Original Article

Efficacy of an Internet-based, individually-tailored smoking cessation program: a randomized trial

Short Title Randomized Trial of Internet-based Smoking Cessation Program

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The authors C. Mavrot, I. Stucki, F. Sager and J.-F. Etter jointly designed the study, conducted the analysis and wrote the manuscript. The author J.-F. Etter collected and administrated the data for this randomized trial. The four authors contributed to and have approved the final manuscript.

Ethical Standard

This research was approved by the relevant ethics committee of the Geneva University Hospital: Comité Départemental d’Ethique de Médecine Interne et de Médecine Communautaire et de Premier Recours, n° de réf. CER: 11-232.

Abstract

Introduction: Self-help computer-based programs are easily accessible and cost-effective interventions with a great recruitment potential. However, each program is different and results of meta-analyses may not apply to each new program; therefore, evaluations of new programs are warranted. The aim of this study was to assess the marginal efficacy of a computer-based, individually-tailored program (the *Coach*) over and above the use of a comprehensive Internet smoking cessation website.

Methods: A two-group randomized controlled trial was conducted. The control group only accessed the website, whereas the intervention group received the *Coach* in addition. Follow-up was conducted by e-mail after three and six months (self-administrated questionnaires). Of 1120 participants, 579 (51.7%) responded after three months and 436 (38.9%) after six months. The primary outcome was self-reported smoking abstinence over four weeks.

Results: Counting dropouts as smokers, there were no statistically significant differences between intervention and control groups in smoking cessation rates after three months (20.2% vs. 17.5%, p=0.25, odds ratio=1.20) and six months (17% vs. 15.5%, p=0.52, odds ratio=1.12). Excluding dropouts from the analysis, there were statistically significant differences after three months (42% vs. 31.6%, p=0.01, odds ratio=1.57), but not after six months (46.1% vs. 37.8%, p=0.081, odds ratio=1.41). The program also significantly increased motivation to quit after 3 months and self-efficacy after 3 and 6 months.

Discussion: An individually-tailored program delivered via the Internet and by e-mail in addition to a smoking cessation website did not significantly increase smoking cessation rates, but it increased motivation to quit and self-efficacy.

Keywords

Tobacco smoking, smoking cessation, Internet, computer program, randomized controlled trial

Introduction

Self-help computer or Internet-based programs are accessible and cost-effective interventions with a great recruitment potential.[1,2] This makes them a valuable method for enhancing the use of support during quit attempts. Meta-analyses have shown the added value of self-help materials compared to no intervention.[3] Moreover, individually-tailored materials are more effective than standardized self-help materials.[3-5]

Internet-based programs are low-threshold interventions and are mostly free of charge, accessible, and easily adjustable.[6] They can be especially effective among smokers with low socioeconomic status.[7] Furthermore, the medium allows for multiple exposures to preventive messages over time.[8] Some repetitiveness and omnipresence can be achieved through these interventions.[9] They allow users to receive messages in a timely manner[10] in different settings and relapse situations.[11,12] Some recent reviews and meta-analyses indicate that self-help interventions based on new technologies are promising large-scale interventions,[11,13] while other reviews suggest that such programs have not yet truly proven effective[14-15] or are effective to a small extent.[4,16]

Consequently, the rationales for our study are as follows: first, as the question has not been definitively settled yet, new randomized trials contribute to this discussion. Second, this program is new and has to be evaluated and the results reported. Third, there is a specific need to study more precisely the effects of tailored components over standard smoking cessation websites, as we do here. In fact, Shahab and McEwen state, "More research is needed to evaluate the relative efficacy of interactive web-based interventions compared with static websites."[11] Chen et al. also underlined, "Neither of the main reviews was able to determine, from the available evidence, what form electronic aids should take."[16]

Accordingly, our contribution to the ongoing debate is to assess the added value, or marginal efficacy, of a new Internet-based, individually-tailored smoking cessation program, the *Coach*, delivered in addition to an existing smoking cessation website, *Stop-Tabac.ch*. The interactive *Coach* is an original program that was developed by scientists from the University of Geneva based on theories of addiction and behavior change. It is similar in principle to other existing programs described in the literature, but original in its content. We know of no equivalent program in French.

