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A Randomized Trial Of Three Approaches to Smoking Cessation

SUMMARY

Three hundred and sixty-six patients volunteered for a smoking cessation trial and were randomly allocated to a control group or to three interventions: a single counselling visit to a physician, eight sessions of group health education or eight sessions of group behavior modification. Progress was assessed by smoking diaries, supported by saliva thiocyanate tests, before and after the intervention and six and 12 months later. Only the two group approaches showed a significant improvement compared to the control group immediately after the intervention; these differences were no longer statistically significant six or 12 months later. The group methods proved to be more cost-effective than the physician intervention. However, when different sub-groups were examined, such as heavy or light smokers, a different pattern of results emerged. For very heavy smokers, the physician-led intervention proved almost as successful as the group approaches. Overall quitting results were disappointing, but the programs appear to be more successful at helping people reduce smoking. (Can Fam Physician 1985; 31:845-851)

SOMMAIRE

Trois cent soixante-six patients se sont volontairement prêtés à une étude sur la cessation du tabagisme et furent distribués au hasard soit à un groupe-contrôle, soit à l'un des trois modèles d'intervention: une seule visite de consultation avec un médecin, huit sessions éducatives en groupe, et huit sessions de groupe visant à modifier le comportement. Les participants ont inscrit leurs progrès individuels dans un journal de tabagisme, et on a mesuré le thiocyanate salivaire avant et après l'intervention, et après six et douze mois. Comparativement au groupe-contrôle, seules les approches de groupe ont révélé une amélioration significative immédiatement après l'intervention; ces différences n'étaient plus valides sur le plan statistique six ou douze mois plus tard. Les méthodes de groupe se sont avérées plus avantageuses du point de vue coût-bénéfice que l'intervention faite par le médecin. Cependant, à l'examen des différents sous-groupes, tels les gros fumeurs ou les fumeurs modérés, on a obtenu différents résultats. Pour les très gros fumeurs, l'intervention du médecin s'est avérée presque aussi utile que les approches de groupe. Les résultats globaux d'arrêt définitif furent décevants, mais les programmes s'avèrent davantage utiles pour aider les gens à diminuer de fumer.

Key words: Smoking cessation, education, behavior modification

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VARIOUS STUDIES have examined the role of the family physician in encouraging patients to stop smoking. The arguments in support of such a role, summarized by Rosser,[1, 2] were boosted by the research findings of Russell,[3] who reported that routine advice against smoking given by family doctors could influence about 5% of smokers to quit, and that the cumulative effect of many physicians giving such advice would exert an important influence on smoking rates at a national level. A randomized trial to replicate Russell's findings in Ontario was carried out at the Family Medicine Centre of the Ottawa Civic Hospital in 1979-1980.[4] The percentage of patients not smoking one year after the intervention was similar to that found by Russell. However, the control group showed a considerably higher quit rate than in Russell's study; there was no significant difference between experimental and control populations. Very few of those who did quit attributed this to the influence of the physician; most stated that it had been a purely personal decision.

At best, therefore, it seemed that the physician may be able to act as a catalyst for someone whose decision is already taken. The poor performance in Russell's control group appears contrary to the observation that an important number of people stop smoking without the assistance of a formal cessation program. Successful change by

the control group has confounded the results of other studies, such as the North Karelia and MRFIT heart disease prevention trials.[5, 6]

Apart from Stewart's study,[4] we have not found other formal attempts to replicate Russell's study, so that the body of knowledge on this issue remains slim. For this reason the study described below contained a low-level intervention comparable to that used by Russell. This is by no means the only type of program which could be applied in a family practice: more intensive, group education programs could be led by a practice nurse. Accordingly, the present trial was designed to see whether more intensive interventions were feasible and effective in encouraging smoking cessation in family practice.

The objectives of the trial were:

1. to compare the impact of three therapies on reducing the amount of cigarets smoked.
2. to analyze what types of smoker best respond to each type of smoking-cessation therapy, and to formulate hypotheses explaining such associations.
3. to indicate the relative costs of each type of therapy, and thereby to compare their cost-effectiveness for identifiable sub-groups of smokers.

