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Happy Ending: a randomized controlled trial of a digital multi-media smoking cessation intervention

Håvar Brendryen & Pål Kraft

Department of Psychology, University of Oslo, Norway

ABSTRACT

Aims To assess the long-term efficacy of a fully automated digital multi-media smoking cessation intervention. **Design** Two-arm randomized control trial (RCT). **Setting** World Wide Web (WWW) study based in Norway. **Participants** Subjects ($n = 396$) were recruited via internet advertisements and assigned randomly to conditions. Inclusion criteria were willingness to quit smoking and being aged 18 years or older. **Intervention** The treatment group received the internet- and cell-phone-based Happy Ending intervention. The intervention programme lasted 54 weeks and consisted of more than 400 contacts by e-mail, web-pages, interactive voice response (IVR) and short message service (SMS) technology. The control group received a self-help booklet. Additionally, both groups were offered free nicotine replacement therapy (NRT). **Measurements** Abstinence was defined as 'not even a puff of smoke, for the last 7 days', and assessed by means of internet surveys or telephone interviews. The main outcome was repeated point abstinence at 1, 3, 6 and 12 months following cessation. **Findings** Participants in the treatment group reported clinically and statistically significantly higher repeated point abstinence rates than control participants [22.3% versus 13.1%; odds ratio (OR) = 1.91, 95% confidence interval (CI): 1.12–3.26, $P = 0.02$; intent-to-treat). Improved adherence to NRT and a higher level of post-cessation self-efficacy were observed in the treatment group compared with the control group. **Conclusions** As the first RCT documenting the long-term treatment effects of such an intervention, this study adds to the promise of digital media in supporting behaviour change.

Keywords Behaviour intervention, digital media, randomized controlled trial, smoking cessation, treatment effects.

Correspondence to: Håvar Brendryen, Department of Psychology, Postboks 1094 Blindern, Oslo 0317, Norway. E-mail: haavabre@psykologi.uio.no
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INTRODUCTION

Digitally delivered smoking cessation interventions are set to play an increasingly important role in the future, due to certain advantages they represent over traditional interventions. While both face-to-face delivered smoking cessation interventions [1] and 'quit-lines' may be effective [2], they are quite resource-intensive. In contrast, traditional print-based self-help materials for smoking cessation are much less costly, but unfortunately have no or, at best, very low efficacy [3]. Interventions delivered by digital media (e.g. e-mails, web pages, text messages, interactive voice recordings, hand-held computers, digital TV) can be made available to large groups of people for little more than the cost of designing the intervention. However, in contrast to most other low-cost interventions, they can provide relevant support and advice in most places and at most times. Hence, the digital media seem to hold potential as a high-reach, cost-effective self-help smoking cessation intervention [4,5].

The present study aimed (i) by means of a randomized control trial (RCT) applying the (ii) intent-to-treat principle, to provide a (iii) direct test of the efficacy of a (iv) fully automated and (v) digitally delivered smoking cessation intervention, targeting (vi) smokers who were already motivated to quit. With reference to these six characteristics, we have been able to identify only three comparable studies [6–8]. All three studies reported increased 3 months post-cessation abstinence rates produced by digital smoking cessation intervention, compared with the relevant control conditions. However, while two of the studies did not assess long-term abstinence [7,8], the third digital intervention investigated failed to produce improved abstinence rates 6 months post-cessation [6]. Additionally, the three trials were potentially limited by the fact that they had low (74% [6])

Table 1 Overview of potential contact points between programme and user during the entire intervention period.

