Effectiveness of a Computer-Tailored Smoking Cessation Program

A Randomized Trial

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Background: From a public health perspective, prevention of cancer and cardiovascular diseases requires effective smoking cessation programs that can be used on a large scale.

Objective: To test the effectiveness of a new computer-tailored smoking cessation program vs no intervention.

Methods: Randomized controlled trial, in the French-speaking part of Switzerland, September 20, 1998, to December 31, 1999. Potential participants were randomly selected from a general population register and recruited by mail. Daily cigarette smokers who wished to participate (N = 2934) were randomized to either the program or no intervention. A mean of 1.5 times per 6 months, participants in the active arm received by mail a computer-tailored counseling letter based on their answers to a questionnaire and stage-matched booklets. The counseling letters were tailored to the participants’ stage of change (categorized as precontemplation [no intention of quitting smoking in the next 6 months], contemplation [seriously considers quitting in the next 6 months], or preparation [has decided to quit in the next 30 days]), level of tobacco dependence, self-efficacy, and personal characteristics. The outcome measure was self-reported abstinence (no puff of tobacco smoke in the past 4 weeks) 7 months after entry into the program.

Results: Abstinence was 2.6 times greater in the intervention group than in the control group (5.8% vs 2.2%, \( P < .001 \)). The program was effective in “precontemplators” who were not motivated to quit smoking at baseline (intervention vs control, 3.8% vs 0.8%; \( P = .001 \)) and was effective regardless of perceived difficulty in quitting smoking at baseline.

Conclusions: The program was effective in increasing smoking cessation rates. Because it can reach a large number of smokers, this program can substantially contribute to disease prevention at a population level.

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SMOKING is the cause of more than 45% of all cancer deaths and of 90% of all lung cancer deaths in the United States. Quitting smoking at age 30 avoids 90% of the subsequent risk of death from lung cancer, but smokers who stop at age 50 or 60 also substantially reduce their risk of developing lung cancer.

Individualized counseling for smoking cessation is effective, but few smokers are willing to attend smoking cessation clinics and many smokers do not receive smoking cessation advice from their physician. Self-help smoking cessation materials can reach large numbers of smokers but may lack effectiveness. Computer technology and psychological theory can be used to produce and disseminate effective individualized self-help smoking cessation materials. Because individually tailored materials consider the relevant characteristics of each participant, smokers may be more interested in reading these materials and more likely to apply the advice included therein. Consequently, tailored materials may be more effective than those intended for all smokers.

Researchers have tested the effectiveness of computer-tailored smoking cessation programs, with positive and negative results. Traditional smoking cessation programs target only the 5% to 20% of smokers interested in quitting immediately, leaving most smokers without support. Interventions directed at smokers who have no immediate intention of quitting are needed. Some smoking cessation programs have been effective in such smokers, sometimes called “precontemplators” and “contemplators,” but others have not. Other subgroups require special attention. In particular, smoking prevalence increased among adolescents dur-
PARTICIPANTS AND METHODS

SETTING AND PARTICIPANTS

Sample-size calculations indicated that a sample of 2000 was necessary to detect a difference in quit rates between 4% (control group) and 7% (intervention group), with a confidence level of 95% and a power of 80%. Expecting a response of 10%, we sent an invitation to participate in the study and the baseline questionnaire to a representative sample of 20,000 residents aged 18 to 60 of the French-speaking part of Switzerland. Smoking prevalence in Switzerland was 33% in 1997. Addresses were randomly selected from a general population register. The purpose of the study, the risk of being attributed at random to a no-intervention control group, and the follow-up procedures were explained in the accompanying letter. Only daily cigarette smokers were eligible for the study. Nonsmokers and smokers who did not want to participate were asked to transmit the questionnaire to a smoker. The Geneva, Switzerland, review board for research in public health approved the trial.

STUDY DESIGN

Daily smokers who wished to participate in the trial were randomly assigned to the intervention or control groups using a list of random numbers. A participant flow chart is presented in the Figure. The follow-up questionnaire was sent out 6 months after receipt of the baseline questionnaire, and nonrespondents received up to 6 reminder mailings.

INTERVENTION AND CONTROL GROUP PROCEDURES

The intervention consisted of personal counseling letters, composed by a computer according to smokers’ answers to a questionnaire, and of stage-matched booklets. The baseline questionnaire was also used to produce the first counseling letter. The intervention was based on the transtheoretical model of change,16,24 the theory of planned behavior,25 theories of relapse prevention26 and tobacco dependence,27 the Agency for Health Care Policy and Research recommendations,20 and other relevant literature.29 The questionnaires, counseling letters, and booklets were also based on extensive qualitative research and pretests conducted in Swiss smokers and ex-smokers.30-32 The counseling letters were illustrated with cartoons and graphs, which were also tailored to each smoker’s responses. The program was tested in hundreds of people for more than a year before the study was conducted.