The present discussion concentrates on the first and third objectives, comparing smoking rates before and six months after the cessation program.

Method

Patients who were routinely scheduled for an appointment with their family physician and who met the following criteria served as subjects:

1. Over age 15
2. At least one year of smoking
3. Currently smoking at least one cigaret per day
4. An expressed willingness to join the study

The patients of 56 physicians representing nine different group practices participated in the study, for a total of 366. Recruitment was achieved via posters and leaflets in the waiting rooms announcing a smoking cessation program. Those interested were given a telephone number to call to register.

Before randomization, social and demographic data were collected from each participant, along with information on smoking history, current smoking habits and a battery of questions concerning attitudes toward smoking. These included the smoking typology scale,[7] questions assessing the individual's determination to quit, and his confidence in being able to do so. These were included as possible predictors of success, to address the second study objective.

As a test of motivation to participate in the trial, subjects were asked to complete the questionnaires at home and return them by mail. Those returning the completed material were randomly assigned to one of the three interventions or to the control group.

Satisfaction with each intervention method was recorded after the intervention. To measure smoking rates, each subject kept a diary to record the number of cigarets smoked daily over one week. To encourage accurate recording, participants were told they might be required to undergo a saliva thiocyanate test. These were carried out on a small sample of those cases who attended the follow-up sessions. Participants who failed to attend the follow-up session returned their diaries by mail. Because the thiocyanate analyses applied to a biased sub-group, we do not present results of the test here. The smoking diary data were analyzed to give mean and median numbers of cigarets smoked per day, and to calculate smoking rates as a percentage of the individual's smoking rate at entry to the trial. Those who had quit smoking were included in calculating each of these rates. Testing occurred before the intervention ('baseline'), immediately post-intervention, and at six and 12 months. Because the duration of the three interventions differed, the post-intervention diaries were completed at slightly different intervals after baseline, ranging from two weeks to two months. The control group completed the second diary one month after the baseline.

Strenuous attempts were made to retain contact with participants during the follow-up period, but there was some attrition, as detailed in the results section. Where a participant provided data at all points except at 12 months, the smoking rates of that patient at the six-month follow-up were used to replace the missing 12-month information. This applied to 20 cases, all of whom were smoking at six months. Cases with missing outcome data at or before the six-month follow-up were

NUTRINEWS

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Dr. Louise Davies, Ph.D., Head of the Gerontology Nutrition Unit of London's Queen Elizabeth College, explains how to motivate the elderly to improve their food habits in her article entitled *Effective Approaches for Reaching Seniors.* For your copy of *Nutrition Quarterly* containing this article, write

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discarded from the analyses; these totalled 30 cases (8.2%).

Interventions

Physician Encouragement. This comprised a 15-minute counselling session tailored to the patient's smoking pattern, using printed material produced by the U.S. National Cancer Institute. This "Helping Smokers Quit Kit" contains an explanatory guide for the physician, written material for the patient and a memo for the nurse. Nicotine gum was not used; the intervention called for one follow-up contact by mail with the patient, enclosing printed material designed to encourage continued attempts to quit. Introductory briefing sessions were held for the 12 physicians who administered this approach.

Group Health Education. This was a more closely structured treatment designed to foster mutual support, to provide and discuss pertinent information and to review problems experienced by group members. The intervention followed the "Operation Kick It" material developed by and used with permission of the British Columbia Lung Association. The material provides a comprehensive manual for the group leader. Subjects met in groups of 10-15 for eight weekly, 90-minute sessions at the Family Medicine Centre. An additional 'booster session' was held two weeks after the last treatment session to review progress and problems. The groups were led either by a registered public health nurse experienced in running lifestyle modification groups or by a special education teacher experienced in leading smoking cessation groups.

