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DEALING WITH MISSING BEHAVIORAL ENDPOINTS IN HEALTH PROMOTION RESEARCH BY MODELING COGNITIVE PARAMETERS IN COST-EFFECTIVENESS ANALYSES OF BEHAVIORAL INTERVENTIONS: A VALIDATION STUDY

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ABSTRACT

Cost-effectiveness analyses (CEAs) of behavioral interventions typically use physical outcome criteria. However, any progress in cognitive antecedents of behavior change may be seen as a beneficial outcome of an intervention. The aim of this study is to explore the feasibility and validity of incorporating cognitive parameters of behavior change in CEAs.

The CEA from a randomized controlled trial on smoking cessation was reanalyzed. First, relevant cognitive antecedents of behavior change in this dataset were identified. Then, transition probabilities between combined states of smoking and cognitions at 6 weeks and corresponding 6 months smoking status were obtained from the dataset. These rates were extrapolated to the period from 6 to 12 months in a decision analytic model. Simulated results were compared with the 12 months' observed cost-effectiveness results.

Self-efficacy was the strongest time-varying predictor of smoking cessation. Twelve months' observed CEA results for the multiple tailoring intervention versus usual care showed €3188 had to be paid for each additional quitter versus €10,600 in the simulated model.

The simulated CEA showed largely similar but somewhat more conservative results. Using self-efficacy to enhance the estimation of the true behavioral outcome seems a feasible and valid way to estimate future cost-effectiveness. Copyright © 2014 John Wiley & Sons, Ltd.

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KEY WORDS: cost-effectiveness analyses; cognitions; behavior change; modeling; self-efficacy

1. INTRODUCTION

Cost-effectiveness analyses (CEAs) in healthcare research and public health are considered an important tool to help decision makers to set funding priorities (Gold *et al.*, 1996). Exploring the cost-effectiveness of a behavioral health intervention, however, should have some implications for the CEA methodology used. Generally,

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health promotion interventions are designed to accomplish behavior change. CEAs of these interventions typically focus on objective outcome measures, that is, physical endpoints such as weight loss, less alcohol consumption, or biochemically validated smoking cessation (Wagner and Goldstein, 2004; Prenger *et al.*, 2012). However, behavior change is a complex process in which several steps need to be taken, including changes in cognitive antecedents of behavior change. Any progress in cognitive steps toward behavior change can be seen as a beneficial outcome of an intervention, assuming that this increases the likelihood to achieve successful behavior change eventually (Velicer *et al.*, 1996). But to date, such intermediate effects are ignored in CEAs of such trials. As most intervention studies have a relatively short follow-up period of 6 months, it is likely that positive intervention effects, such as awareness of unhealthy habits or increased willingness to change, are achieved during the follow-up period, whereas physical outcomes cannot yet be measured. Not accounting for this delayed behavior change may lead to biased estimates of (cost-)effectiveness of behavioral interventions (Green, 1977; Jackson and Waters, 2005; Martin *et al.*, 1996; Pieterse *et al.*, 2001; Prenger *et al.*, 2013; Smith *et al.*, 2007; Wagner and Goldstein, 2004). An alternative way to the demanding approach of extending relatively short follow-up periods and expanding the range of outcome measures is to use intermediate determinants of behavior to model behavior change over a longer period, such as cognitions.

There is a considerable body of research that shows there are strong and consistent individual differences in health behaviors. Some of these differences can be attributable to sociodemographic variables (e.g., gender and socioeconomic status), which are not readily open to change. However, research has shown that some of these differences may also be attributable to the, more amenable to change, social cognitive determinants of behavior change (Armitage and Conner, 2000). Cognitive determinants of behavior, such as self-efficacy or outcome expectancies, can predict health behavior change (e.g., Ajzen, 1991; Armitage and Conner, 2000; Bandura, 1986; Conner and Norman, 2005; De Vries *et al.*, 1988; Painter *et al.*, 2008). As a consequence, progression (or decline) in these determinants can be seen as intermediate behavior change. The cognitive determinants are derived from theories, which are used to explain and predict behavior (change) (e.g., Noar and Zimmerman, 2005; Painter *et al.*, 2008). Examples are the transtheoretical model (Prochaska *et al.*, 1992), the theory of planned behavior (Ajzen, 1991; Fishbein and Ajzen, 2010), the social cognitive theory (Bandura, 1986), and the I-change model (ICM) (De Vries *et al.*, 2003). These theories define cognitive antecedents of behavior change and state that behavior is a result of determinants such as intention, self-efficacy, and attitudes. For example, Figure 1 shows the ICM (de Vries *et al.*, 2003).

According to the ICM, the most proximal predictor of behavior is the intention to perform this behavior. A person's behavioral intention can be predicted by three motivational constructs: attitude, perceived social influence, and self-efficacy. The concept of attitude entails both the perceived advantages (pros) and disadvantages (cons) of a specific behavior. Perceived social influence refers to three related but distinct constructs: perceived social norms, social modeling, and social pressure. Perceived social norms refer to the perceived opinions held by others in the person's social environment (e.g., partner and family). Social modeling refers to perceived behavior of other people, whereas social pressure refers to perceived pressure or support from people in the social environment to perform that behavior. Self-efficacy refers to a person's level of confidence that he or she can perform the target behavior. A positive attitude toward desired behavior, a high self-efficacy, and a social environment that is perceived as positive toward the behavior are all hypothesized to have a positive influence on the intention to perform the desired behavior.