Stop-Tabac.ch *and the* Coach

The *Stop-Tabac.ch* website, created in 1997, provides free information and support for smoking cessation. It covers different aspects of tobacco addiction, such as risks, mechanisms of dependence, smoking substitutes, tips for quitting and relapse prevention. Information is provided through text pages, videos, booklets, discussion forums and testimonials. Most of its content is available in the three Swiss national languages (German, French and Italian). *Stop-Tabac* has been continuously adapted based on the scientific literature, evaluations and users' feedback, but it was stable during the trial duration in order to allow the assessment.

In supplement to this comprehensive website, the new *Coach* program, developed by the same group, provides individualized counseling (information, encouragement, advice and follow-up) through personalized messages in French that are tailored to participants based on their answers to questionnaires. It accompanies participants through the process of smoking cessation and relapse prevention. It is targeted at both those who are motivated and those who are unmotivated to quit, as well as at current and former smokers. The program aims at enhancing participants' knowledge (risks, benefits, addiction, withdrawal symptoms, relapse situations), skills (coping strategies,

use of evidence-based treatments), motivation, self-efficacy and capacity for action (preparation for the quit attempt).

Both *Stop-Tabac* and the *Coach* are based on the transtheoretical model of behavior change[17-18] and theories of relapse prevention[19] and tobacco dependence.[20] Both are non-commercial programs. In the present trial, we assessed the incremental effect of the *Coach* tailored program over and above the *Stop-Tabac* website.

Methods

Trial design

Through a randomized controlled trial, we compared a control group that had access only to the *Stop-Tabac* website with an intervention group that additionally benefited from the *Coach* individually-tailored program. The duration of the *Coach* intervention for the intervention group, as well as the duration of the control, was 6 months from enrollment. Participants in the control group were informed that they could access the *Coach* program after the trial.

Recruitment and participants

Participants were recruited between March 2012 and March 2013 from among spontaneous visitors of *Stop-Tabac.ch*. The experiment was not advertised elsewhere. The eligibility criteria for participating in the trial were: be a current or ex-smoker; be 18 years or older; provide valid e-mail and postal addresses and a phone number; provide informed consent. We included former smokers because the program also targets them (consolidation of quit attempts). On the website page labeled 'Coach' (readable from computers, not from tablets or mobile phones), visitors were invited to join the study and informed about the aims and procedures of the trial, including randomization and the possibility to be assigned to a control group receiving no

additional intervention than access to the basic website. Thus, the participants were not blind to treatment conditions. No incentive was offered for participation.

Randomization

A list of random numbers was used. Participants were assigned automatically by a computer either to the intervention group that received the program *Coach* or to the control condition, which did not.

Questionnaires

All eligible participants completed the same questionnaires: a baseline questionnaire upon entry into the study (T-0) and follow-up questionnaires three and six months after enrollment (T-3 and T-6). The answers were used both to conduct the trial and to tailor the feedback elements of the *Coach* for the intervention group.

The first part of the questionnaire was used at T-0, T-3 and T-6. It covered sociodemographics, smoking status (smoker/ex-smoker, wants to quit progressively or abruptly, quit date) and level of addiction (cigarettes per day, minutes to first cigarette of the day). It also covered attitudes toward smoking, including motivation to quit, withdrawal symptoms, use of self-change strategies and self-efficacy (i.e., confidence in ability to refrain in typical relapse situations). Motivation to quit was measured by 5 items (e.g., "Cigarettes will damage my health"), withdrawal symptoms by 8 items (e.g., "I am feeling anxious"), self-change strategies by 5 items (e.g., "In order to refrain from smoking, I avoid places where people smoke"), self-efficacy by 7 items (e.g., "I am able to refrain from smoking after a meal"). The items could be answered on a five-point scale with options ranging from never to always (or from "totally disagree" to "fully agree"). These items were drawn from validated scales. Their test-retest reliability, internal consistency, sensitivity to change and predictive validity were assessed extensively. We used or selected items from the Cigarette Dependence Scale, the Cigarette Withdrawal