Component	*Weeks 1–2*	*Weeks 3–6*	*Weeks 7–8*	*Weeks 9–10*	*Weeks 11–15*	*Weeks 16–54*
E-mail	○○○○○○○	○○○○○○○				
Web page	••••••••	••••••••				
Text message	-------	-------	-------	-------	- -	-
Log-on call		\\\\\\\	\\\\\\\			
Log-off call		///////	///////	///////	/ /	/

The table shows all daily contact points during 6 sample weeks. The sample weeks are repeated to form the entire 54-week intervention period. Each cell represents one intended contact, with the exception of text messages where one dash may represent one, two or three messages depending on week number (i.e. weeks 1–2: two messages; weeks 3–6: three messages; during weeks 7–8 the number of messages was gradually reduced from three to one each day; in weeks 9–54 one dash represents just one text message). E-mails, text messages and the log-off calls are proactive (i.e. programme initiated), while opening the web pages and the log-on calls are reactive (i.e. user-initiated).

or very low (43% [7] and 56% [8]) response rates at the final collection of abstinence data.

The present study aimed to contribute to the existing literature in two ways. First, it is the first of its kind (see above) to report 12 months post-cessation abstinence data produced by a digital smoking cessation intervention. Additionally, because follow-up response rates and observed treatment effects are likely to deflate over time, which would make it more difficult to detect long-term effects in a reliable way, we applied a multi-mode (i.e. both text and voice) strategy for data collection, because this strategy may seem to represent a promising method of reducing the prevalence of response attrition [6].

Hypotheses

The present study tested the hypothesis that a fully automated, digital smoking cessation intervention named Happy Ending (HE) would produce higher 12-month abstinence rates than the use of a self-help smoking cessation booklet. Additionally, we expected the digital intervention, compared with the control intervention, to result in a higher proportion of nicotine replacement therapy (NRT) users, improved adherence to NRT and increased levels of post-cessation self-efficacy. Finally, we tested the hypothesis that increased NRT adherence and post-cessation self-efficacy would mediate the treatment effect of digital intervention.

SUBJECTS AND METHODS

Subjects

Subjects were recruited by means of banner advertisements in internet newspapers. The recruiting campaign lasted from 9 September–18 September 2005. People who were willing to make an attempt to quit smoking on 17 October were aged 18 years or older, smoked 10 or more cigarettes daily and had access to the internet, e-mail and a cell-phone on a daily basis were candidates for inclusion in the study. Seven hundred and 50 people completed the baseline questionnaire. Of those, 140 people did not meet the inclusion criteria. To reduce the risk of communication across experimental conditions, 36 subjects who we suspected knew each other were taken out of the pool. This was conducted based on family name, postal address, e-mail address, cell-phone number or internet provider address. Finally, 103 subjects with missing values on any item were taken out, leaving 471 people in the pool of eligible subjects. According to a power analysis, only 400 subjects were required. Hence, 71 subjects were excluded randomly due to cost concerns.

Happy Ending: the multi-channel, digital media smoking cessation intervention

Happy Ending is a fully automated and digitally delivered smoking cessation intervention. Table 1 shows the potential contact points between Happy Ending and the client for the entire programme period. Note from Table 1 that until week 11 the intervention has multiple daily contact points and is highly intensive, but from week 11 onwards the intervention switches to a markedly lower intensity. Early in the morning, the user receives an e-mail with instructions to open the day's web page. Each day for 6 weeks, the client opens a web page that is unique to that particular programme day. By means of cell-phone, the user receives one pre-recorded audio message, and up to three text messages throughout each day. The audio message is received when the client logs on to the programme in the morning, by calling an interactive voice response (IVR) service. Each evening the client receives a proactive log-off call, which asks whether or not they have been smoking. If so, the client will receive the automatically launched relapse prevention therapy (i.e. listen to a pre-recorded audio message) which relates to the specific number of lapses the client has reported. See Table 1 for details on the number of contact points and their distribution over the programme period. If the user does not log on to the programme or answers the log-off call, they will receive a reminder call, and up to two

reminder text messages. The programme also includes a craving helpline. The helpline is IVR-based and is available 24 hours a day from day 15 (cessation day) throughout the programme. We stress that each contact point, including the reminders, the telephone calls and the helpline, was 100% automated on the intervention side.