The motivational factors such as attitude, perceived social influence, and self-efficacy are predicted by several premotivational factors. These include predisposing factors, awareness factors, and information factors. Furthermore, the ICM defines postmotivational factors. The ICM recognizes that intention is a necessary prerequisite for behavior change to occur but argues that in bridging the gap between intention and behavior (e.g., Armitage and Conner, 2001), several postmotivational factors play a role. Perceived barriers to change might increase the gap between intention and behavior. On the other hand, ability factors such as an individual's skills to perform the desired behavior and the formation of action plans are assumed to aid in overcoming these barriers to change and thus to decrease the so-called intention-behavior gap (de Vries *et al.*, 2003). The focus of the current study is primarily on the motivational factors preceding behavior change as defined by the ICM.

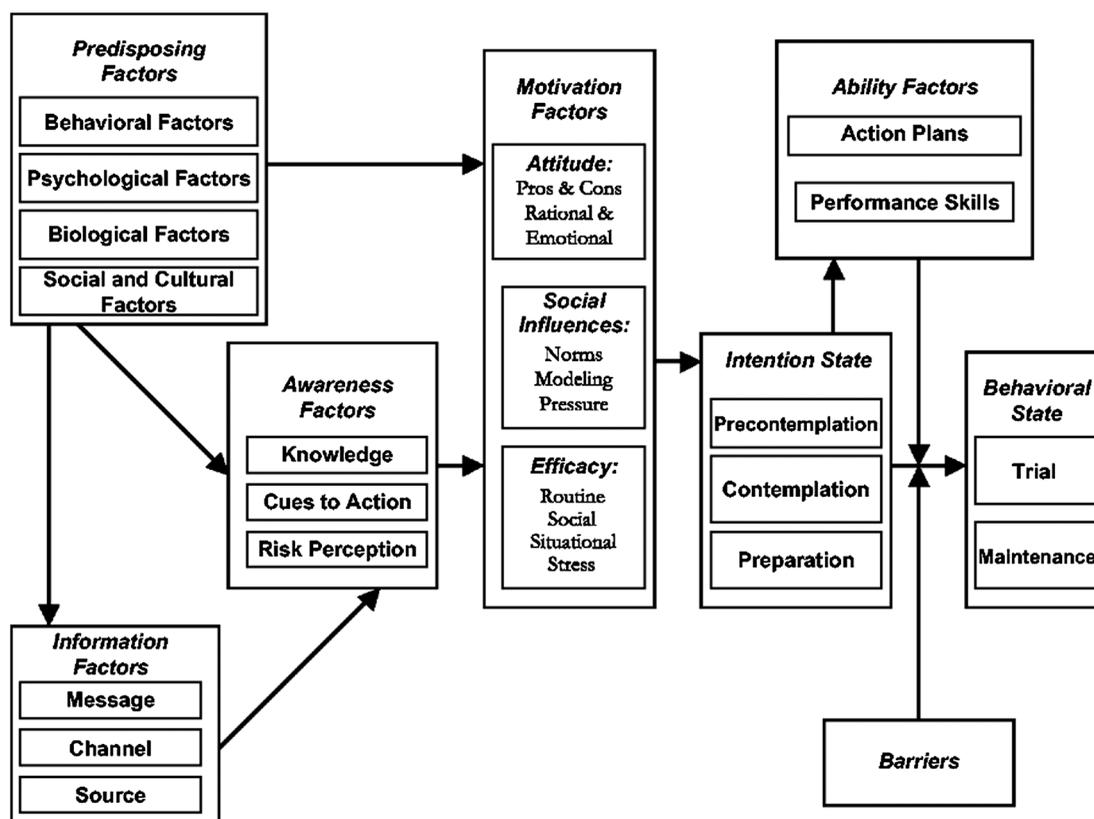


Figure 1. The I-change model (de Vries *et al.*, 2003)

Few studies have been conducted on the inclusion of intermediate behavior change in CEAs by means of changed cognitions. Our recent review on the role of cognitions in CEAs of behavioral interventions found that the use of cognitive parameters in calculating cost-effectiveness outcomes is to some extent recognized but still in its infancy (Prenger *et al.*, 2012). One of the frameworks that was distinguished when considering the inclusion of cognitions in CEA consisted of an approach to model final physical endpoints based on intermediate, cognitive measures of behavior change.

