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Results of the PAS Study: A Randomized Controlled Trial Evaluating the Effectiveness of a Web-Based Multiple Tailored Smoking Cessation Program Combined With Tailored Counseling by Practice Nurses

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ABSTRACT

This study investigated the effects of Web-based multiple computer tailoring and counseling by a practice nurse (MTC) compared with computer tailoring without counseling (MT) and usual care (UC) on smoking cessation rates, via a randomized controlled trial with 414 Dutch adult smokers, recruited by 91 practice nurses from May 2009 to June 2010. Logistic multilevel regression analyses were conducted with 24-hour point prevalence, 7-day point prevalence, and prolonged abstinence after 6 and 12 months as dependent variables and experimental condition as the independent variable. After 6 and 12 months, 38% and 56% of respondents were followed up, respectively. At both follow-ups, no main effects of the interventions could be identified when comparing them with care as usual and with each other—neither in analyses using available data nor in analyses using a negative scenario in which respondents lost to follow-up were considered to still be smoking. A Web-based multiple computer-tailored smoking cessation program combined with a single face-to-face counseling session by a practice nurse may not be more effective than this computer-tailored program alone or than usual smoking cessation care in the general practice setting. Yet before concluding that the addition of counseling to Web-based computer tailoring cannot be successful, more research needs to be conducted to identify the optimal number of counseling sessions to be combined with the Web-based program and to how to best attune the two modalities.

Tobacco smoking is the most preventable cause of illness and premature death worldwide (U.S. Department of Health and Human Services [USDHHS], 2004; World Health Organization [WHO], 2008), and it is important that smokers are supported in their attempts to quit. A health communication strategy that has been proven effective in increasing smoking cessation rates is computer tailoring (Lancaster & Stead, 2005; Noar, Benac, & Harris, 2007). Computer-tailored health communication interventions are characterized by providing feedback adapted to the individual users' characteristics, using a computerized process (Dijkstra & de Vries, 1999; Velicer & Prochaska, 1999). Compared with nontailored interventions, interventions that are tailored to the respondent's personal characteristics and situation are more successful in attracting and keeping smokers' attention (de Vries & Brug, 1999; Strecher et al., 2008), resulting in more careful processing of information (Dijkstra, 2005). While a single computer-tailored feedback message is already successful in increasing smoking cessation rates (Te Poel, Bolman, Reubsaet, & de Vries, 2009), providing feedback on multiple occasions (multiple computer tailoring) further increases this effect (Borland, Balmford, & Hunt, 2004; Dijkstra, de Vries, Roijackers, & van Breukelen, 1998b).

Computer-tailored interventions are increasingly delivered through the Internet (Lustria, Cortese, Noar, & Glueckauf, 2009; Shahab & McEwen, 2009). This medium is highly accessible (Centraal Bureau voor de Statistiek, 2011; Internet World Stats, 2010), can reach a large audience with low costs, and offers the opportunity to participate at convenient moments in time (Civljak, Sheikh, Stead, & Car, 2010). Yet the effect sizes of Web-based computer tailoring as a standalone health communication intervention remain only small to medium (Lustria et al., 2013).

Combining Web-based multiple computer tailoring with a second effective intervention might increase its effectiveness—and may even result in effects that exceed the sum of the two interventions' individual effects (Naik & Raman, 2003). This increased effectiveness has been suggested to be caused by a process called multiple source perception: the idea that messages delivered via different media are perceived as more convincing and credible than messages delivered via a single medium (Voorveld, Neijens, & Smit, 2011). Indeed, the combination of a single printed tailored intervention with

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telephone counseling has been found to have a small though significant additional effect on smoking cessation rates compared to the tailored intervention only (Curry, McBride, Grothaus, Louie, & Wagner, 1995; Sutton & Gilbert, 2007). Moreover, a study that combined multiple (i.e., three) printed tailored feedback letters with proactive telephone calls from a counselor revealed small but positive effects after a 12-month follow-up period when compared with tailored feedback only (Prochaska et al., 2001).

While these results are promising, however, no earlier research has studied the effectiveness of a smoking cessation intervention that combines Web-based multiple computer tailoring with face-to-face counseling delivered by a practice nurse (PN). Nonetheless, smoking cessation advice provided face-to-face by a general practitioner (GP) has been found to be effective in increasing smoking cessation rates and to outperform telephone counseling (Lemmens, Oenema, Knut, & Brug, 2008; Stead, Bergson, & Lancaster, 2008). GPs, however, often experience a lack of time and skills to support smokers to quit (Hoving, Mudde, & de Vries, 2007; Yarnall, Pollak, Krause, & Michener, 2003). As nurse-delivered smoking cessation interventions can also be effective (Lemmens et al., 2008; Rice & Stead, 2008) and Dutch GPs often employ a PN (Hingstman & Kenens, 2007), involving PNs in smoking cessation counseling can be a viable alternative.

Therefore, this study aimed to answer the following research question: What is the effectiveness of a Web-based multiple computer-tailored smoking cessation program combined with face-to-face counseling by a PN (MTC) in comparison with the computer-tailored program as a stand-alone intervention (MT) and usual care (UC)? The main hypothesis in this study was that a combination of two of the few effective methods for smoking cessation (i.e., Web-based multiple computer tailoring and counseling by a health professional; MTC) would yield more effects on smoking cessation rates than the Web-based program alone (MT) and that both MTC and MT would outperform UC.