Group Behavior Modification. The third approach represented a more highly structured group intervention derived from psychological theories. The intervention included behavioral rehearsal, at which subjects practised responses for turning down cigarets and non-verbal actions to cope with the urge to smoke and the side effects of quitting. The program also taught cognitive restructuring, which provided a method for challenging beliefs concerning obstacles to smoking cessation, relaxation procedures, cognitive coping and various methods of maintaining cessation and preventing relapse.

The behavior modification course comprised eight therapy sessions held twice a week for two weeks and once a week for four further weeks at the Family Medicine Centre. As in the health education approach, a 'booster session' was held two weeks after the end of treatment. The behavior modification groups were led by one of two therapists who held masters of education degrees in psychology.

Control Group. Subjects allocated to the control group were told that their smoking status would be reviewed in two, six and 12 months' time (simultaneously with follow up of the treatment groups). This was designed to assess the impact on smoking habits of recording smoking levels.

Results

Ninety patients were allocated to physician intervention, 90 to group health education, 93 to group behavior modification and 93 to the control group. To evaluate the comparability of the groups, sociodemographic data were examined; if the randomization was adequate, there should be no significant differences between the groups. This was the case for 13 of 14 demographic variables examined; there was a statistically significant difference between the groups only in terms of occupation (chi square 30.2, 18 d.f., $p < 0.04$).

Average age of the study sample was 36.3 (range 16-70); 60% were female; 45% had a university education; 59% were employed fulltime, and 54% were married. The average number of cigarets smoked at baseline was 23.8 per day. Eighty-six percent had tried to quit in the past, having made an average of four attempts; 49% stated that it was extremely or very likely that they would be able to quit with the program.

Participants were followed for one year; by the six-month follow-up three in the physician group, six in the behavior modification group and 15 of the controls could not be contacted. The following results are based on the remaining 336 patients. Follow-up for the control group was more difficult mainly because, being less involved in the study, they tended to be less careful about informing us of changes in address. The average smoking rate at baseline for the 336 cases was 25 cigarets per day.

Outcomes

Smoking Rates. Table 1 shows the mean and median smoking rates in each of the groups, and the percentages not smoking. The three intervention groups started with comparable smoking rates; the control group was

TABLE 1
Mean and Median Numbers of Cigarets Smoked; Numbers Quitting at Intake, Post-Intervention, Six and 12 Months Later

Intervention	Mean No. Cigs. Smoked/ Day	Median No. Cigs. Smoked/ Day	% Not Smoking	% of Baseline Smoking Rate
Physician Encouragement (N=87)				
baseline	25.2	24.7	0	100
post	15.3	15.4	17.2	66.0
six mo.	19.6	21.6	11.5	83.0
12 mo.	20.2	24.6	14.9	86.5
Group Health Education (N=84)				
baseline	26.2	25.2	0	100
post	12.9	10.5	34.5	54.2
six mo.	17.4	18.0	20.2	72.3
12 mo.	18.2	19.8	16.7	81.7
Group Behavior Modification (N=87)				
baseline	25.0	24.7	0	100
post	12.5	7.75	39.1	46.7
six mo.	18.5	19.25	18.4	73.0
12 mo.	18.5	19.9	17.2	77.1
Control (N=78)				
baseline	23.4	22.5	0	100
post	20.1	20.5	10.3	91.9
six mo.	21.5	24.5	17.9	93.2
12 mo.	21.7	23.5	14.1	95.0

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Nitroglycerin is a potent vasodilator and causes a slight decrease in mean blood pressure (approximately 10-15 mm Hg) in some patients when used in therapeutic dosages. Caution should be exercised in using the drug in patients who are prone to, or who might be affected by hypotension.

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Tolerance to this drug and cross tolerance to other nitrates or nitrites may occur.

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Headache is the most common side effect, especially when higher dosages of Nitrong SR are used. Headache may be treated with concomitant administration of mild analgesics. If headache is unresponsive to such treatment, the dose of Nitrong SR should be reduced or the use of the product discontinued.