Scale, the Attitudes Towards Smoking scale, the Smoking Self-Efficacy scale, the Self-Change Strategies scale and the Attitudes Towards NRT scale, and we also developed several questions specifically for the *Coach*.[21-26]

The second part of the questionnaire concerned the use of smoking cessation aids. We firstly assessed the use of nicotine replacement therapy (NRT) and smoking cessation medications at the three time points. We secondly assessed at T-3 and T-6 the self-reported use of other smoking cessation aids in the two groups (*Stop-Tabac* website, other websites, physician, smoking cessation clinics, support group, quitline).

In addition to the self-assessment questionnaire, we tracked the frequency of use of the *Coach* in the intervention group within our system (visits to the personal page) to determine whether the program was actually used by the participants.[27]

Treatment conditions

Only the intervention group received the *Coach* intervention. Both groups could access the *Stop-Tabac* website. All participants were allowed to use smoking cessation aids available elsewhere (websites, quitlines, NRT, etc.).

The *Coach* program consisted of 3 elements:

1) A series of automatic, personalized feedback reports that were assembled by the computer based on the participant's answers to the tailoring questionnaire. Each report sent to the participants consisted of 30 feedback items selected automatically from a stockpile of over 300 items. These items included paragraphs of text, images and graphs showing the respondents' scores. Different answers to the tailoring questions produced different paragraphs in the feedback reports. A specific set of decision rules was created to link participants' answers to the questionnaires with the library items. To select the feedback items from the library, we used cutpoints for each variable or multi-item scale.

The questionnaires, feedback items, decision rules and algorithms were developed by the research team based on its clinical and research experience and on pretests with smokers. The decision rules and algorithms were empirical and were not formally validated. Participants received a progress report for each of the three answered questionnaires.

2) A personal web page with progress graphs, for a visual representation of change over time in the levels of tobacco dependence, withdrawal symptoms, motivation and self-efficacy.

3) A series of automatic, individually-tailored, proactive e-mail messages that took into account each participant's smoking status, quit date (past or future) and level of dependence. These generic statements were also selected from the stockpile of items. The number of messages depended on the content and frequency of participant reactions to the program as reported in the personal page (smoking status and potential relapses) and on their quit date (depending on how close it was).

The hypothesis being tested was whether the *Coach* program increased smoking cessation rates in addition to the effects of the *Stop-Tabac* website.

Instruments

At baseline and after three and six months, participants were invited to answer online questionnaires. Up to six reminders were sent by e-mail to non-respondents, who were not contacted through other means.

Outcome measure

The primary outcome was self-reported one month smoking abstinence (not a puff of tobacco during the past four weeks). No biochemical validation was performed.

Statistical analysis

Regarding the primary outcome, we conducted both intention-to-treat analyses (ITT), in which non-respondents at follow-up were considered smokers, and analyses including only the respondents. We used t-tests to compare means, Wilcoxon tests to compare medians and Fisher tests to compare proportions. We regressed the number of visits to the program on the outcome for determining the effect of the program's intensity of use on the chance of quitting. When relevant, ex-smokers were analyzed separately from baseline smokers.

Results

Study population

The number of participants who registered in the study was 1226. Of these, 1160 participants were randomized because 66 persons did not complete the registration process. Among these 1160 participants, 40 were eliminated (11 because of double registrations and 29 because they did not complete the baseline questionnaire). The analysis was based on the remaining 1120 participants (intervention group: 559; control condition: 561) (Figure 1).

The response rate was 51.7% (579/1120) after three and 38.9% (436/1120) after six months. Response rates differed significantly between the intervention and control groups at the three-month follow-up (but not at 6 months): 48.1% in the intervention group and 55.3% in the control group (OR=1.33; 95% confidence interval (CI) 1.05-1.70). Of the baseline characteristics, age, use of NRT and gender predicted attrition: at the two follow-ups, older participants were more likely to respond (three months: mean age=38.1 versus 34.7, $P<0.0001$, six months: mean age=38.8 versus 35, $P<0.0001$), and participants using NRT were more likely to respond (3 months: OR=3.46 (95% CI 2.60-4.63), 6 months: OR=1.82 (95% CI 1.40-2.38)). Women were less likely to respond

than men at six months (OR=0.61; 95% CI 0.47-0.81). None of these predictors of dropout differed significantly between groups.