Theoretical framework

The Web-based multiple computer-tailored program and the counseling protocol that was developed to guide the counseling sessions were grounded in the I-Change Model (ICM; de Vries et al., 2003). The ICM is a behavior change theory that includes theoretical concepts from several sociocognitive models, such as the Transtheoretical Model (Prochaska & DiClemente, 1983), the Theory of Planned Behavior (Ajzen, 1985), Social Cognitive Theory (Bandura, 1986), and the Health Belief Model (Janz, Champion, & Strecher, 2002). The ICM proposes that a person's behavioral intention is the most direct predictor of behavior. Intention, in turn, is predicted by three motivational constructs: attitude, perceived social influence, and self-efficacy. According to the ICM, a person's attitude entails both the perceived advantages and disadvantages of the behavior. Perceived social influence refers to three related, though different, constructs: perceived social norms, social modeling, and social pressure. Perceived social norms reflect the perceived opinions held by others in the social environment, whereas social modeling refers to the perceived behavior of these others, and social pressure represents their perceived pressure or support to perform the behavior. Self-efficacy refers to a person's level of confidence that she or he is able to perform the behavior. In studies that also used the ICM as a theoretical framework, a positive attitude toward smoking cessation, a social environment that is perceived as positive concerning smoking cessation, and a high self-efficacy to quit have all been found to positively influence a person's intention to quit smoking (Dijkstra & de Vries, 2000; Hoving, Mudde, & de Vries, 2006; Panday, Reddy, Ruiter, Bergstrom, & de Vries, 2007; Vitoria, Salgueiro, Silva, & de Vries, 2009; de Vries & Mudde, 1998). Next to these motivational factors, the ICM includes several premotivational factors, including predisposing, awareness, and information factors. In addition, the ICM recognizes that although intention is a necessary prerequisite for behavior change to occur, several postmotivational factors play a role in bridging the gap between intention and behavior (Armitage & Conner, 2001). Although perceived barriers to change are expected to increase this gap, ability factors such as an individual's skills to refrain from smoking and the formation of action plans (i.e., preparatory and coping planning) are assumed to decrease this gap.

Methods

The study was approved by the Medical Ethics Committee of Maastricht University and the University Hospital Maastricht (MEC 08–3-037; NL22692.068.08) and is registered in the Dutch Trial Register (NTR1351). A full description of the study protocol can be found elsewhere (Smit, de Vries, & Hoving, 2010).

The interventions

Web-based multiple computer-tailored smoking cessation program

Feedback principles were derived from earlier studies (Dijkstra, de Vries, & Roijackers, 1998a; Hoving, Mudde, Dijk, & de Vries, 2010; te Poel et al., 2009). Feedback messages were tailored to several respondent characteristics: gender, attitude, social influence, self-efficacy, intention to quit, preparatory and coping plans, and smoking behavior. Feedback was personalized, descriptive, item-based, and iterative or progress comparative (Harrington & Noar, 2012). An example of a tailored feedback message is provided in the appendix. Another example and several screenshots of the intervention can be found somewhere else (Smit et al., 2010; Smit, de Vries, & Hoving, 2012a). In line with current guidelines (Chavannes et al., 2007), the intervention advised smokers who reported smoking more than 10 cigarettes per day to discuss the use of smoking cessation medication with their GP. Feedback letters at baseline, after 6 weeks, and after 6 months consisted of four to five pages; the feedback letter 2 days after respondents' quit date consisted of only one page. After questionnaire completion, feedback letters were visible on the computer screen and sent to the respondent by email.

Tailored counseling by PNs

For respondents in the MTC group, the tailored feedback letter that MT respondents received at 6-week follow-up was replaced by a counseling meeting with a PN. After receiving the first tailored feedback letter, MTC respondents were

prompted to schedule this meeting within the next 6 to 8 weeks. PNs were provided with a summary of the respondents' situation at 6-week follow-up and a counseling protocol to assist them during these sessions. This protocol included the same theoretical constructs as the Web-based program and also advised PNs to discuss smoking cessation medication with patients who smoked more than 10 cigarettes per day. After 6 months, PNs contacted their patients by telephone to enquire about their progress toward permanent cessation and, if needed, provide additional support.

Usual care

Respondents in the UC group received smoking cessation guidance according to Dutch standard practice, which can vary from brief stop-smoking advice to intensive counseling consisting of four or more sessions (Chavannes et al., 2007; Partnership Stop met Roken, 2009). PNs were instructed to provide respondents in the UC group with cessation support as they were accustomed to provide.

Recruitment and procedure

In the first half of 2009, all participating PNs were visited by a member of the research team. This visit aimed to explain the study procedures and the counseling protocol, as well as to secure a working relationship with each PN.

From May 2009 to June 2010, the 91 participating PNs recruited Dutch adult smokers for participation in the study. To aid PNs in the recruitment of smokers, they were provided with recruitment materials that they could use according to their personal needs and preferences. These recruitment materials consisted of desk displays, recruitment letters, recruitment texts for general practices' website, business cards, and posters. Moreover, incentives in the form of small presents were sent to each PN who had recruited 5 and 10 smokers, respectively. Smokers were eligible to participate when they were motivated to quit within 6 months, were 18 years or older, understood Dutch sufficiently, and had access to the Internet. Interested smokers could sign up on the study website, where they were informed that the study was financed by the Dutch Cancer Society and conducted by researchers from Maastricht University in cooperation with the Dutch Expert Center on Tobacco Control (STIVORO). The website also included information about the objectives of the study, the randomization procedure, and the incentive provided when respondents completed all questionnaires (i.e., a €10 gift voucher).

Respondents could choose their own user name and password and were informed that no one but the research team was able to retrieve this information. However, as respondents had to report their e-mail address when applying for the study, we were able to identify respondents with multiple identities and remove them from further analyses. After signing an online informed consent form, participants were randomly allocated to receive MTC, MT, or UC. Randomization took place at respondent level and was conducted by means of a computer software randomization device. Subsequently, respondents were asked to fill out the baseline questionnaire. After completion of this questionnaire, all respondents were asked to set a quit date within the next 4 weeks. Based on positive results from previous studies (Dijkstra et al., 1998a; te Poel et al., 2009), it was expected that questionnaire completion and receipt of tailored feedback (in both the MTC and MT conditions), would result in respondents' increased motivation to quit and a willingness to set a quit date in the near future, a form of action planning previously shown to increase cessation behavior (Balmford, Borland, & Burney, 2010). This reasoning is supported by the high rates of response to this question, ranging from 90% (MTC) to 88% (MT) and 91% (UC).

Respondents were prompted by e-mail to fill in follow-up questionnaires 2 days after the set quit date and at 6-week, 6-month, and 12-month follow-up. When follow-up questionnaires were not completed 1 week after the invitation, an e-mail reminder was sent, followed-up by a phone call to collect data for the 12-month follow-up.