Less frequently, postural hypotension, an increase in heart rate, faintness, flushing, dizziness, nausea and vomiting have been reported.

Symptoms and treatment of overdosage
Symptoms of overdosage are primarily related to vasodilation, including cutaneous flushing, headache, nausea, dizziness and hypotension.

Methemoglobinemia is also possible.

No specific antidote is available. Treatment should primarily be symptomatic and supportive.

Dosage and administration
Adult: Recommended initial dosage is 1 tablet 3 times a day before breakfast, late afternoon before meal and before retiring. Dosage may be increased progressively up to 2 tablets 3 times a day.

Availability
Sustained-Release Tablets of 2.6 mg — Bottles of 100 and 1000.

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slightly (but not significantly) lower. Over the course of the study, the control group showed a slight but not significant decline in smoking rates. The three interventions all showed a similar pattern of initial decline, followed by a return towards the baseline smoking level. Analyses of variance followed by Tukey's test showed that all three interventions achieved significant reductions in smoking rates at all follow-up measurements compared to their own baselines ($p < 0.01$). At the post-program measurement, smoking rates in the two group interventions were significantly ($p < 0.01$) lower than the control group, but the average smoking rate in the physician group did not differ significantly from that in the control group. Mean smoking rates in the intervention groups at six and 12 months showed no significant differences from the control group.

A similar pattern appeared when the results were analyzed in terms of smoking rates expressed as a percentage of baseline smoking rate and in terms of the proportions of cases who quit. In each instance the initial results showed significant advantages to the group interventions, with the physician intervention showing a lesser impact. By the six-month follow-up the rates do not differ significantly from those in the control group.

These results agree with those of the previous study[4] for the physician intervention, although the present rates of quitting were somewhat higher. It is of course disappointing that the interventions proved no more successful in the long term than the attention-placebo control group. However, mean smoking rates of those in the control groups who quit at entry to the trial was 12.6 cigarets per day, compared to 22.7 for quitters in the other groups; those who ceased smoking in the control group were mostly lighter smokers. We infer from this that active intervention programs may be of most benefit for heavier smokers, who are less likely to quit on their own. For convenience in studying this, the subjects were classed into tertiles by baseline smoking rate. For 'light' smokers (averaging 12.1 cigarets per day at baseline) there were no differences in quit-rates among the interventions at 12 months, and no difference between interventions and the control group. Amongst those smoking more heavily, however, a *trend* in the predicted direction emerged. For the 'heavy' smokers (averaging 37 cigarets per day at baseline) the physician intervention was as effective in reducing smoking rates as were the group interventions at the six and 12 month measurements; at both times the active interventions showed an advantage (non-significant) compared with the control group.

Satisfaction. The level of satisfaction expressed with each intervention varied widely: 53% of the health education and 56% of the behavior modification participants stated that the program had helped them "very much". Only 8% expressed this level of satisfaction with the physician intervention, and none of the control group stated that the program had helped them very much. Thirty-three percent of the physician intervention group and 44% of the controls stated that the intervention had not helped at all. Participants were asked to estimate how much they had learned through the programs; 74% of the health education group said they had learned a lot about their smoking, as compared to 68% of the behavior modification group, and only 14% of the physician group. Eighty-one percent of the health education group participants would strongly recommend it to their friends, as would 83% of the behavior modification participants and 32% of the physician group.

Cost-Effectiveness

Because the control group showed some progress at no direct cost in terms of attending for therapy, the performance of the active interventions can be assessed by comparing them with the outcome of the control.

Costs for the physician encouragement intervention were assessed as follows: $24.50 billable under the Ontario Health Insurance Plan for a counselling session, plus $5 estimated per patient visit for clinic running expenses and an estimated $2 travel and parking expense per patient. Patient loss of earnings have not been costed. The total is $31.50 per patient.