To our knowledge, only three studies have modeled intermediate behavior change in CEAs of behavioral interventions (Prenger *et al.*, 2013; Smith *et al.*, 2007; Wagner and Goldstein, 2004). In all three studies, stages-of-change data (Prochaska *et al.*, 1992) were modeled to predict future behavior change. Wagner and Goldstein (2004), for instance, presented a hypothetical example of incorporating these stages in CEA methodology and concluded that CEA results may be biased by ignoring intermediate effects. A CEA of a computer-based cessation intervention in primary care by advancing a smoker's cognitive stage of change (transtheoretical model) also showed that effects may be underestimated by solely focusing on the physical outcome of smoking cessation (Smith *et al.*, 2007). Also, the results of our recent study showed that the already dominant intervention at 1-year follow-up became even more dominant after modeling the 12 months' stages of change to a 2-year follow-up, which corroborates the underestimation of ignoring intermediate effects (Prenger *et al.*, 2013).

In the present study, intermediate behavior change was modeled in a CEA of two behavioral interventions for smoking cessation by means of cognitions derived from social cognitive theories.

The aim of this study was to model cognitive parameters into a cost-effectiveness model of two behavioral interventions in order to explore the feasibility and validity of incorporating intermediate behavioral change in

CEAs. For this purpose, we used an existing dataset of a randomized controlled trial on two Internet-based smoking cessation interventions that were compared with usual care for their cost-effectiveness at 12 months' follow-up. We replicated its CEA calculating cost-effectiveness results at 6 months' follow-up and modeled intermediate behavior change estimates to predict cost-effectiveness results at 12 months. To accomplish this, several steps were taken. First, relevant cognitive parameters that precede smoking cessation were identified. Second, intermediate 6 months' cost-effectiveness results were calculated. Third, probabilities for the transition of intermediate to final endpoints (i.e., behavior) were obtained from the data. Fourth, these rates were applied to estimate smoking cessation at 12 months in a decision analytic cost-effectiveness model. Lastly, these simulated CEA outcomes were compared with the observed trial-based CEA outcomes.

2. METHODS

2.1. Sample

Data from the Personal Advice in Stopping Smoking (PAS) study were used (Smit *et al.*, 2010). The PAS study is a three-armed randomized controlled multicenter trial with 1-year follow-up that evaluated the (cost-)effectiveness of an Internet-based multiple tailored smoking cessation program with (multiple tailoring and counseling [MTC]) and without (multiple tailoring [MT]) tailored counseling by practice nurses, compared with care as usual (CAU) consisting of standard practice. A total of 414 smokers were included in the PAS study and randomly assigned: 163 received MTC, 132 received MT, and 119 received CAU. All missing patients at the follow-ups were assumed to be smokers. More details on the PAS study design are published elsewhere (Smit *et al.*, 2010).

Baseline characteristics are presented in Table I. No significant baseline differences were found regarding demographics, cognitions, or costs between the three treatment arms, except for self-efficacy. Participants randomized to the CAU group appeared to have a significant lower self-efficacy toward quitting, compared with both intervention groups, as they were not randomized on the basis of cognitive parameters.

2.2. The PAS study

The PAS study compared the more intensive MTC program, the less intensive MT program, and CAU. In the MT program, respondents received a total of four feedback letters: at baseline, 2 days after the quit date, after 6 weeks, and after 6 months. Feedback was personalized, adjusted to changes a respondent had made since

Table I. Baseline characteristics of the three treatment arms of the Personal Advice in Stopping Smoking study ($n=414$)

	MTC	MT	CAU	
$N=414$	$N=163$	$N=132$	$N=119$	p -value
Age (mean, SD)	48.1 (12.0)	47.8 (12.5)	48.1 (11.3)	NS
Male (n , %)	60 (36.8)	55 (41.7)	51 (42.9)	NS
Education (n , %) ^a				
Low	56 (34.4)	38 (28.8)	39 (32.8)	NS
Middle	68 (41.7)	63 (47.7)	56 (47.1)	
High	39 (23.9)	31 (23.5)	24 (20.2)	
Intention to quit (mean, SD) (1 = very surely not, 7 = very surely yes)	6.41 (0.71)	6.40 (0.73)	6.24 (0.78)	NS
Intention to stay quit (mean, SD) (1 = very surely not, 7 = very surely yes)	6.21 (0.87)	6.20 (0.87)	5.97 (0.93)	NS
Pros of quitting (mean, SD) (1 = no pros, 5 = many pros)	3.62 (0.80)	3.50 (0.70)	3.47 (0.76)	NS
Pros of smoking (mean, SD) (1 = no pros, 5 = many pros)	2.52 (0.76)	2.54 (0.76)	2.53 (0.67)	NS
Self-efficacy (mean, SD) (1 = surely not, 5 = surely yes)	3.45 (0.73)	3.45 (0.68)	3.11 (0.77)	<0.001
Social support (mean, SD) (1 = no support, 5 = much support)	3.64 (0.88)	3.53 (0.92)	3.47 (1.02)	NS
Social modeling (mean, SD) (1 = nobody, 1 = all of them)	2.63(1.09)	2.86 (1.03)	2.82 (1.12)	NS
Social norms (mean, SD) (1 = no smoking norm, 5 = smoke norm)	1.73 (0.99)	1.88 (1.11)	1.76 (0.76)	NS

MTC, multiple tailoring and counseling; MT, multiple tailoring; CAU, care as usual; SD, standard deviation.