Baseline measurements

Three demographic variables were measured: age, gender, and educational level ("low": primary school/basic vocational school; "medium": secondary vocational school/high school degree; "high": higher vocational school/college degree/university degree). Addiction level was measured by the abbreviated Fagerström Test for Nicotine Dependence (FTND), resulting in a mean score ranging from 0 = *not addicted* to 10 = *highly addicted* (Heatherton, Kozlowski, Frecker, & Fagerstrom, 1991). The number of past quit attempts was assessed with one item, asking respondents how often they had tried to quit smoking in the past. Depressive symptoms were measured with 10 items from the Centre for Epidemiologic Studies–Depression scale (CES-D; Bouma, Ranchor, Sanderman, & Sonderen, 1995), measured on a 4-point Likert-type scale. A mean depression score was calculated (0 = *no depressive symptoms*; 3 = *many depressive symptoms*). Preparatory plans were assessed by five items, asking whether a respondent planned to undertake preparatory actions for their quit attempt, like removing all smokers' requisites from the home (no/yes). An index was calculated representing the number of action plans made. Coping plans were assessed by nine items, asking whether a respondent aimed to make specific plans to cope with potentially difficult situations, such as when being offered a cigarette (no/yes). When respondents indicated to be willing to make a plan for a particular situation, an open-ended question guided them to formulate this plan in the form of an implementation intention (Gollwitzer & Sheeran, 2006; e.g., If I am being offered a cigarette, then … [open-ended; to be completed by respondent]). An index was calculated representing the number of coping plans made.

Follow-up measurements

At 6 and 12 months after baseline, three self-reported measures of abstinence were assessed. Prolonged abstinence was assessed by asking whether the respondent had refrained from smoking since the previous measurement (no/yes). At 6-month follow-up, prolonged abstinence referred to abstinence

since 6-week follow-up (i.e., 4.5 months) and at 12-month follow-up to abstinence since 6-month follow-up (i.e., 6 months). In addition, 24-hour and 7-day point prevalence abstinence was assessed, by asking whether the respondent had refrained from smoking during the last 24 hours or 7 days (no/yes). After 12 months, self-reported abstinence was cotinine validated using a saliva swab test.

Sample size calculation

Based on earlier research (Dijkstra et al., 1998a; Hoving et al., 2010), we expected 10% point prevalence abstinence in the control condition, 20% in the MT condition, and 30% in the MTC condition. To be able to detect this difference (at $\alpha = .05$ with power .80), almost 300 respondents per intervention were necessary at the end of the trial (DSS Research, n.d.). Taking into account an expected 20% of attrition over the trial period, an initial number of 1100 respondents needed to be recruited. As we expected an additional attrition rate of 20% in the MTC condition, we aimed to include around 1200 respondents. As we estimated that PNs would each be able to recruit 15 smoking participants, we aimed to recruit at least 80 PNs.

Statistical analyses

Sample characteristics were determined using descriptive analyses in SPSS 15.0, while we tested for significant ($p < .05$) differences between the three groups using one-way analyses of variance with Tukey's HSD post hoc comparisons, chi-squared tests, and, in case of nonnormally distributed variables, Kruskal–Wallis tests. As PNs work in general practices and respondents were nested within these practices, we used logistic multilevel regression analyses in MLwiN 2.15 (Rasbash, Steele, Browne, & Goldstein, 2009) to determine selective dropout and the effect of the interventions on primary outcome parameters. Employing first-order penalized quasi-likelihood estimation (Rasbash et al., 2009), all available data were analyzed.

A top-down approach was used, starting with the most extensive model, including main effects of the interventions and potential covariates (i.e., age, gender, educational level, addiction level, number of past quit attempts, depression score, and number of preparatory and coping plans; identified based on the ICM and findings from previous studies: e.g., Fucito et al., 2011; Strecher, Shiffman, & West, 2006)), a random intercept, and random slopes. First, nonsignificant random effects were removed from the model. Second, nonsignificant covariates were removed. Random effects and covariates were considered significant when $p < .10$, thus using a conservative approach in excluding these effects (Rosnow & Rosenthal, 1989), whereas intervention effects were considered significant when $p < .05$. To test the robustness of the results, a sensitivity analysis was conducted replacing all missing values for the outcome measures based on a negative scenario in which all dropouts were considered to still be smoking.

Results

Sample characteristics

In line with the Consolidated Standards of Reporting Trials (CONSORT; Schulz, Altman, & Moher, 2010), Figure 1 shows the flow of respondents. We identified 58 respondents who initiated the baseline questionnaire multiple times using the same e-mail address. Of these respondents, only the identity created first was included in further analyses. Of the 445 remaining respondents assessed for eligibility, 9 (2%) were nonsmokers at baseline and 22 (5%) were not motivated to quit within 6 months. Ultimately, 414 (93%) respondents were randomized into the MTC ($n = 163$), MT ($n = 132$), or UC ($n = 119$) group. Respondents had a mean age of 48 years, 166 (40%) were male, and 187 (45%) had a medium level of education. No significant differences between the three groups were found regarding baseline characteristics (Table 1).

Dropout analysis

Of the 414 respondents, 157 (38%) were followed up after 6 and 232 (56%) after 12 months. Retention after 6 months was unrelated to experimental condition, but significantly higher among respondents with a high versus a low level of education (odds ratio [OR] 1.97; $p = .03$). Retention after 12 months was also unrelated to experimental condition, but significantly predicted by older age (OR 1.03; $p = .01$) and experiencing fewer depressive symptoms (OR .63; $p = .04$; results not tabulated).

Effects of the intervention on smoking abstinence

After 6 months, 47% of respondents reported abstinence for the past 24 hours, 41% for the past 7 days, and 27% reported prolonged abstinence. After 12 months, these percentages were 28%, 27%, and 20%, respectively (Table 1). Respondents reporting abstinence after 12 months ($n = 64$) were asked to undergo a cotinine test. For 30 respondents (response rate = 47%), validation went successfully and confirmed smoking status; eight respondents refused participation, one test went not successfully, and 25 tests were not conducted or not returned to the research team. Our analyses revealed no main effects of the intervention on abstinence assessed after 6 or 12 months (see Tables 2 and 3, respectively).