Baseline characteristics

The mean age of participants was 36.5 years, and 65.7% were women (736/1120). Most baseline participants (94.6%, 1060/1120) were current smokers, and 5.4% (60/1120) were former smokers. There were no significant differences at baseline between intervention and control groups regarding age, gender, level of dependence, proportion of baseline smokers, attitudes towards smoking, motivation, or use of NRT and medications (Table 1).

Use of the intervention

In the intervention group, 25.2% (141/559) of participants connected to their personal page only once (i.e., at registration). The median number of connections to the personal page was 3, and the median number of e-mail messages received was 47 per person. In the intervention group, the intensity of use of the program was associated with quitting smoking at six months: quitters connected to the program 9 times on average, compared with 3 times for those still smoking (W=32808, $P<0.0001$).

Main outcome

For the 60 baseline ex-smokers, there was no difference between intervention and control groups regarding the main outcome. Considering all participants (baseline and ex-smokers) in the ITT analysis (i.e., non-respondents were considered as still smoking), 20.2% (113/559) of the intervention group was abstinent at three months, versus 17.5% (98/561) in the control group. This difference was not statistically significant (OR=1.20; 95% CI 0.88-1.64). The six-month difference was not significant either, with 17% (95/559) abstinence in the intervention group versus 15.5% (87/561) in the control group (OR=1.12;

95% CI 0.80-1.55). Considering only baseline smokers, there was also no significant difference (Table 2). When analyzing the data without dropouts (i.e., only the respondents), the differences between intervention and control groups were statistically significant after three months, whether including all participants (OR=1.57, 95% CI 1.10-2.23) or only baseline smokers (OR=1.58, 95% CI 1.09-2.30). After six months, the difference was not significant (Table 3).

Use of other cessation aids

At three and six months, there were no statistically significant differences between intervention and control groups regarding the use of other cessation aids. Considering all trial participants, the reported use of NRT at three (OR=2.59; 95% CI 1.63-4.15) and six months (OR=2.30; 95% CI 1.32-4.07) was associated with higher quit rates, which either captures the efficacy of NRT or the fact that its use is a sign of high motivation Similarly, the reported use of any other behavioral cessation aids at three months was associated with higher quit rates (both groups merged: OR=1.79; 95% CI 1.09-2.96) (Table 4).

Attitudes towards smoking

There were differences between the two groups for some of the attitudinal variables at the follow-ups (Table 5). In particular, after three months, self-efficacy and motivation to quit were higher in the intervention than in the control group (*P*=0.0002 versus *P*=0.019), as well as self-efficacy after six months among baseline smokers.

Discussion

Marginal effect of the Coach

We found that an Internet-based, individually-tailored smoking cessation program *Coach* delivered over the *Stop-Tabac* website did not increase quit rates, but

significantly increased self-efficacy and motivation to quit smoking at three months among the whole intervention group, as well as self-efficacy after six months among baseline smokers. The effects on self-efficacy and motivation confirm the capacities of these programs to empower users regarding attitudes towards smoking.

Participants of both groups were spontaneous visitors of the *Stop-Tabac* website, and were thus already motivated to use Internet-based tools, which might have reduced the likelihood of finding differences. Moreover, *Stop-Tabac* is already effective in itself: an earlier version of *Stop-Tabac* (tailored materials by postal mail) produced a 2.6 times greater cessation rate in the intervention group than in the control group which did not receive the intervention.[28] In the present trial, the effectiveness of *Stop-Tabac* (accessible to all participants) might have reduced the differences between both groups. This mitigated result could also be due to the sample size. To detect an odds ratio of 1.35 with a power of 80% at a significance level of 0.05, a sample of 4000 participants would have been needed. Statistically significant results might have been found with a bigger sample size.