^aLow, vocational training; middle, advanced vocational training; high, high vocational/university training.

inclusion, and tailored to several respondent characteristics: gender, cognitive variables (attitude, social influence, and self-efficacy), intention to quit smoking, goal and relapse prevention strategies (action and coping plans), and smoking behavior. In the MTC program, respondents received a counseling session by their practice nurse instead of the third tailored feedback letter at 6 weeks' follow-up and an additional telephone contact after 6 months (Smit *et al.*, 2010). CAU consisted of standard practice and could vary from a brief intervention consisting of a single stop-smoking advice to more intensive interventions consisting of at least four consultations (Partnership Stop met Roken, 2009).

2.3. Measurements

Baseline characteristics and cognitive determinants of behavior change were collected using a written questionnaire consisting of 54 questions based on the ICM (De Vries *et al.*, 2003; Smit *et al.*, 2010). Variables relevant to the present study included demographics (gender and education level), intention to quit (single combined item of intention to quit and stay quit), self-efficacy (eight items, Cronbach's $\alpha=0.89$), social norm (three items, Cronbach's $\alpha=0.76$), social support (three items, Cronbach's $\alpha=0.61$), social modeling (three items, Cronbach's $\alpha=0.36$), pros of quitting (six items, Cronbach's $\alpha=0.72$), cons of quitting (six items, Cronbach's $\alpha=0.66$), and having experienced a previous quit attempt at baseline (dichotomous single item). The Likert scales used are in principle considered to produce ordinal data. However, there appears to be a consensus in methodological literature that these scales in general result in findings similar to data obtained with interval scales (Gregoire and Driver, 1987; Jenkins and Taber, 1976; Rasmussen, 1989). Measurements at baseline, 6 weeks, 6 months, and 12 months were used for analyses.

Self-reported point prevalence abstinence was the primary outcome of the present study, assessed by one item asking whether the respondent had refrained from smoking during the past 7 days (0=yes, 1=no). Although Smit *et al.* (2013) focused on prolonged abstinence (i.e., being abstinent from smoking for at least 6 months), this was not possible in the present study because of the short-term variations in cognitions and behavior that were accounted for in this study.

2.4. Time-varying regression analyses

Time-varying regression analyses were used to select the relevant cognitions to be included in the prediction model. Cox proportional hazard (PH) models with time-varying covariates were fit to test the longitudinal relationship between potential social cognitive factors (intention to quit, pros and cons of quitting, self-efficacy, social norms, social support, and social modeling) and smoking abstinence (point prevalent abstinence) over the study period of 1 year using its predefined measurements at baseline, 6 weeks, 6 months, and 12 months of follow-up. Also, gender, education level, intervention, and having experienced a previous quit attempt were additionally tested. This produces a time-varying survival model that reports covariate effects as a hazard ratio (HR), also interpreted as relative risks. The HRs are based on the combined follow-up data. It is presumed that the log HR is additively related to the covariates by the linear predictor (Berger *et al.*, 2003). This leads to the assumption of PHs, which implies that the ratio of two hazards is independent of time (Berger *et al.*, 2003; Fox, 2002). To describe the dynamic development of the hazards, the Cox PH model can be modified to a dynamic Cox model by allowing the effects to vary with time (Berger *et al.*, 2003). A time-varying covariate is defined as any variable whose value for a given subject may differ over time. We used mean values between time assessments for the time-varying covariates to be able to incorporate values of all four measurements in the analyses. Mean cognitive values for the period from baseline to 6 weeks, 6 weeks to 6 months, and 6 to 12 months of follow-up were calculated to examine its relation to smoking cessation at 6 weeks, 6 months, and 12 months of follow-up.

The Cox model analyzes different *periods*, which were characterized by the starting point and endpoint between two measurements. As participants could quit smoking and relapse in the same period, subjects that reached the event of abstinence should not automatically leave the model as in regular survival analysis but continue the process of quitting after cessation. Therefore, it is necessary that each period for an individual appears as a separate observation. Additionally, we adjusted for the fact that the periods within one patient are

dependent (Fox, 2002). Because data consist of multiple observations per subject, the robust variance estimate was used to account for the repeated observations of each subject (Fox, 2002; Kleinbaum and Klein, 2005). A backward elimination procedure was applied to remove predictors from the Cox models that did not appear to contribute significantly to the outcome ($p < 0.05$). These variables were eliminated individually until parameter estimates for all remaining variables were associated with p -values of less than 0.05.

For the Cox models, survival libraries implemented in R packages were used (Fox, 2002). All cognitive variables were included in the models as main effects. The possibility of collinearity between the observed covariates was assessed with bivariate correlation analyses using SPSS 18.0 (Chicago: SPSS Inc.). All missing patients at multiple follow-ups were assumed to be smokers. For missing values of cognitive variables, complete case analysis was applied.