Procedure

Based on computer-generated random digits, 400 people were allocated randomly to either the Happy Ending intervention (HE group) or control condition (booklet group). After randomization (23 September), the subjects received an e-mail which told them that the study was concerned with evaluating various aids for smoking cessation, and informed them about the intervention they were about to receive. They were not informed about the intervention provided to the other group. Participants were instructed to continue smoking as usual until the prescribed quitting date, although they would receive the booklet (or Happy Ending) 2 weeks before this date.

Participants in the booklet group were told that they would receive a booklet published by the Norwegian Directorate for Health and Social Affairs, and were encouraged to read the booklet thoroughly prior to the cessation date. The booklet contains general cessation information, a 48-day quit calendar, a 10-day quit log, the telephone number of the national quit-line and links to relevant and open on-line tobacco cessation resources.

Prior to the quitting date, all participants in both groups received a sample packet of NRT products. They were told that the use of NRT was voluntary. Furthermore, they were informed about the possibility of ordering more NRT products by e-mail. Subjects could choose between gum (2 mg or 4 mg) and patches (15 mg/16 hours). Both the self-help booklet and HE recommended the use of NRT and contained information about such products and their use. The subjects were not informed about the interventions under study (i.e. Happy Ending and the booklet) prior to signing up for the study. Free supply of NRT, however, was part of the recruitment inducement (in Norway, NRT is usually not free/subsidized). Subjects received no further reimbursement for their participation. There were no restrictions on the use of other smoking cessation strategies.

Data were collected by means of web-based questionnaires at the baseline and at 1, 3, 6 and 12 months post-cessation. An e-mail containing a link to the questionnaire was sent to the subjects. Two subsequent e-mail reminders were sent to non-responders. Finally, telephone interviews were performed with non-responders.

Variables

Abstinence was defined as having been totally smoke-free ('not even a puff') for the last 7 days. Data on abstinence was based on self-report. Missing values were coded as smokers. The main outcome in this trial was repeated point abstinence at 1, 3, 6 and 12 months post-cessation. Data on NRT use were collected at 1 month by means of two items: (i) have used or tried to use NRT during this quit attempt (yes/no); and (ii) the number of days of NRT use during the past week (NRT adherence). Nicotine dependence was assessed by the Fagerström Test for Nicotine Dependence (FTND) [9]. Smoking cessation self-efficacy (SE) was assessed at baseline and at 1 month post-cessation with two items rated on seven-point scales. The two items scores were averaged to form the SE score. Cronbach's α coefficient for pre-cessation SE was 0.83. The change in SE scores was calculated by subtracting post-cessation SE from pre-cessation SE.

Data analysis

An alpha level of 0.05 (two-tailed) was chosen for all statistical tests in this study. All χ^2 tests applied Yates' continuity correction. Applying the intent-to-treat principle, χ^2 tests for experimental conditions were carried out to detect treatment effect. The moderating role of baseline characteristics on abstinence was investigated using logistic regression.

A χ^2 test was employed to test whether there was a higher proportion of NRT users in the treatment versus the control condition. Moreover, *t*-tests were used to test for differences in NRT adherence and self-efficacy changes between conditions.

Hierarchical logistic regression was applied to test whether NRT adherence or self-efficacy change mediated the effect from experimental condition on abstinence [10]. These analyses were based on a complete case approach. Experimental condition was entered in block one, while one of the potential mediators was entered into the model in block two. The analysis was repeated for each of the two potential mediators.

RESULTS

Programme use, attrition and subject characteristics

At baseline, there were no variables on which treatment and control subjects differed significantly (Table 2). The flow of participants is depicted in Fig. 1. Four subjects of 400 were excluded after randomization because of erroneous allocation (i.e. they did not fulfil the inclusion criteria). Three of them had been signed up by family members without consent, while one person reported

Table 2 Baseline sample characteristics.