Replicating these analyses using a negative scenario, that is, regarding dropouts as smokers, yielded similar results.

Discussion

The results from this study suggest that a Web-based multiple computer-tailored smoking cessation program combined with face-to-face counseling by a PN is no more effective than this computer-tailored program alone or than usual smoking cessation care in the general practice setting. Moreover, the computer-tailoring program without counseling was not more effective than care as usual either. Our hypothesis that the combination of both interventions would yield more effects on smoking

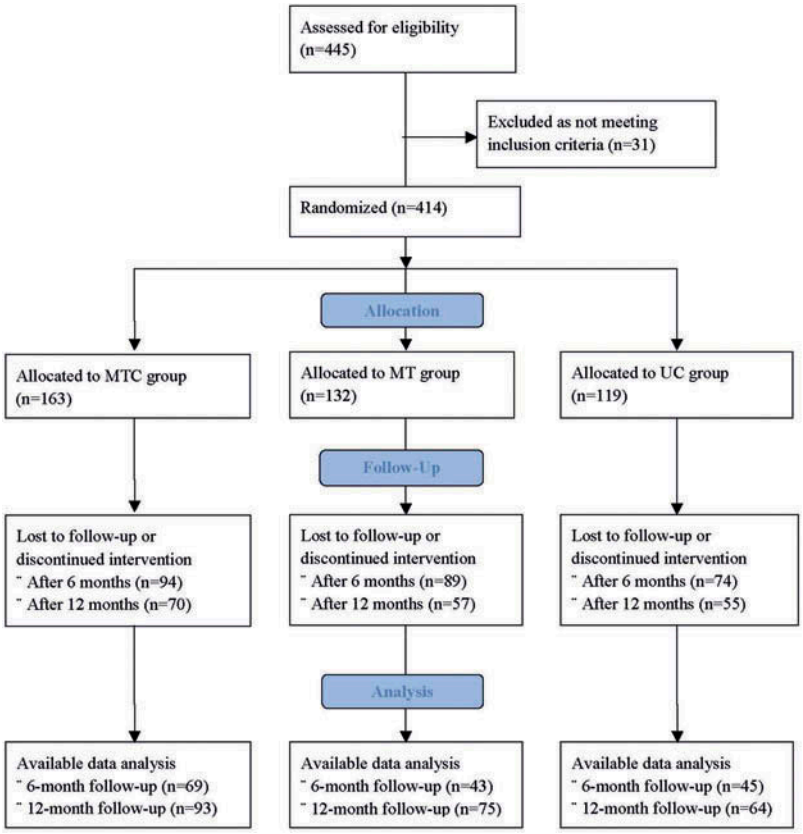

Figure 1. Respondent flow.

Table 1. Baseline sample characteristics and abstinence rates at 6-month and 12-month follow-up of Dutch smoking adults recruited from May 2009 to June 2010.

	Overall sample (n = 414)	MTC group (n = 163)	MT group (n = 132)	UC group (n = 119)
Age[a]	48.0 (11.9)	48.1 (12.0)	47.8 (12.4)	48.1 (11.3)
Male gender[b]	40.1 (166)	36.8 (60)	41.7 (55)	42.9 (51)
Educational level				
High[b]	22.7 (94)	23.9 (39)	23.5 (31)	20.2 (24)
Medium[b]	45.2 (187)	41.7 (68)	47.7 (63)	47.1 (56)
Low[b]	32.1 (133)	34.4 (56)	28.8 (38)	32.8 (39)
FTND score (1–10)[a]	5.4 (2.1)	5.3 (2.2)	5.6 (2.0)	5.3 (2.1)
Number of previous quit attempts[c]	3 (2–4)	3 (2–4)	3 (2–4.3)	3 (2–5)
CES-D score (1–3)[a]	.8 (.6)	.8 (.5)	.9 (.7)	.8 (.5)
Number of preparatory plans[a]	2.9 (1.3)	2.9 (1.3)	2.9 (1.2)	2.8 (1.3)
Number of coping plans[a]	4.8 (2.7)	4.8 (2.6)	5.0 (2.8)	4.6 (2.8)
Six-month follow-up	Overall sample (n = 157)	MTC group (n = 69)	MT group (n = 43)	UC group (n = 45)
24-hour ppa	46.5 (73)	44.9 (31)	53.5 (23)	42.2 (19)
7-day ppa	41.4 (65)	36.2 (25)	51.2 (22)	40.0 (18)
Prolonged abstinence	27.4 (43)	24.6 (17)	30.2 (13)	28.9 (13)
Twelve-month follow-up	Overall sample (n = 232)	MTC group (n = 93)	MT group (n = 75)	UC group (n = 64)
24-hour ppa	27.6 (64)	22.6 (21)	36.0 (27)	25.0 (16)
7-day ppa	26.7 (62)	21.5 (20)	36.0 (27)	23.4 (15)
Prolonged abstinence	19.8 (46)	15.1 (14)	26.7 (20)	18.8 (12)

Note. MTC = multiple tailoring and counseling; MT = multiple tailoring; UC = usual care; FTND = Fagerström Test for Nicotine Dependence; CES-D = Center for Epidemiologic Studies–Depression scale; ppa = point prevalence abstinence.
[a]Mean (*SD*).
[b]Percent (N).
[c]Median (interquartile range).

cessation rates than the Web-based program alone, and that both the combination and the Web-based program would outperform usual care, should therefore be rejected.

Based on previous studies (Curry et al., 1995; Sutton & Gilbert, 2007), we hypothesized that the replacement of one of four tailored feedback letters (i.e., the third) by a single, face-to-face counseling session with a PN and the addition of a telephone call 6 months after baseline (i.e., in addition to the fourth tailored feedback letter) would significantly add to the effect of the Web-based program. Yet the results suggest that this was not the case. Potentially, one counseling session and one telephone call were not sufficient to yield an additional effect on smoking abstinence. This is supported by the finding that the effect of smoking cessation counseling is weaker when

Table 2. Intervention effects on smoking abstinence assessed after 6 months (n = 157).

