatments that can produce long-term abstinence rates outside of the narrow 25 to 30% range [*5*,*37*]. This limitation has held even though these studies have been done with samples that were implicitly or explicitly recruited as being ready to quit smoking. This has been true even for some of the best combinations, such as counseling plus nicotine gum (27%) or counseling plus the nicotine patch (27%) [*33*,*38*].

The good news is that the ES interventions with or without counseling are approaching high levels of abstinence when applied to entire populations of smokers where less than 20% are prepared to quit. The bad news is that the field may be stuck in a relatively narrow range of long-term efficacy. Future research with the ES plus nicotine replacement where indicated or with faded counseling may lead to the enhancements needed to increase the impact of population-based smoking cessation interventions.

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