	Treatment $n = 197$	*Control* $n = 199$
Female	100 (50.8)	99 (49.8)
Has a college degree	83 (42.1)	79 (39.7)
Age	35.9 ± 10.0	36.4 ± 10.5
FTND	4.8 ± 2.2	4.9 ± 2.2
Cigarettes per day	18.3 ± 5.9	18.1 ± 5.8
Pre-cessation self-efficacy	4.9 ± 1.3	5.1 ± 1.3

Numbers represent number of observations with percentage of observations in parentheses for dichotomous variables, and mean ± standard deviation for continuous variables, respectively. FTND: Fagerström Test for Nicotine Dependence.

Table 3 Mean number of active client actions for three components of Happy Ending.

Active client action	*Range*	*Mean*	*SD*	*%*
Log-on call	0–42	30	16	71.4
Opening web pages	0–44	30	13	68.2
Responding to log-off call	0–104	69	35	66.3

The table shows to what extent subjects adhere to three components of the intervention ($n = 197$). Theoretical range and observed range coincide completely. SD: standard deviation.

having quit smoking 2 weeks prior to the commencement of the study. Consequently, the final number of participants was 396 (197 in the HE group and 199 in the booklet group).

Computerized logging routines revealed that to a large extent, subjects in the treatment condition adhered to the intended programme (see Table 3 for details of programme adherence and Table 1 for details of intervention design). Few clients, however, called the craving helpline; 55% never called the helpline, 25% called once or twice, and 20% called three times or more.

In total, 45 subjects discontinued the HE intervention, and 25 did so during the first 6 weeks. Most subjects withdrew by using the quit options provided automatically by the programme on the web-page or during the log-off call; hence, they did not give any reasons for withdrawal. Eight subjects discontinued the intervention by making a telephone call or sending an e-mail to the experimenter. Five of these reported stressful life events as the cause of programme discontinuation, while three reported that HE was too intrusive. During data collection, the subjects who withdrew from the programme were approached by web and telephone interviews in exactly the same way as programme participants and subjects in the control group. Only two subjects declined to answer surveys—one subject from each experimental condition. Programme satisfaction was high. At 1 month, 5.1% of the subjects found HE 'not at all helpful', 48.2% found HE to be 'helpful', while 44.7% reported HE to be 'very helpful' (missing: 2.0%).

Table 4 Web, telephone and total response rate in percentages across conditions at specified time-points.

	Web		*Phone*		*Total*	
Time post-cessation	*Treat.*	*Contr.*	*Treat.*	*Contr.*	*Treat.*	*Contr.*
1 month	91.9	91.5	6.6	5.5	98.5	91.0
3 months	86.3	83.9	7.1	7.0	93.4	91.0
6 months	78.7	75.4	14.7	16.6	95.4	94.0
12 months	77.7	80.4	18.3	11.1	95.9	91.5

Non-responders to web surveys were approached by telephone. Figures below the right-most column spanner (labelled total) represent the sum of responses from web- and telephone-based surveys. Column heads represent abbreviations of treatment condition ($n = 197$) and control condition ($n = 199$), respectively.

The response rates found in this study were generally high, across both experimental condition and time (Table 4).

Abstinence

The main finding was that repeated point abstinence (i.e. abstinence at 1, 3, 6 and 12 months) was significantly higher in the treatment group (44 subjects, 22.3%) compared with the control condition [26 subjects, 13.1%; $\chi^2 = 5.23$, odds ratio (OR) = 1.91, confidence interval (CI): 1.12–3.26, $n = 396$, $P = 0.02$]. Point prevalence rates were statistically significantly higher on every follow-up occasion (Table 5) and the ratio of abstinence rates was similar on each occasion.

No interaction effect was observed between experimental condition and any of the baseline characteristics on the main outcome.

NRT adherence

The vast majority in both groups used NRT (93% in the HE group and 87% in the booklet group); the difference was not significant ($\chi^2 = 3.31$, $P = 0.07$).