The questionnaires used to produce the tailored counseling letters assessed the participants’ demographic characteristics, stage of change, level of tobacco dependence, attitudes toward smoking, self-efficacy, use of self-change strategies, and intention to use nicotine replacement therapy. A participant’s stage of change was categorized as precontemplation (no intention of quitting smoking in the next 6 months), contemplation (seriously considers quitting in the next 6 months), or preparation (has decided to quit in the next 30 days).24 We used validated scales to measure these variables.30,33

After returning the questionnaire, participants in the intervention group received by mail an 8-page personal counseling letter and two 16-page booklets corresponding to their current stage of change and to the next stage. Two months and 4 months after entering the study, participants in the intervention group were invited to answer a new tailored questionnaire to receive a new counseling letter. On average, participants received counseling 1.5 times per 6 months. Almost half of the participants (49%) received counseling only once, 40% twice, and 11% 3 times or more.

After returning the baseline questionnaire, members of the control group received a letter indicating that they had been attributed to that group. We did not contact them again until the follow-up survey.

OUTCOME MEASURES AND STATISTICAL ANALYSES

The main outcome measure was 1-month abstinence (not having taken even a puff of tobacco smoke—cigarette, cigar, pipe, or other—in the past 4 weeks), which is the criterion recommended by the Food and Drug Administration for assessing smoking cessation in clinical trials.34 We also assessed 1-week abstinence (no puff of tobacco smoke in the past 7 days), which is the criterion used in a recent guideline to assess smoking cessation in randomized trials.35 In addition to questions asked at baseline, the follow-up questionnaire also included the quit date for ex-smokers. The program effectiveness was measured by the ratio of proportions of baseline smokers who were abstinent at follow-up. We used an intention-to-treat analysis, in which all persons absent at follow-up were considered to be smokers.

Because time to follow-up differed between the 2 groups, we conducted a time-failure analysis, using proportional hazards regression models, with the quit date for ex-smokers as time of event and the return date of the questionnaire as time of censoring. For nonrespondents, the date of censoring was set to 1 day after receipt of the last questionnaire.

We tested the effectiveness of the program in subgroups of participants, stratifying by age, sex, educational level, stage of change, level of tobacco dependence (number of cigarettes per day), perceived difficulty in quitting, and past quit attempts. We used multivariate logistic regression models to assess the effectiveness of the program after adjustment for baseline characteristics of participants, and to identify independent predictors of smoking cessation. We used $\chi^2$ tests to compare proportions, t tests to compare means, and Cox proportional hazards regression models for time-failure analyses.36

The aim of this study was to test the effectiveness of a new computer-tailored smoking cessation program in a general population setting. In particular, we were interested in testing whether precontemplators, contem-
Flow chart of participants in the randomized controlled trial.

RESULTS

BASELINE CHARACTERISTICS AND FOLLOW-UP RATES

At baseline, the intervention and control groups were similar (Table 1). The sample included a substantial proportion of smokers not yet ready to quit (precontemplators), but, on average, smokers in this study were more motivated to quit smoking than a representative sample of smokers in Geneva, comprising 74% precontemplators, 22% contemplators, and 4% who were ready to quit.17

Follow-up rates were 76% in the intervention group and 92% in the control group (P<.001, overall response of 84%). The median time between the baseline and follow-up surveys was 7.1 months (25th, 50th, and 75th percentiles in the intervention and control groups: 187, 208, and 260 days and 182, 191, and 211 days, respectively; P<.001). Feedback from participants indicated that some members of the intervention group were tired of our successive mailings, which probably explains why the response rate was lower in this group.

ABSTINENCE RATES

At follow-up, assuming that all nonrespondents were smokers, the 4-week abstinence was 2.6 times greater in the intervention than in the control group (95% confidence interval [CI], 1.7-3.8) (Table 2). The 7-day abstinence was 8.0% in the intervention group and 3.3% in the control group (P<.001). In time-to-event analysis, the relative hazard of quitting smoking in the intervention group was 2.1 (95% CI, 1.4-3.2). When this analysis was limited to the first 180 days following the baseline survey, the relative hazard was 2.2 (95% CI, 1.4-3.5). After day 180, the relative hazard of quitting became non-significant (relative hazard = 1.6; 95% CI, 0.6-4.3). Therefore, the between-group difference in quit rates did not appear to be affected by the difference in time to follow-up.