Strengths and limitations of the study

A first strength of our study was to assess the program via severe criteria: four-week abstinence and six-month follow-up. A second strength was to measure the frequency of use of the program. More frequent use of the *Coach* was associated with higher quit rates. This might capture the effect of the program or might reflect the fact that more motivated participants were more likely to use the program and succeed in quitting. A third strength was to test the use of other smoking cessation aids. This allowed to know whether there was a disequilibrium between both groups (e.g., the control group could have more actively searched for cessation aids elsewhere), which was not the case.

The sample size (1120 participants) constitutes one limitation of the study. Another limit was the follow-up response rate. High dropout rates often occur in Internet studies and can pose problems of generalizability.[29] However, our response rate was in line with similar studies using web-based follow-ups.[30-31] Eysenbach[27] states that web-based trials can lose "as many as about half of the patients". This phenomenon is typical of trials based on low-intensity mediums.[32] Finally, the proportion of participants who used the *Coach* only once was high (25.2%), which decreased its impact. This demonstrates the necessity of systematically assessing participation in low-intensity interventions and of elaborating programs capable of retaining participants and enhancing usage rate.[33]

Conclusions

In ITT analysis (i.e., considering dropouts as smokers), our study did not find evidence of the effectiveness of an individually-tailored computer intervention (the *Coach*) delivered over a comprehensive smoking cessation website (*Stop-Tabac*). It nevertheless showed that the *Coach* increased self-efficacy and motivation to quit after three months, and increased self-efficacy after six months. Moreover, non-ITT quit rates (i.e., including only the respondents) showed significant difference between intervention and control groups at three months (but not at six months), which suggests that both self-efficacy and motivation are crucial for helpful support in smoking cessation and that programs should not neglect one of these two variables over the medium-term.

Our results provide elements to the ongoing debate on the efficacy of Internet-based programs. While reviews and meta-analyses indicate that self-help interventions based on new technologies are promising,[11,13] authors have recently raised the question of which form electronic aids should take.[11,16] Hence, the question of the combination of different components is crucial. Our study detected a difference when delivering a

tailored program over a comprehensive smoking cessation website, but only in non-ITT analysis and as far as the program achieved enhancement of both motivation and self-efficacy among participants. Because of the lack of unanimity about the efficacy of the various forms of Internet-based interventions[14,15] and their combinations, new programs such as the *Coach* still have to be systematically assessed and the results shared for inclusion in future meta-analyses.

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Declaration of Conflicting Interests

The authors declare that there is no conflict of interest.

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TABLES

Table 1.

Participant characteristics at baseline – no statistically significant differences

	Control (*n* = 561)	*n missing*	Intervention (*n* = 559)	*n missing*
% Female	66.5% (372)	*2*	65.2% (364)	*1*
Mean age (SD)[a]	36.8 (11.2)	*71*	36.1 (10.4)	*62*
% Smoker	93.4% (524)	*0*	95.9% (536)	*0*
Mean cigarettes per day (SD)[a]	17.5 (8.1)	*1*	17.2 (8.4)	*1*
Median time from waking (quartile)[b]	15 (5, 45)	*8*	15 (5, 45)	*9*
% Using bupropion medication	2.6% (14)	*12*	3.1% (17)	*12*
% Using nicotine replacement therapy	32.2% (180)	*2*	30.2% (168)	*2*
Mean Motivation, 1-5 score (SD)[c]	4.7 (0.6)	*1*	4.7 (0.6)	*0*
Mean Withdrawal, 1-5 score (SD)[c]	4.0 (1.1)	*1*	3.9 (1.1)	*4*
Mean Strategy, 1-5 score (SD)[c]	2.8 (1.1)	*1*	2.8 (1.0)	*7*
Mean Self-efficacy, 1-5 score (SD)[c]	2.8 (1.1)	*0*	2.8 (1.1)	*0*

[a] Standard deviation. [b] 1st quartile, 3rd quartile. [C] Value was computed by taking the mean of all the rank-ordered scores (1-5) of the items belonging to one variable.