	Prolonged abstinence			7-day ppa			24-hour ppa		
Overall intervention effect	χ^2(df = 2) = 0.539; p = .764			χ^2(df = 2) = 3.00; p = .223			χ^2(df = 2) = 1.373; p = .503		
Final model	OR	95% CI	p	OR	95% CI	p	OR	95% CI	p
MTC vs. MT	.731	.304–1.756	.484	.477	.204–1.115	.087	.670	.302–1.487	.325
MTC vs. UC	.804	.336–1.924	.624	.835	.353–1.979	.683	1.090	.496–2.396	.831
MT vs. UC	1.100	.427–2.834	.843	1.751	.679–4.512	.246	1.627	.674–3.931	.279
Number of preparatory plans	1.500	.957–1.750	.094	1.500	1.105–2.046	.009	1.347	1.022–1.776	.035
Number of previous quit attempts	.			1.077	.992–1.169	.078			
CES-D	.526	.285–.972	.040	.532	.288–.983	.044			

Note. MTC = multiple tailoring and counseling; MT = multiple tailoring; UC = usual care; ppa = point prevalence abstinence; CES-D = Center for Epidemiologic Studies–Depression scale.

Table 3. Intervention effects on smoking abstinence assessed after 12 months (n = 232).

	Prolonged abstinence			7-day ppa			24-hour ppa		
Overall intervention effect	χ2(df = 2) = 3.245; p = .197			χ^2(df = 2) = 3.950; p = .139			χ^2(df = 2) = 3.360; p = .186		
Final model	OR	95% CI	p	OR	95% CI	p	OR	95% CI	p
MTC vs. MT	.491	.224–1.073	.074	.511	.254–1.028	.060	.519	.235–1.066	.074
MTC vs. UC	.755	.319–1.785	.522	.889	.412–1.914	.761	.839	.382–1.846	.066
MT vs. UC	1.539	.669–3.540	.311	1.738	.809–3.734	.156	.618	.279–1.367	.235
Number of previous quit attempts							1.046	.992–1.103	.096

Note. MTC = multiple tailoring and counseling; MT = multiple tailoring; UC = usual care; ppa = point prevalence abstinence.

interventions are brief (Rice & Stead, 2008), suggesting that more personal contact with a health professional is needed to result in increased effectiveness. Therefore, it may be premature to conclude that the addition of counseling to Web-based computer tailoring cannot be successful. The results from this study rather indicate that future research should aim to identify the optimal number of face-to-face and/or telephone counseling sessions to be combined with the Web-based program. Also, it is conceivable that PNs' counseling was not congruent with the content and/or style of the computer-tailoring program. This may suggest that additional training is required for PNs on how to attune their counseling to this program. This is another question that remains to be answered in future research.

The Web-based computer-tailoring program without counseling appeared to be no more effective than usual care either. This was unexpected, as previous research indicated computer tailoring to be an effective smoking cessation method (Lancaster & Stead, 2005; Noar et al., 2007). Also, another study showed significant positive effects of this specific intervention on smoking abstinence rates assessed after a follow-up period of 6 weeks (Smit et al., 2012a). In that study, however, intervention effects were no longer detected after a 6-month follow-up period. This might suggest that many smokers have relapsed to smoking between 6 weeks and 6 months after initiating usage of the Web-based program. This may be explained by the fact that in both studies respondents only received feedback at fixed points in time; it was not possible to obtain additional feedback or support at difficult times. The integration of ecological momentary assessment, collecting real-time data by, for example, smart phones, might enable us to provide feedback more instantly (Gwaltney, Shiffman, Balabanis, & Paty, 2005; Shiffman et al., 2007) and might be used to further improve the intervention.

Another difference between this study and the previous study is the control group; in the previous study this was a no-intervention control group, while the present study used usual smoking cessation care as a control condition. At the same time, usual care for smoking cessation in Dutch general practices has been shown to vary considerably (Chavannes et al., 2007; Partnership Stop met Roken, 2009), and variation in standard care provided to control groups may substantially influence effect sizes of behavior change interventions (de Bruin, Viechtbauer, Hospers, Schaalma, & Kok, 2009). While we had no access to any (electronic) health records to determine the amount of care that was received by these respondents, anecdotal evidence obtained via interviews with PNs suggests that usual care was rather intensive. We therefore believe that the effects of both interventions on smoking abstinence rates might have been larger when another—less intensive—control group would have been used. The pragmatic nature of the present study is, however, also one of its strengths.

Although the results from the present study are not as promising as expected, investigating the potential of integrating innovative strategies as computer tailoring in the (primary) care setting remains an important venue for future research, especially considering the increasingly limited budgets in the health care sector. The success rates found in the present study were—as expected—greater than the success rates found as a result of single computer-tailored feedback (te Poel et al., 2009) and comparable to the success rates of single computer-tailored feedback as an adjunct to telephone counseling (Sutton & Gilbert, 2007), further strengthening this idea. As computer-tailored feedback can be automatically generated and is increasingly delivered through the Internet (Lustria et al., 2009; Shahab & McEwen, 2009), the integration of Web-based computer-tailored interventions in the care setting might limit the burden on health professionals and patients, might reduce facility and administrative costs, and could potentially be time- and cost-saving (Smit, Evers, de Vries, & Hoving, 2013). More research is, however,

needed to identify how to best attune the two modalities of the Internet and face-to-face communication.

Limitations

Several limitations were present. First, the study suffered from high rates of attrition, although these were not extraordinary when compared to other studies (Shahab & McEwen, 2009; Wangberg, Bergmo, & Johnsen, 2008). The combination of high attrition and a rather low inclusion rate led to this study being underpowered to conduct some of the analyses. We aimed to include 80 PNs and estimated them to be able to include approximately 15 smokers each, which would result in 1200 respondents in total. Even though we included more PNs than required according to this calculation, the recruitment of smokers by these PNs appeared to be much more challenging than anticipated. On the one hand, this may be explained by our respondents being more likely to suffer from respiratory and cardiovascular diseases than respondents recruited using a mass media approach (Smit, Hoving, Cox, & de Vries, 2012b). Due to these smoking-related health complaints and the perceived urgency to quit that may result therefrom, these smokers might have preferred a more intensive approach to smoking cessation, such as intensive counseling or group therapy. On the other hand, PNs may have only invited those smokers that they personally considered sufficiently motivated to quit, resulting in a number of smokers not even being invited to participate (Smit et al., 2012b). Future research should thus not only aim to identify strategies that would ensure the sustained use of (partly) Web-based interventions, but also investigate innovative strategies that would motivate smokers to participate in these interventions in the first place.