2.5. Six months' cost-effectiveness

To create a starting point from which future cost-effectiveness can be estimated, cost-effectiveness was calculated for the 6-month time horizon. This analysis was conducted from a societal perspective, corresponding to the original 12 months' economic evaluation study (Smit *et al.*, 2013). Intervention costs, healthcare costs, and patient costs were identified as relevant. These costs were assessed using a 3-month retrospective costing questionnaire consisting of open-ended questions and administered at 6 weeks, 6 months, and 12 months of follow-up. Healthcare and patient costs were valued using the updated version of the Dutch manual for cost analysis in healthcare research (Hakkaart-van Roijen *et al.*, 2010). All cost prices were indexed to the year 2011. A more detailed prescription of the measurement and valuation of costs was described by Smit *et al.* (2013). Incremental costs and effects were calculated for both treatments and CAU. Subsequently, net monetary benefits were calculated, enabling us to compare the three groups directly with each other regarding their cost-effectiveness. Using a range of thresholds for the willingness to pay (WTP), the likelihood was calculated that each treatment would be most efficient. This was visualized by means of cost-effectiveness acceptability curves (CEACs). All analyses were conducted according to the intention-to-treat principle.

2.5.1. Uncertainty analyses. Sampling uncertainty around the estimates of cost-effectiveness and cost utility was taken into account using nonparametric bootstrap resampling techniques (1000 replications). Bootstrap analyses were conducted using Microsoft Office Excel 2007. All other analyses were conducted using SPSS 18.0.

2.6. Simulated 12 months' cost-effectiveness

To predict smoking status at 12 months' follow-up by means of information on smoking status and cognitive parameters (depending on Cox regression results), a predictive model was needed. For clarity, the simulated model is based on the assumption that a change in cognitive determinants induces behavior change, which in turn affects eventual cost-effectiveness for the three interventions in this study. Decision trees were used to outline the smoking and cognitive states a respondent could experience over the time frame of 6 to 12 months. These pathways were used to calculate future behavioral change, the associated costs, and subsequently the incremental cost-effectiveness of the three study groups. Probabilities were extracted from the data to determine the distribution in categories consisting of a combination of smoking behavior and level of cognition per treatment arm at 6 months' follow-up. Thus, participants were divided in separate 'states' of the cognition(s). For example, for self-efficacy, questions were answered on a 5-point Likert scale. A person can therefore be in a category of being a smoker and having reported a low value on the self-efficacy scale (i.e., being a smoker and assuming a low chance to quit smoking based on the person's low confidence to achieve smoking cessation). Additionally, a separate state was included for those with missing values on self-efficacy.

For the predictive model, only the strongest predictor of behavior change was included for two main reasons. First, the dataset was restricted because of its sample size. Dividing multiple states would increase the need for more data, as otherwise several states or categories would be empty. Furthermore, increasing complexity results in a 'bushy' decision tree, which reduces its feasibility.

2.6.1. Transition probabilities. Rates for estimating the transition from 6 months' intermediate outcomes to 12 months' final behavior were based on rates from 6 weeks to 6 months of follow-up observed in the data. In other words, to predict future behavioral change by means of smoking behavior and the value of cognition(s), probabilities were calculated between being in a certain category of a smoke-cognitive combination at 6 weeks of follow-up and smoking status at 6 months of follow-up. A precondition for applying this method is that tests for the PH assumption in the Cox regression analyses should be nonsignificant, meaning that the HRs can be assumed to be similar across periods. As the randomization procedure has not accounted for differences in cognitions at baseline, transition probabilities were calculated separately for both treatment arms and CAU to account for bias between groups.

2.6.2. Costs. Costs were based on the costs of the PAS study for the first 6 months' follow-up. For the 6 to 12 months' follow-up, intervention costs were set to 0. Summed mean costs regarding general practitioners, medical specialists, hospital, alternative healer, mental health care, prescribed and 'over the counter' medication, medical aids and assistive devices, and other care were included in the analyses. Because of the different expected costs associated with smoking status, we calculated separate costs for smokers and quitters, on the basis of smoking status at 6 months' follow-up.

2.6.3. Cost-effectiveness analysis. Both costs and effects were estimated for the treatment arms and CAU by means of the predictive model for 12 months' follow-up. Incremental costs and effects were thereafter calculated for each of the three treatments studied. After uncertainty analyses as described in the succeeding text, net monetary benefits were calculated, and the results were plotted in a CEAC.

2.6.4. Uncertainty analyses. All variables were evaluated for uncertainty in sensitivity analyses. Uncertainty regarding data inputs was quantified by means of Monte Carlo simulation with 1000 iterations to explore the variation of the total costs, as well as the costs per quitter, and the amount of quitters by varying all cost parameters and distribution (6 months) and transition probabilities (6–12 months) simultaneously over their ranges and the associated 95% confidence intervals (CIs). Specifically, for those categories in the model containing 0 or 1 respondent in the trial data, additional sensitivity analyses explored the impact of assumptions that consequently had to be made. For the overall sensitivity analyses, the ranges of the confidence intervals were maximized for the categories containing 0 or 1 respondent in the trial data. Furthermore, it was assumed that of those respondents, 50% would quit smoking, and 50% would continue smoking. The additional sensitivity analyses used the same maximized confidence intervals around the parameters but varied in assumptions made for the future behavior of the respondents: (i) on the basis of the assumptions of the ICM, low self-efficacy categories (1 and 2) result in smoking, higher self-efficacy categories (3 and 4) result in quitting, and the missing-data category always results in smoking (intention to treat); (ii) all participants in these categories are assumed to be smokers at 12 months' follow-up; and (iii) all participants in these categories are assumed to be quitters at 12 months' follow-up. A gamma distribution was assumed for all costs and a logistic normal distribution for all probabilities. Sensitivity analyses were performed using @Risk5.5 for Excel (Palisade Corporation, 2010).