Table 2.

Self-reported smoking abstinence (no puff in the previous 4 weeks) at 3-month and 6-month follow-up – no statistically significant differences (intention-to-treat analysis)

	Control	Intervention	*OR*	95% CI	*P* Value
Including all participants randomized to control or intervention groups					
n	561	559			
3-months[a]	17.5% (98)	20.2% (113)	1.20	0.88-1.64	0.252
6-months[a]	15.5% (87)	17.0% (95)	1.12	0.80-1.55	0.518
Including only baseline smokers					
n	524	536			
3-months[a]	15.7% (82)	18.3% (98)	1.21	0.86-1.69	0.288
6-months[a]	13.7% (72)	15.1% (81)	1.12	0.78-1.60	0.542

[a] In brackets: number of quitters.

Table 3.

Self-reported smoking abstinence (no puff in the previous 4 weeks) at 3-month and 6-month follow-up – statistically significant differences at 3-month follow-up (analysis without dropouts)

	Control	Intervention	*OR*	95% CI	*P* Value
Including all participants randomized to control or intervention groups					
n	561	559			
3-months [a]	31.6% (98)	42.0% (113)	1.57	1.10-2.23	0.012*
6-months [a]	37.8% (87)	46.1% (95)	1.41	0.94-2.10	0.081
Including only baseline smokers					
n	524	536			
3-months [a]	28.6% (82)	38.7% (98)	1.58	1.09-2.30	0.014*
6-months [a]	34.1% (72)	42.9% (81)	1.45	0.95-2.22	0.080

[a] In brackets: number of quitters.
* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

Table 4.

Reported use of cessation aids at 3-month and 6-month follow-up – no statistically significant differences

	Control	Intervention	*OR* (95% CI)	*P* Value
3-months				
n	*310*	*269*		
Nicotine therapy	35.2%	43.1%	0.72 (0.45-1.13)	0.15
n missing	*114*	*116*		
Behavioral support outside study	67.7%	74.2%	0.73 (0.44-1.19)	0.20
n missing	*115*	*114*		
6-months				
n	*230*	*206*		
Nicotine therapy	35.6%	42.5%	0.75 (0.44-1.28)	0.30
n missing	*84*	*93*		
Behavioral support outside study	66.7%	73.5%	0.72 (0.41-1.28)	0.28
n missing	*83*	*93*		

Table 5.

Attitudes towards smoking at 3 and 6-month follow-ups (standard deviation in brackets)

	Control	Intervention	*P* Value
Including all participants			
3-months			
Motivation to quit	4.7 (0.8)	4.8 (0.5)	0.019*
Withdrawal symptoms	3.5 (1.0)	3.3 (1.1)	0.0496*
Self-change strategies	2.7 (1.0)	2.7 (1.1)	0.775
Self-efficacy	3.4 (1.3)	4.0 (1.3)	0.0002***
6-months			
Motivation to quit	4.8 (0.5)	4.8 (0.4)	0.122
Withdrawal symptoms	3.4 (1.1)	3.3 (1.2)	0.354
Self-change strategies	2.5 (1.1)	2.5 (1.1)	0.826
Self-efficacy	3.7 (1.3)	4.0 (1.2)	0.051
Including only baseline smokers			
3-months			
Motivation to quit	4.6 (0.8)	4.8 (0.5)	0.012*
Withdrawal symptoms	3.4 (1.0)	3.2 (1.1)	0.0440*
Self-change strategies	2.6 (1.0)	2.7 (1.1)	0.66
Self-efficacy	3.4 (1.3)	4.0 (1.3)	0.0002***
6-months			
Motivation to quit	4.7 (0.5)	4.8 (0.4)	0.110
Withdrawal symptoms	3.4 (1.1)	3.2 (1.2)	0.214
Self-change strategies	2.5 (1.1)	2.5 (1.1)	0.841
Self-efficacy	3.6 (1.3)	4.0 (1.2)	0.040*

* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$.

FIGURE 1

Consort diagram *Coach* program – Randomized trial