Second, we were unable to use continued abstinence as an outcome measure, because all respondents were asked to set a quit date within 4 weeks from filling out the baseline questionnaire and were not obliged to quit instantly. Nonetheless, continued abstinence has been critiqued to be too strict and to classify too many successes as failures (West, Hajek, Stead, & Stapleton, 2005). As we used prolonged abstinence instead, we were still able to measure a rather long period of abstinence.

Third, randomization took place at respondent level, which could possibly have led to some degree of contamination. Yet as PNs swore an oath of secrecy and patients are usually reluctant to talk about the content of their general practice visits with other patients, we believe contamination has been kept to a minimum. Moreover, randomization on a PN level seemed even more unfavorable because PNs who would have been allocated to the control group would most probably have had even more difficulties including—and retaining—enough smokers (Lindstrom, Sundberg Petersson, Adami, & Tonnesen, 2009).

Conclusions

This study suggests that a Web-based multiple computer-tailored smoking cessation program combined with a single face-to-face counseling session by a PN is no more effective than this computer-tailored program alone or than usual smoking cessation care in the general practice setting. Before concluding that the addition of counseling to Web-based computer tailoring cannot be successful, however, future research needs to be conducted to identify the optimal number of counseling sessions to be combined with the Web-based program and to how to best attune the two modalities.

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Hein de Vries is scientific director of Vision2Health, a company that licenses evidence-based innovative computer-tailored health communication tools.

References

Ajzen, I. (1985). From intentions to actions: A theory of planned behaviour. In J. Kuhl & J. Beckmann (Eds.), *Action-control: From cognition to behavior* (pp. 11–39). Heidelberg, Germany: Springer.

Armitage, C. J., & Conner, M. (2001). Efficacy of the theory of planned behaviour: A meta-analytic review. *British Journal of Social Psychology*, *40*, 471–499. doi:10.1348/014466601164939

Balmford, J., Borland, R., & Burney, S. (2010). The influence of having a quit date on prediction of smoking cessation outcome. *Health Education Research*, *25*, 698–706. doi:10.1093/her/cyq013

Bandura, A. (1986). *Social foundations of thought and action: A social cognitive theory*. Englewood Cliffs, NJ: Prentice Hall.

Borland, R., Balmford, J., & Hunt, D. (2004). The effectiveness of personally tailored computer-generated advice letters for smoking cessation. *Addiction*, *99*, 369–377. doi:10.1111/j.1360-0443.2003.00623.x

Bouma, J., Ranchor, A. V., Sanderman, R., & Sonderen, E. V. (1995). *Het meten van symptomen van depressie met de CES-D: Een handleiding*. Groningen, The Netherlands: Noordelijk Centrum voor Gezondheidsvraagstukken, Rijksuniversiteit Groningen.

Centraal Bureau voor de Statistiek. (2011, October 25). *ICT gebruik van personen naar persoonskenmerken*. Retrieved from http://www.webcitation.org/69ORVvulz

Chavannes, N. H., Kaper, J., Frijling, B. D., Van der Laan, J. R., Jansen, P. W. M., Guerrouj, S., & Wind, L. A. (2007). NHG-Standaard Stoppen met roken. *Huisarts & Wetenschap*, *50*, 306–314. doi:10.1007/978-90-313-6614-9_90

Civljak, M., Sheikh, A., Stead, L. F., & Car, J. (2010). Internet-based interventions for smoking cessation. *Cochrane Database of Systematic Reviews*, *9*, Cd007078. doi:10.1002/14651858.CD007078.pub3

Curry, S. J., McBride, C., Grothaus, L. C., Louie, D., & Wagner, E. H. (1995). A randomized trial of self-help materials, personalized feedback, and telephone counseling with nonvolunteer smokers. *Journal of Consulting and Clinical Psychology*, *63*, 1005–1014. doi:10.1037/0022-006X.63.6.1005

De Bruin, M., Viechtbauer, W., Hospers, H. J., Schaalma, H. P., & Kok, G. (2009). Standard care quality determines treatment outcomes in control groups of HAART-adherence intervention studies: Implications for the interpretation and comparison of intervention effects. *Health Psychology*, *28*, 668–674. doi:10.1037/a0015989

de Vries, H., & Brug, J. (1999). Computer-tailored interventions motivating people to adopt health promoting behaviours: Introduction to a

new approach. *Patient Education and Counseling*, *36*, 99–105. doi:10.1016/S0738-3991(98)00127-X

de Vries, H., & Mudde, A. (1998). Predicting stage transitions for smoking cessation applying the attitude-social influence-efficacy model. *Psychology & Health*, *13*, 369–385. doi:10.1080/08870449808406757

de Vries, H., Mudde, A., Leijs, I., Charlton, A., Vartiainen, E., Buijs, G., & Kremers, S. (2003). The European Smoking prevention Framework Approach (EFSA): An example of integral prevention. *Health Education Research*, *18*, 611–626. doi:10.1093/her/cyg031

Dijkstra, A. (2005). Working mechanisms of computer-tailored health education: Evidence from smoking cessation. *Health Education Research*, *20*, 527–539. doi:10.1093/her/cyh014

Dijkstra, A., & de Vries, H. (1999). The development of computer-generated tailored interventions. *Patient Education and Counseling*, *36*, 193–203. doi:10.1016/S0738-3991(98)00135-9

Dijkstra, A., & de Vries, H. (2000). Clusters of precontemplating smokers defined by the perception of the pros, cons, and self-efficacy. *Addictive Behaviors*, *25*, 373–385. doi:10.1016/S0306-4603(99)00073-8

Dijkstra, A., de Vries, H., & Roijackers, J. (1998a). Long-term effectiveness of computer-generated tailored feedback in smoking cessation. *Health Education Research*, *13*, 207–214. doi:10.1093/her/13.2.207