Among the 1-month abstainers, the mean number of days of NRT use was higher in the treatment condition [M = 5.1, standard deviation (SD) = 2.6] than the control condition (M = 3.9, SD = 3.0; $t_{107.4} = 2.43$, $P = 0.02$); hence, HE succeeded in persuading NRT users to use NRT more frequently. Note, however, that the proportion of subjects ordering additional NRT in the treatment condition (81%) was not significantly higher than in the control condition (74%; $\chi^2 = 2.26$, $P = 0.13$), indicating that adherence to NRT was not influenced by access. Finally, the treatment effect was not mediated by NRT adherence.

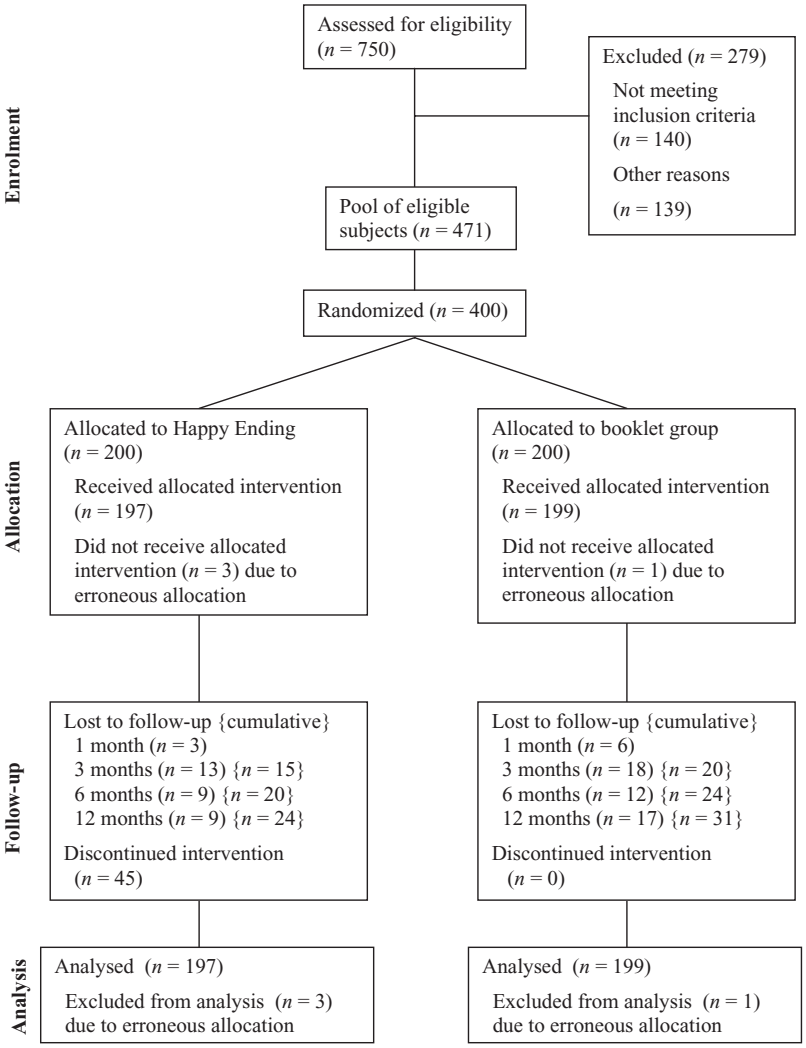

Figure 1 Flowchart. Note that cumulative loss to follow-up is shown in brackets; that is, missing either on the most recent follow-up, or on one of the previous follow-ups

Table 5 Abstinence rates across conditions at specified time-points.

	Treatment n = 197		*Control n = 199*				
Time post-cessation	*n*	*%*	*n*	*%*	*OR*	*CI*	*P*
1 month	99	50.3	59	29.6	2.40	1.59–3.62	0.001
3 months	88	44.7	57	28.6	2.01	1.33–3.05	0.001
6 months	73	37.1	43	21.6	2.14	1.37–3.33	0.001
12 months	74	37.6	48	24.1	1.89	1.23–2.92	0.005

Abstinence was based on 7-day point prevalence (intent-to-treat). OR: odds ratio; CI: confidence interval.