Both group interventions comprised nine 90 minute sessions; the leader's salary and travel expenses were calculated at $28.25 for each session. The numbers of patients attending each session varied; an average of ten is used in the following calculations for both of the group methods. The cost of the materials for the group behavior

modification program was estimated at $2.50, whereas material for the physician and health education sessions was free. The clinic running expenses were lower, as the groups were held after hours and did not use the normal nursing or reception staff: $0.85 per patient per session. Parking and transport for each patient per session were again estimated at $2. Behavior modification accordingly cost $53.58 per patient, assuming an average of ten patients per session. For the health education approach the cost per patient was $51.08.

Calculating the cost-effectiveness of the interventions has taken into account the quit rate achieved for no cost in the control group; therefore we have costed the improvement achieved over that shown by the controls. This was only statistically significant for the two group interventions, at the immediate post-program testing, and therefore only these results are considered relevant. The behavior modification approach cost $186 for each smoker to quit; the health education program cost $210 per quitter. The physician approach cost $449 per quitter.

Discussion

There was a very slow rate of intake to the trial. Despite efforts before the trial began to estimate the demand for the smoking cessation assistance we provided, the familiar volunteer evaporation phenomenon occurred, and very few patients attending the clinics agreed to join. Only by strenuous efforts could we recruit the 360 patients required, and the planned recruitment phase of the trial had to be lengthened. Smoking cessation may be less attractive than it was previously, and family physicians may not experience great demand for a service of this type. Nonetheless, it did prove feasible to operate group cessation methods in a family medicine centre, although the attendance at the evening sessions was poor. Very few group members attended all the appointed sessions. The analyses presented above ignore this and include everyone in the group to which they were allocated, whether or not they completed the intervention. On the positive side, the trial, although small, was quite successful in its random allocation and the rate of follow-up to six months, at least, was good.

In terms of quit rates, the results at six months were very disappointing, and did not differ significantly from the quit rate in the control group. However, the programs appear to be more effective in helping people to *reduce* their smoking, especially the heavy smokers. In the process of reducing and eventually stopping smoking, there may be distinct phases, at each of which a different form of intervention is appropriate. Any one of the interventions is influential in helping the heavier smoker cut down, but eventual quitting is largely achieved by personal efforts.

Why were we not more successful in demonstrating that the family physician has a role to play in smoking cessation counselling? As in the present study, our previous study[4] showed no benefit compared to a control group. Meanwhile, a recent British study by Jamrozik has shown that the doctor can achieve slight gains compared to a control group.[8] In Jamrozik's study, 11% of the control group quit, compared to 14% in our study, while 15% of the physician group quit—similar to our 14.9%. Several comments may be relevant. The British study was very large, but achieved only a 72% follow-up response at 12 months. The statistical power in our study is lower than in the British study. Perhaps more importantly, not all of the patients in our physician intervention group received the cessation advice from their own family physician: some saw a doctor whom they did not know. In future studies we should also pay close attention to the cessation rates achieved by the control group. It would be valuable to examine whether the quit-rates are higher in an attention-placebo control group (who fill in questionnaires) than in an equivalent group who do not. Anecdotal evidence from the present study suggests that many people decided to quit once the process of keeping a smoking diary forced them to become consciously aware of their smoking patterns. Keeping diaries may prove the simplest cessation approach of all.

We are currently analyzing the predictors of success, and several of the findings are consonant with current theories of smoking cessation. One predictor of success was the smoker's history of previous attempts to quit, including the length of time he or she had managed to go without cigarets at the last attempt. Other studies have also argued that success in quitting increases with the number of attempts made; this may indicate that a physician should continue to encourage a smoker who reports several unsuccessful attempts at quitting. Moderate predictors of the individual's ability to quit were his feelings of confidence that he would be successful, as recorded before the program began. Stronger associations were noted between quitting and the questions asked immediately after the intervention, concerning satisfaction with the program, and confidence that progress would be maintained.

Our overall conclusions are that the two group interventions are equivalent in their effectiveness, and are in general more successful than the physician approach. However, the success of the physician approach among heavy smokers warns against abandoning this method completely, and our analysis will continue to examine the interactions between type of smoker, type of intervention and success rates. ◉

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