Dijkstra, A., de Vries, H., Roijackers, J., & van Breukelen, G. (1998b). Tailoring information to enhance quitting in smokers with low motivation to quit: Three basic efficacy questions. *Health Psychology*, *17*, 513–519. doi:10.1037/0278-6133.17.6.513

DSS Research. (n.d.). *Researcher's toolkit*. Retrieved from http://www.webcitation.org/5xLwjt2EA

Fucito, L. M., Latimer, A. E., Carlin-Menter, S., Salovey, P., Cummings, K. M., Makuch, R. W., & Toll, B. A. (2011). Nicotine dependence as a moderator of a quitline-based message framing intervention. *Drug and Alcohol Dependence*, *114*, 229–232. doi:10.1016/j.drugalcdep.2010.09.012

Gollwitzer, P. M., & Sheeran, P. (2006). Implementation intentions and goal achievement: A meta-analysis of effects and processes. *Advances in Experimental Social Psychology*, *38*, 69–119. doi:10.1016/S0065-2601(06)38002-1

Gwaltney, C. J., Shiffman, S., Balabanis, M. H., & Paty, J. A. (2005). Dynamic self-efficacy and outcome expectancies: Prediction of smoking lapse and relapse. *Journal of Abnormal Psychology*, *114*, 661–675. doi:10.1037/0021-843X.114.4.661

Harrington, N. G., & Noar, S. M. (2012). Reporting standards for studies of tailored interventions. *Health Education Research*, *27*, 331–342. doi:10.1093/her/cyr108

Heatherton, T. F., Kozlowski, L. T., Frecker, R. C., & Fagerstrom, K. O. (1991). The Fagerstrom test for nicotine dependence: A revision of the Fagerstrom tolerance questionnaire. *British Journal of Addiction*, *86*, 1119–1127. doi:10.1111/j.1360-0443.1991.tb01879.x

Hingstman, L., & Kenens, R. J. (2007). *Cijfers uit registratie van huisartsen - peiling 2007 [Figures from GP registration, 2007]*. Utrecht, The Netherlands: NIVEL.

Hoving, C., Mudde, A. N., & de Vries, H. (2007). Intention to implement a smoking cessation expert system in Dutch general practice. *Health Education*, *107*, 307–315. doi:10.1108/09654280710742591

Hoving, C., Mudde, A. N., Dijk, F., & de Vries, H. (2010). Effectiveness of a smoking cessation intervention in Dutch pharmacies and general practices. *Health Education*, *110*, 17–29. doi:10.1108/09654281011008726

Hoving, E. F., Mudde, A. N., & de Vries, H. (2006). Smoking and the O pattern: Predictors of transitions through the stages of change. *Health Education Research*, *21*, 305–314. doi:10.1093/her/cyl033

Internet World Stats. (2010). *Internet usage statistics: The Internet big picture*. Retrieved from http://www.webcitation.org/5xLwg1Msm

Janz, N. K., Champion, V. L., & Strecher, V. J. (2002). The health belief model. In K. Glanz, B. K. Rimer, & F. M. Lewis (Eds.), *Health behavior and health education: Theory, research, and practice* (pp. 45–66). San Francisco, CA: Jossey-Bass.

Lancaster, T., & Stead, L. F. (2005). Self-help interventions for smoking cessation. *Cochrane Database of Systematic Reviews*, *3*, 1–91. doi:10.1002/14651858.CD001118.pub2

Lemmens, V., Oenema, A., Knut, I. K., & Brug, J. (2008). Effectiveness of smoking cessation interventions among adults: A systematic review of reviews. *European Journal of Cancer Prevention*, *17*, 535–544. doi:10.1097/CEJ.0b013e3282f75e48

Lindstrom, D., Sundberg Petersson, I., Adami, J., & Tonnesen, H. (2009). Disappointment and drop-out rate after being allocated to control group in a smoking cessation trial. *Contemporary Clinical Trials*, *31*, 22–26. doi:10.1016/j.cct.2009.09.003

Lustria, M. L. A., Cortese, J., Noar, S. M., & Glueckauf, R. L. (2009). Computer-tailored health interventions delivered over the Web: Review and analysis of key components. *Patient Education and Counseling*, *74*, 156–173. doi:10.1016/j.pec.2008.08.023

Lustria, M. L. A., Noar, S. M., Cortese, J., van Stee, S. K., Glueckauf, R. L., & Lee, J. (2013). A meta-analysis of Web-delivered tailored health behavior change interventions. *Journal of Health Communication*, *18*, 1039–1069. doi:10.1080/10810730.2013.768727

Naik, P. A., & Raman, K. (2003). Understanding the impact of synergy in multimedia communications. *Journal of Marketing Research*, *40*, 375–388. doi:10.1509/jmkr.40.4.375.19385

Noar, S. M., Benac, C. N., & Harris, M. S. (2007). Does tailoring matter? Meta-analytic review of tailored print health behavior change interventions. *Psychological Bulletin*, *133*, 673–693. doi:10.1037/0033-2909.133.4.673

Panday, S., Reddy, S. P., Ruiter, R. A., Bergstrom, E., & de Vries, H. (2007). Determinants of smoking among adolescents in the Southern Cape-Karoo region, South Africa. *Health Promotion International*, *22*, 207–217. doi:10.1093/heapro/dam018

Partnership Stop met Roken. (2009). *Richtlijn Behandeling van tabaksverslaving herziening 2009*. Retrieved from http://www.webcitation.org/6D3ROknsb

Prochaska, J. O., & DiClemente, C. C. (1983). Stages and processes of self-change of smoking: Toward an integrative model of change. *Journal of Consulting and Clinical Psychology*, *51*, 390–395. doi:10.1037/0022-006X.51.3.390

Prochaska, J. O., Velicer, W. F., Fava, J. L., Ruggiero, L., Laforge, R. G., Rossi, J. S., & Lee, P. A. (2001). Counselor and stimulus control enhancements of a stage-matched expert system intervention for smokers in a managed care setting. *Preventive Medicine*, *32*, 23–32. doi:10.1006/pmed.2000.0767

Rasbash, J., Steele, F., Browne, W. J., & Goldstein, H. (2009). *A user's guide to MLwiN, v2.10*. Bristol, UK: Centre for Multilevel Modelling, University of Bristol.