Using the criterion of 4-week abstinence, the program produced 1 additional quitter for every 28 participants. The program was as effective among men as among women. It was effective among smokers who were in the precontemplation or contemplation stages of change at baseline, but not among smokers who were in the preparation stage at baseline. The interaction term for stage by program participation was statistically significant (Table 2). The program was more effective in smokers who said at baseline that quitting smoking would be easy than it was in those who said that it would be very difficult. Those who had made a quit attempt during the year before enrollment were more likely to quit smoking than those who had not, but the program doubled the odds of quitting in both groups. The program was effective among very heavy smokers (>35 cigarettes per day) and among teenagers (aged 15-19), but these results were statistically significant only when the 7-day abstinence criterion was used to compare the intervention group vs the controls (very heavy smokers, 7.9% vs 1.6%, P=.02; teenagers, 14.9% vs 3.9%, P=.02). The program was not effective among the least educated and was most effective among the most educated. However, in multivariate analyses with interaction terms, the effect of age and educational level on program effectiveness was not statistically significant.

In multivariate analysis, the effectiveness of the program remained unchanged after adjustment for baseline characteristics of participants (level of tobacco dependence, stage of change, past quit attempts, perceived difficulty in quitting, age, sex, and educational level). In a multivariate model, statistically significant predictors of 4-week abstinence were participation in the program (odds ratio [OR]=2.8), having made a quit attempt in the previous year (OR=1.6), stage of change (OR=2.0 per stage), and time to the first cigarette in the morning, an indicator of tobacco dependence (OR=1.1 per hour) (P<.03 for all).

Table 1. Baseline Characteristics of Study Participants*

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Intervention</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of participants</td>
<td>1467</td>
<td>1467</td>
</tr>
<tr>
<td>Age, mean (SD), y</td>
<td>36.6 (12.0)</td>
<td>36.0 (11.9)</td>
</tr>
<tr>
<td>Men</td>
<td>721 (49.1)</td>
<td>680 (46.4)</td>
</tr>
<tr>
<td>School years, mean (SD)</td>
<td>14.2 (2.9)</td>
<td>14.2 (2.9)</td>
</tr>
<tr>
<td>Stage of change</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Precontemplation</td>
<td>606 (41.3)</td>
<td>595 (40.6)</td>
</tr>
<tr>
<td>Contemplation</td>
<td>747 (50.9)</td>
<td>759 (51.7)</td>
</tr>
<tr>
<td>Preparation</td>
<td>114 (7.8)</td>
<td>113 (7.7)</td>
</tr>
<tr>
<td>Cigarettes per day, mean (SD)</td>
<td>20.1 (10.4)</td>
<td>19.6 (10.1)</td>
</tr>
<tr>
<td>Minutes to first cigarette of the day, mean (SD)</td>
<td>67.7 (94.0)</td>
<td>72.3 (103.2)</td>
</tr>
<tr>
<td>Made a quit attempt in previous year</td>
<td>582 (39.7)</td>
<td>606 (41.3)</td>
</tr>
<tr>
<td>Perceived difficulty to quit on a 0-10 scale, mean (SD)</td>
<td>7.8 (2.5)</td>
<td>7.8 (2.5)</td>
</tr>
</tbody>
</table>

*Data are given as number (percentage) unless otherwise indicated.
ADHERENCE TO THE PROGRAM

Eighty-nine percent of respondents in the intervention group said that they had read at least 1 counseling letter, and 65% said that they had read at least 1 stage-matched booklet. There was an association between the number of counseling letters read and smoking cessation (4-week abstinence of 2% for no letter read, 6% for 1, 9% for 2, 11% for 3, and 32% for 4; test for linear trend, \( P = .002 \)). Among quitters in the intervention group, 19% said that the counseling letters helped them quit “a lot,” 19% “fairly,” 30% “somewhat,” and 32% “not at all.”