3. RESULTS

3.1. Time-varying Cox regression analyses

The results of the Cox regression analyses showed that all cognitive variables added significantly to the prediction of smoking cessation when tested univariately, except for the pros toward quitting. In addition, being highly educated and having experienced a previous quit attempt showed a significant positive effect on cessation. Figure 2 shows the cognitive development over time for all cognitions for both smokers and quitters at 12 months' follow-up.

Univariate significant predictors were fit to the multivariate Cox regression model to examine their independent association with smoking cessation. Table II shows the final time-varying model.

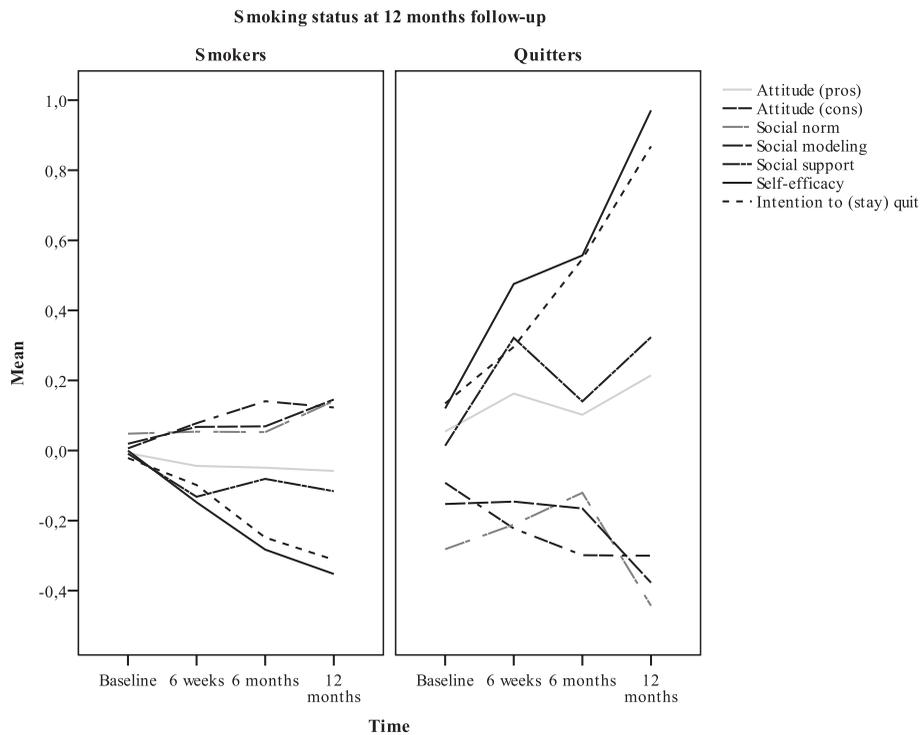


Figure 2. Cognitive development over time for smokers and quitters at 12 months

Table II. Summary of the final time-varying model of smoking cessation for the Personal Advice in Stopping Smoking study based on four measurements, $n = 414$ (890 cases, 28.3% missing)

	β	SE (β)	Robust SE (β)	Hazard ratio	95% CI	Z	p
Self-efficacy	1.54	0.14	0.13	4.68	3.61–6.08	11.56	<0.001
Intention to quit	0.40	0.13	0.11	1.49	1.20–1.85	3.66	<0.001
Social modeling	-0.43	0.11	0.11	0.65	0.53–0.80	-4.04	<0.001
Baseline previous quit attempt	0.11	0.06	0.05	1.12	1.01–1.24	2.21	0.03

Covariates were standardized. Indication for smoking status: 0 = smoking, 1 = smoking abstinence. Concordance = 0.86 ($SE = 0.03$), $R^2 = 0.282$. Wald test = 252.9 ($df = 4$), $p = 0$. Robust = 177, $p = 0$. SE, standard error.

Self-efficacy added 25.6% to the explained variance in smoking cessation over time when tested univariately ($\beta = 1.76$, $HR = 5.83$, 95% CI: 4.60–7.38, $p < 0.001$). Intention to quit added 11.8% to the explained variance ($\beta = 1.06$, $HR = 2.90$, 95% CI: 2.34–3.58, $p < 0.001$). Tests for the PH assumptions indicated that for the multivariate model, HRs could be assumed to be equal for all periods analyzed. For social modeling, the univariate explained variance was 4.4%, and having experienced a previous quit attempt at baseline showed an explained variance of 0.3% ($\beta = 0.10$, $HR = 1.11$, 95% CI: 1.01–1.22, $p < 0.05$).