Rice, V. H., & Stead, L. F. (2008). Nursing interventions for smoking cessation. *Cochrane Database of Systematic Reviews*, *1*, Cd001188. doi:10.1002/14651858.CD001188.pub3

Rosnow, R. L., & Rosenthal, R. (1989). Statistical procedures and the justification of knowledge in psychological science. *American Psychologist*, *44*, 1276–1284. doi:10.1037/0003-066X.44.10.1276

Schulz, K. F., Altman, D. G., & Moher, D. (2010). CONSORT 2010 Statement: Updated guidelines for reporting parallel group randomised trials. *Trials*, *11*, 32. doi:10.4103/0976-500X.72352

Shahab, L., & McEwen, A. (2009). Online support for smoking cessation: A systematic review of the literature. *Addiction*, *104*, 1792–1804. doi:10.1111/j.1360-0443.2009.02710.x

Shiffman, S., Balabanis, M. H., Gwaltney, C. J., Paty, J. A., Gnys, M., Kassel, J. D., & Paton, S. M. (2007). Prediction of lapse from associations between smoking and situational antecedents assessed by ecological momentary assessment. *Drug and Alcohol Dependence*, *91*, 159–168. doi:10.1016/j.drugalcdep.2007.05.017

Smit, E. S., de Vries, H., & Hoving, C. (2010). The PAS study: A randomized controlled trial evaluating the effectiveness of a Web-based multiple tailored smoking cessation programme and tailored counselling by practice nurses. *Contemporary Clinical Trials*, *31*, 251–258. doi:10.1016/j.cct.2010.03.001

Smit, E. S., de Vries, H., & Hoving, C. (2012a). Effectiveness of a Web-based multiple computer tailored smoking cessation program: A randomized controlled trial among Dutch adult smokers. *Journal of Medical Internet Research*, *14*, e82. doi:10.2196/jmir.1812

Smit, E. S., Evers, S. M. A. A., de Vries, H., & Hoving, C. (2013). Cost-effectiveness and cost-utility of Internet-based computer tailoring for

smoking cessation. *Journal of Medical Internet Research*, *15*, e57. doi:10.2196/jmir.2059
Smit, E. S., Hoving, C., Cox, V. C. M., & de Vries, H. (2012b). Influence of recruitment strategy on the reach and effect of a Web-based multiple tailored smoking cessation intervention among Dutch adult smokers. *Health Education Research*, *27*, 191–199. doi:10.1093/her/cyr099
Stead, L. F., Bergson, G., & Lancaster, T. (2008). Physician advice for smoking cessation. *Cochrane Database of Systematic Reviews*, *4*, Cd000165. doi:10.1002/14651858.CD000165.pub3
Strecher, V. J., McClure, J. B., Alexander, G. L., Chakraborty, B., Nair, V. N., Konkel, J. M., & Pomerleau, O. F. (2008). The role of engagement in a tailored Web-based smoking cessation program: Randomized controlled trial. *Journal of Medical Internet Research*, *10*, 373–381. doi:10.1016/j.amepre.2007.12.024
Strecher, V. J., Shiffman, S., & West, R. (2006). Moderators and mediators of a Web-based computer-tailored smoking cessation program among nicotine patch users. *Nicotine and Tobacco Research*, *8* (Suppl 1), S95–101. doi:10.1080/14622200601039444
Sutton, S., & Gilbert, H. (2007). Effectiveness of individually tailored smoking cessation advice letters as an adjunct to telephone counselling and generic self-help materials: Randomized controlled trial. *Addiction*, *102*, 994–1000. doi:10.1111/j.1360-0443.2007.01831.x
te Poel, F., Bolman, C., Reubsaet, A., & de Vries, H. (2009). Efficacy of a single computer-tailored e-mail for smoking cessation: Results after 6 months. *Health Education Research*, *24*, 930–940. doi:10.1093/her/cyp036
U.S. Department of Health and Human Services. (2004). *The health consequences of smoking: A report of the Surgeon General*. Washington, DC: Department of Health and Human Services, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health.
Velicer, W. F., & Prochaska, J. O. (1999). An expert system intervention for smoking cessation. *Patient Education and Counseling*, *36*, 119–129. doi:10.1016/S0738-3991(98)00129-3
Vitoria, P. D., Salgueiro, M. F., Silva, S. A., & de Vries, H. (2009). The impact of social influence on adolescent intention to smoke: Combining types and referents of influence. *British Journal of Health Psychology*, *14*, 681–699. doi:10.1348/135910709X421341
Voorveld, H. A. M., Neijens, P. C., & Smit, E. G. (2011). Opening the black box: Understanding cross-media effects. *Journal of Marketing Communications*, *17*, 69–85. doi:10.1080/13527260903160460
Wangberg, S. C., Bergmo, T. S., & Johnsen, J. A. (2008). Adherence in Internet-based interventions. *Patient Preference and Adherence*, *2*, 57–65. doi:10.2147/PPA.S
West, R., Hajek, P., Stead, L., & Stapleton, J. (2005). Outcome criteria in smoking cessation trials: Proposal for a common standard. *Addiction*, *100*, 299–303. doi:10.1111/j.1360-0443.2004.00995.x
World Health Organization. (2008). *WHO report on the global tobacco epidemic, 2008: The MPOWER package*. Geneva, Switzerland: World Health Organization.
Yarnall, K., Pollak, K., Krause, K., & Michener, J. (2003). Primary care: Is there enough time for prevention? *American Journal of Public Health*, *93*, 635–641. doi:10.2105/AJPH.93.4.635

Appendix

Example of a tailored feedback message for a participant who reported to still be smoking at 6-week follow-up and who perceives a higher social norm toward nonsmoking but experiences less social support since baseline.

What does your social environment think?

More than last time, you have the idea that people in your social environment think that you should better not smoke. That is good, because this can help you to permanently choose not to smoke.
Nonetheless, you unfortunately experience support for not smoking from only few people. Perhaps you can once more think about who may be able to help you? Or think of someone who may want to quit smoking with you? Quitting smoking together is easier than doing so just by yourself. And if you ever feel unable to maintain your non-smoking behavior, these people might be able to help you to persist. Use this opportunity!