Post-cessation self-efficacy

Pearson's *r* between pre- and post-cessation SE was 0.31 ($P < 0.001$). The level of post-cessation SE was significantly higher in the treatment condition (M = 5.10, SD = 1.41) than in the control condition (M = 4.38, SD = 1.31; $t_{379} = 5.18$, $P < 0.001$), as hypothesized. However, we do not know whether this was caused directly by HE or by the improved level of abstinence found in the HE group.

When tested formally [10], a complete mediation effect over SE change was found. However, this is not the same as saying that HE caused improved self-efficacy, which then caused a higher abstinence rate. Another possible causal chain is that the ameliorated abstinence rate in the HE group may have caused the improved

self-efficacy. In fact, causality might be operating in both directions simultaneously.

Notwithstanding these problems regarding causality inferences, it is worth noting an interesting pattern across smoking status with respect to changes in levels of SE from baseline to 1-month post-cessation day. Among those who were non-smokers at 1 month in both experimental conditions, a positive change score was observed, meaning that having succeeded in becoming a non-smoker led to increased self-efficacy. This increase, however, was significantly higher in the HE group (M = 0.71, SD = 1.38) than in the booklet group (M = 0.04, SD = 1.43; $t_{154} = 2.88$, $P = 0.005$), suggesting that HE at least amplified the positive effect of success on SE. Among those who were currently smoking, on the other hand, the HE group showed a trivial increase in SE (M = 0.10, SD = 1.85), while the booklet group showed a decrease in SE (M = –0.63, SD = 1.42). The reduction in SE level was significantly higher for those in the control than those in the treatment condition ($t_{164.97} = 3.20$, $P = 0.005$), which suggests that HE reduces the negative effect that a failure to quit has on SE. To sum up, regardless of smoking status, a higher level of improvement in post-cessation SE was found in the treatment group compared to the booklet group.

Ancillary analysis

A complete case analysis showed the repeated point abstinence rate at 12 months to be 25.4% (treatment) versus 15.5% (control), respectively; $\chi^2 = 4.58$, OR = 1.86, CI: 1.08–3.20, $P = 0.03$. Compared with the intent-to-treat analysis, this represents a small increase in abstinence rate for both groups. When the subjects who performed fewer than five actions on each of the categories of log-on calls, opening web pages or answering log-off calls were excluded, the abstinence rate in the treatment condition was 27.1%.

DISCUSSION

This trial demonstrated the efficacy of the fully automated digital multi-media smoking cessation intervention Happy Ending (HE) over a 44-page self-help booklet in producing increased repeated point abstinence up to 12 months. HE failed to persuade subjects to become NRT users, but succeeded in producing higher NRT adherence. Nevertheless, NRT adherence did not mediate the treatment effect of HE on abstinence. However, HE resulted in improved levels of post-cessation self-efficacy among both current smokers and non-smokers.

Previous trials [6–8] on comparable interventions have documented a treatment effect for up to 3 months following cessation. Hence, the current trial is the first RCT to document an improved outcome in terms of long-term abstinence compared with a relevant control group, and restricting the comparison to digitally delivered and fully automated smoking cessation interventions. Moreover, the effect size (i.e. odds ratio) for long-term abstinence found in this trial is in the range of those reported in meta-analyses of NRT [11], telephone counselling [2], physicians' [12] or nurses' advice [13], group counselling [14] and individual counselling with smoking cessation specialists [1].

NRT adherence did not mediate treatment effects, suggesting that the success of HE can be explained by the psychological support provided by the programme. Exactly what caused the treatment effect is not clear at this stage. The observed self-efficacy mediation of the treatment effect can only be considered to be suggestive of the 'psychological effect' of the programme, because we do not know for certain the direction of cause(s) and effect(s) between abstinence and self-efficacy. Due to the complex and multi-faceted nature of HE, there are probably several mechanisms at play. Consequently, further research is necessary to detect the active intervention ingredients and their relative contributions. However, the ability of the intervention to increase post-cessation self-efficacy and to decrease the negative effects of failure (i.e. reduced self-efficacy) could be worth examining.