As self-efficacy showed by far to be the strongest predictor of smoking cessation over time, this covariate was selected for use in the prediction of future behavior change in the CEA of MT, MTC, and CAU.

3.2. Prediction model

3.2.1. Six months' distribution of participants. Of the respondents assigned to CAU, 84.9% (95% CI: 78.3–92) smoked at 6 months; in the MT group, 83.3% (95% CI: 76.8–90.4) smoked; and in the MTC group, 84.7%

(95% CI: 79.1–90.3) self-reported to have been smoking during the past 7 days. Table III shows the distribution of respondents according to their 6 months' smoking status and level of self-efficacy.

3.2.2. Transition probabilities. To predict future behavioral change by means of smoking behavior and self-efficacy, probabilities were calculated from being in a certain (0 = smoker or 1 = quitter) smoking status and a state of self-efficacy (1–4 and missing) at 6 weeks of follow-up to having a 0 or 1 smoking status at 6 months of follow-up for each treatment arm. For self-efficacy, construct means were divided into the following categories: 1 = 1–1.99, 2 = 2–2.99, 3 = 3–3.99, and 4 = 4–5. Transition probabilities for each treatment arm are shown in Table IV.

3.2.3. Costs. Six months' costs for smokers (€611) and quitters (€439) were extrapolated to the period of 6 to 12 months' follow-up in the model. Mean costs per category, as well as mean total costs, were among the input parameters for the simulated model.

3.2.4. Decision analytic model. Figure 3 shows a part of the decision analytic model for the distribution among those who had quit and their cognitive states (Q1 = quit, low self-efficacy to Q4 = quit, and high self-efficacy) after 6 months' follow-up, the transition probabilities for the prediction of future behavioral change at 12 months follow-up, and their associated costs for the MTC treatment arm of the PAS study.

3.3. Cost-effectiveness results

Observed CEA results at 12 months showed that for respondents in the MTC group, costs were higher, whereas effects were lower than for those in the CAU and MT groups. Thus, MTC was dominated by the other two treatments. For the MT group, €5100 had to be paid for each additional respondent being (prolonged) abstinent (Smit *et al.*, 2013). In the present study, however, we focused on point prevalence abstinence, for which analyses showed similar results. MTC was dominated by the other two treatments, and for the MT group, €3188 had to be paid for each additional respondent being abstinent.

For 6 months, the mean total costs for each participant within the MTC group during the first 6 months were €770, €538 for the MT, and €324 for the CAU group. Self-reported quitting was, respectively, 17%, 18%, and 17%. Cost per quitter was €4530 within MTC, €2990 within MT, and €1872 within the CAU group. The costs generated by subjects of the CAU group were thus considerably lower. Table V shows the MTC to be dominated by both MT and CAU, and the incremental costs per quitter for MT versus CAU were estimated at €21,400.

Table III. Probabilities for distribution of respondents among states of smoking status and self-efficacy at 6 months

Smoking status, self-efficacy	<i>n</i>	<i>p</i> (95% CI)	<i>n</i>	<i>p</i> (95% CI)	<i>n</i>	<i>p</i> (95% CI)
	CAU (<i>n</i> = 119)		MT (<i>n</i> = 132)		MTC (<i>n</i> = 163)	
S, 1	4	0.040 (0.001–0.122)	3	0.027 (0.001–0.058)	1	0.007 (0.001–0.021)
S, 2	6	0.059 (0.012–0.157)	5	0.045 (0.005–0.085)	8	0.058 (0.018–0.098)
S, 3	13	0.129 (0.062–0.269)	11	0.11 (0.05–0.169)	19	0.138 (0.079–0.197)
S, 4	4	0.040 (0.001–0.079)	1	0.009 (0.001–0.027)	16	0.116 (0.061–0.171)
S, missing	74	0.733 (0.645–0.821)	90	0.818 (0.744–0.891)	94	0.681 (0.602–0.760)
Q, 1	0	0.000*	0	0.000*	0	0.000*
Q, 2	0	0.000*	0	0.000*	0	0.000*
Q, 3	3	0.167 (0.001–0.343)	0	0.000*	1	0.04 (0.001–0.118)
Q, 4	15	0.833 (0.657–0.999)	21	0.955 (0.867–0.999)	23	0.92 (0.811–0.999)
Q, missing	0	0.000*	1	0.045 (0.001–0.133)	1	0.04 (0.001–0.118)

S, smoker; Q, quitter; missing, missing value; 1 (low) to 4 (high), categories of self-efficacy; CAU, care as usual; MT, multiple tailoring intervention; MTC, multiple tailoring plus counseling intervention; *n*, number of participants; 95% CI, 95% confidence interval; *p*, probability of being in a certain smoke-cognition category at 6 months.

*The assumption was made that for the actual point values of 0, the point value was 0.001.