COMMENT

This study showed that a computer-tailored smoking cessation program carried out by mail increased by 2.6 the 4-week abstinence rate in daily smokers at 7 months. The program was effective despite stringent evaluation criteria (intention-to-treat analysis and no puff of tobacco smoke in the past 4 weeks). The relative prevalence rate of quitting smoking observed in this study exceeded the OR of 1.7 reported in a meta-analysis of nicotine replacement therapy for smoking cessation.\(^7\) Our intervention also succeeded in recruiting many smokers with low motivation to quit and in increasing their quit rates. This is a substantial contribution because most existing smoking cessation interventions target only the minority of smokers who are ready to quit immediately, with few smoking cessation interventions having been effective in precontemplators.\(^6,18\)

Our results showed that the program was effective in teenagers and heavy smokers in terms of 1-week abstinence, although by design the size of the trial precluded formal testing of program effectiveness in subgroups. In previous studies, another computer-tailored intervention was ineffective in heavy smokers,\(^3,38\) one was effective,\(^8\) and the others did not report results for heavy smokers.\(^1,16,18\) In addition, several previous smoking cessation programs have been ineffective in adolescents.\(^1,15,21\)

PUBLIC HEALTH EFFECT

This program was successfully used in a large population of smokers, using a proactive recruitment strategy. The program tested in this trial is now available at no charge on the Internet, in French, English, Italian, and Danish.\(^39\) More than 40,000 smokers have obtained an individual counseling letter by mail or on the Internet. These smokers are regularly invited to obtain follow-up

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**Table 2. Smoking Cessation Rates After 7 Months for Participants in a Computer-Tailored Smoking Cessation Program and in a No-Intervention Control Group**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>No. *</th>
<th>Program</th>
<th>Control</th>
<th>( P ) Value</th>
<th>( P ) Value for Interaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>All participants</td>
<td>2934</td>
<td>5.8</td>
<td>2.2</td>
<td>&lt;.001</td>
<td>.29</td>
</tr>
<tr>
<td>Men</td>
<td>1401</td>
<td>5.8</td>
<td>2.8</td>
<td>.005</td>
<td></td>
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<tr>
<td>Women</td>
<td>1533</td>
<td>5.8</td>
<td>1.8</td>
<td>&lt;.001</td>
<td></td>
</tr>
<tr>
<td>Stage of change at baseline</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Precontemplation</td>
<td>1201</td>
<td>3.8</td>
<td>0.8</td>
<td>.001</td>
<td></td>
</tr>
<tr>
<td>Contemplation</td>
<td>1506</td>
<td>6.7</td>
<td>2.2</td>
<td>&lt;.001</td>
<td></td>
</tr>
<tr>
<td>Preparation</td>
<td>227</td>
<td>10.5</td>
<td>9.7</td>
<td>.84</td>
<td></td>
</tr>
<tr>
<td>Cigarettes per day</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤12 (Light smokers)</td>
<td>695</td>
<td>7.2</td>
<td>2.8</td>
<td>.007</td>
<td></td>
</tr>
<tr>
<td>13-24</td>
<td>1411</td>
<td>6.6</td>
<td>2.1</td>
<td>&lt;.001</td>
<td></td>
</tr>
<tr>
<td>≥25 (Heavy smokers)</td>
<td>787</td>
<td>3.5</td>
<td>1.6</td>
<td>.09</td>
<td></td>
</tr>
<tr>
<td>≥35 (Very heavy smokers)</td>
<td>262</td>
<td>5.7</td>
<td>1.6</td>
<td>.09</td>
<td></td>
</tr>
<tr>
<td>Made a quit attempt in past year</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>.95</td>
</tr>
<tr>
<td>Yes</td>
<td>1188</td>
<td>8.4</td>
<td>3.3</td>
<td>&lt;.001</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>1731</td>
<td>4.1</td>
<td>1.5</td>
<td>.001</td>
<td></td>
</tr>
<tr>
<td>Perceived difficulty to quit on a 0-10 scale</td>
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<td></td>
<td></td>
<td></td>
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<tr>
<td>0-4</td>
<td>296</td>
<td>10.0</td>
<td>0.7</td>
<td>&lt;.001</td>
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<tr>
<td>5-9</td>
<td>1564</td>
<td>6.1</td>
<td>2.8</td>
<td>.001</td>
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</tr>
<tr>
<td>10</td>
<td>1065</td>
<td>4.2</td>
<td>1.9</td>
<td>.03</td>
<td></td>
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<tr>
<td>Age, y</td>
<td></td>
<td></td>
<td></td>
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<td>.51</td>
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<tr>
<td>15-19</td>
<td>150</td>
<td>8.1</td>
<td>2.6</td>
<td>.14</td>
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<td>20-29</td>
<td>849</td>
<td>3.7</td>
<td>2.5</td>
<td>.31</td>
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<td>30-39</td>
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<td>6.2</td>
<td>2.3</td>
<td>.006</td>
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<td>40-49</td>
<td>629</td>
<td>6.8</td>
<td>1.6</td>
<td>.001</td>
<td></td>
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<td>50-79</td>
<td>498</td>
<td>6.6</td>
<td>2.5</td>
<td>.03</td>
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<td>School years</td>
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<td>3-10</td>
<td>213</td>
<td>3.9</td>
<td>3.6</td>
<td>.92</td>
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<tr>
<td>11-18</td>
<td>2446</td>
<td>6.0</td>
<td>2.1</td>
<td>&lt;.001</td>
<td></td>
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<tr>
<td>≥19</td>
<td>229</td>
<td>6.7</td>
<td>0.9</td>
<td>.02</td>
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</table>