The response attrition rate was low in this trial compared with similar trials [6–8]. The use of short questionnaires (e.g. only three items at 12-month follow-up), multiple reminders, the combination of e-mail and telephone follow-up, collecting cell-phone numbers rather than landline phone numbers and distributing the follow-up calls across morning, evening, weekday and weekends (for each non-responder) are factors that probably contributed to a high response rate. Due to the high intensity of the programme, HE will not be acceptable to all smokers. Intrusiveness contributed to programme dropout. However, an overwhelming majority of users found HE to be helpful in their attempt to quit, suggesting that the high intensity is a minor problem for most.

Generalizability is a main concern with this trial, due to recruitment by self-selection. Additionally, NRT being part of recruitment inducement may have influenced the representativeness of our sample (i.e. the results may apply only to smokers willing to use NRT). Hence, further trials are necessary to address this.

In summary, this trial demonstrates that a digital, automated, interactive intervention increased quit rates, and shows that psychological support can be provided effectively by means of modern mass communication technology. Moreover, being the first RCT to document the long-term treatment effect from such an intervention, and showing effect sizes comparable to other acknowledged cessation methods, this trial adds significantly to

the promise of applying digital media in smoking cessation interventions.

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Declaration of interest

The second author has a financial interest in the intervention under scrutiny, as a shareholder of Happy Ending AS.

References

1. Lancaster T., Stead L. F. Individual behavioural counselling for smoking cessation. *Cochrane Database Syst Rev* 2005; **2**: CD001292.
2. Stead L. F., Perera R., Lancaster T. Telephone counselling for smoking cessation. *Cochrane Database Syst Rev* 2006; **3**: CD002850.
3. Lancaster T., Stead L. F. Self-help interventions for smoking cessation. *Cochrane Database Syst Rev* 2005; **3**: CD001118.
4. Strecher V. J. Computer-tailored smoking cessation materials: a review and discussion. *Patient Educ Couns* 1999; **36**: 107–17.
5. Walters S. T., Wright J. A., Shegog R. A review of computer and internet-based interventions for smoking behavior. *Addict Behav* 2006; **31**: 264–77.
6. Rodgers A., Corbett T., Bramley D., Riddell T., Wills M., Lin R.-B. *et al.* Do u smoke after txt? Results of a randomised trial of smoking cessation using mobile phone text messaging. *Tob Control* 2005; **14**: 255–61.
7. Strecher V. J., Shiffman S., West R. Randomized controlled trial of a web-based computer-tailored smoking cessation program as a supplement to nicotine patch therapy. *Addiction* 2005; **100**: 682–8.
8. Swartz L. H. G., Noell J. W., Schroeder S. W., Ary D. V. A randomised control study of a fully automated internet based smoking cessation programme. *Tob Control* 2006; **15**: 7–12.
9. Heatherton T. F., Kozlowski L. T., Frecker R. C., Fagerström K.-O. The Fagerström Test for Nicotine Dependence: a revision of the Fagerström tolerance questionnaire. *Br J Addict* 1991; **86**: 1119–27.
10. Baron R. M., Kenny D. A. The moderator–mediator variable distinction in social psychological research: conceptual, strategic and statistical considerations. *J Pers Soc Psychol* 1986; **51**: 1173–82.
11. Silagy C., Lancaster T., Stead L., Mant D., Fowler G. Nicotine replacement therapy for smoking cessation. *Cochrane Database Syst Rev* 2004; **3**: CD000146.
12. Lancaster T., Stead L. F. Physician advice for smoking cessation. *Cochrane Database Syst Rev* 2004; **4**: CD000165.
13. Rice V. H., Stead L. F. Nursing interventions for smoking cessation. *Cochrane Database Syst Rev* 2004; **1**: CD001188.
14. Stead L. F., Lancaster T. Group behaviour therapy programmes for smoking cessation. *Cochrane Database Syst Rev* 2005; **2**: CD001007.