*Numbers of participants vary because of missing data.
counseling, including Internet participants if they indicate their e-mail address. The public health effect of a smoking cessation intervention is the product of its effectiveness among participants times its recruitment rate in the population. This is a low-intensity intervention, leading to low abstinence rates. But given its massive recruitment capacity, either by mail or on the Internet, this program has the potential to have a large effect on public health. However, this study only assessed the effectiveness of the mail version of the program, and we do not know whether the Internet version is equally effective.

**LIMITATIONS OF THE PROGRAM**

The intervention was not effective among the least educated smokers, but globally, the interaction between educational level and program effectiveness was not statistically significant. Therefore, results in small subgroups (deciles) should be considered with caution. The program subsumes strong reading skills and a habit of learning from printed materials. Whether a simplified and more readable version of the program would be effective is questionable, but this issue deserves scrutiny. Historically, declines in smoking rates have been stronger among the more educated. Developing smoking cessation programs adapted to the least educated smokers remains a challenge.

The program was ineffective among smokers in the preparation stage of change. Qualitative research to understand the reasons for this finding is under way. It is possible that the counseling paragraphs targeted at smokers in the preparation stage of change should be improved to include more information on relapse situations and pharmacotherapy.

Most smokers need several attempts before they quit for good. Therefore, successive interactions are deemed indispensable for effective smoking cessation interventions. We observed an association between the number of counseling letters read and smoking cessation, which could mean that receiving more counseling letters resulted in higher quit rates. However, participants more motivated to quit asked for more counseling letters; therefore, a selection bias rather than a dose-response effect could explain the increased quit rates among those who received several letters. Finally, almost half of the participants received only 1 counseling letter. The reluctance of respondents to fill out subsequent questionnaires raises a concern about the feasibility of a more intensive intervention.

**LIMITATIONS OF THIS STUDY**

We treated all nonrespondents as smokers, but there were more nonrespondents in the intervention group than in the control group. If proportions of nonsmokers among nonrespondents were similar in both study arms, the program effectiveness would be greater than that reflected in our data. Differential selection bias could explain our findings only in the unlikely event that all nonparticipants in the intervention group were smokers and 60% of nonparticipants in the control group were nonsmokers.

We conducted no biochemical verification of smoking status for several reasons. First, sustained abstinence from smoking cannot be easily biochemically verified, given the short half-life of markers of exposure to tobacco smoke. Second, collecting saliva or blood samples for cotinine determination or expired carbon monoxide levels would have decreased participation rates. Third, biochemical verification will not change the results of most smoking cessation studies, because self-report is generally accurate in adults and because large between-group differences in misreporting are unlikely. A study conducted in a similar population showed that, for the association between saliva cotinine and self-report of smoking, the area under the receiver operating characteristic curve was 0.95, and that most cases of disagreement were because of occasional smokers. Furthermore, at least 2 studies indicated that in intervention trials, self-report of smoking was not at all or only minimally biased in intervention groups compared with controls; therefore, such bias would not explain our results.

Measurement of other self-reported characteristics of participants, including stage of change, level of tobacco dependence, educational level, and others, may have lacked precision, but was not biased with regard to the intervention because assessment preceded randomization.

Because the study was not initially powered to assess the effectiveness of the program in subgroups, all subgroup analyses should be considered with caution. The effectiveness of computer-tailored programs in specific groups (eg, the less educated and teenagers) requires formal testing.

Finally, this study was designed to test the effectiveness of a multicomponent program against no intervention. Therefore, we cannot say which component of the program was most effective (tailored letters, booklets, or successive interactions). Experiments that separately test each of these components may be necessary. For instance, to establish whether computer tailoring contributed to the effectiveness of this program, one would need to compare the program with a nontailored program of similar content and intensity.

We conclude that a computer-tailored program was effective among smokers recruited in a general population, including smokers usually resistant to change, such as teenagers, precontemplators, and very heavy smokers. This program can assist physicians in helping their patients who smoke, and it can substantially contribute to disease prevention at a population level.

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REFERENCES