Table IV. Transition probabilities for state at 6 weeks (smoking status and self-efficacy) to being a smoker at 6 months' follow-up

Smoking status, self-efficacy	<i>n</i>		<i>p</i> (95% CI)		<i>n</i>		<i>p</i> (95% CI)	
	CAU (<i>n</i> = 119)	MT (<i>n</i> = 132)	CAU (<i>n</i> = 119)	MT (<i>n</i> = 132)	MTC (<i>n</i> = 163)	MTC (<i>n</i> = 163)	CAU (<i>n</i> = 119)	MT (<i>n</i> = 132)
S, 1	3	0	0.99**	0.499*** (0.001–0.999)	1	0.499 (0.001–0.999)		
S, 2	17	12	0.944 (0.836–0.999)	0.99**	14	0.875 (0.71–0.999)		
S, 3	9	14	0.818 (0.585–0.999)	0.875 (0.71–0.999)	23	0.92 (0.811–0.999)		
S, 4	3	8	0.75 (0.317–0.999)	0.800 (0.547–0.999)	15	0.882 (0.726–0.999)		
S, missing	56	67	0.949 (0.892–0.999)	0.971 (0.931–0.999)	71	0.986 (0.958–0.999)		
Q, 1	0	0	0.499*** (0.001–0.999)	0.499*** (0.001–0.999)	0	0.499*** (0.001–0.999)		
Q, 2	0	0	0.499*** (0.001–0.999)	0.499*** (0.001–0.999)	0	0.499*** (0.001–0.999)		
Q, 3	3	1	0.99**	0.499 (0.001–0.999)	1	0.333 (0.001–0.877)		
Q, 4	10	7	0.476 (0.258–0.693)	0.318 (0.119–0.517)	13	0.464 (0.276–0.652)		
Q, missing	0	1	0.499*** (0.001–0.999)	0.99 (0.927–0.999)	0	0.499*** (0.001–0.999)		

For quitters, transition probabilities are (1 - *p*).

S, smoker; Q, quitter; missing, missing values; 1–4, categories of self-efficacy; CAU, care as usual; MT, multiple tailoring intervention; MTC, multiple tailoring plus counseling intervention; *n*, number of participants; 95% CI, 95% confidence interval; *p*, transition probability between being in a certain smoke-cognition category at 6 months and smoking status at 12 months.

*The assumption was made that for the actual point values of 0, the point value was 0.001.

**The assumption was made that for the actual point values of 1, the point value was 0.99.

***The assumption was made that for categories where no cases were present for smokers and quitters, the probability was 0.499.

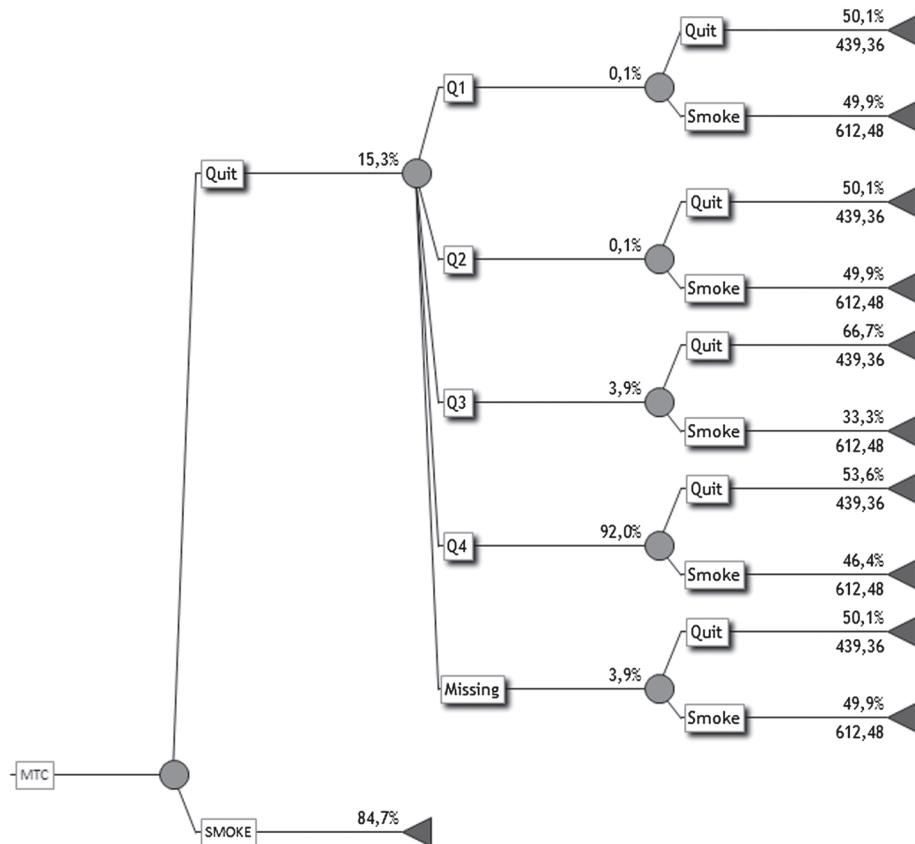


Figure 3. Decision analytic tree of pathways for the 'quitters' (Q) arm of the multiple tailoring and counseling treatment group for the time frame of 6–12 months, including percentages and costs (€)

Table V. Incremental costs (€) and effects per abstinent smokers for the three treatment groups studied

Intervention	Costs per participant	Probability abstinent	Incremental costs	Incremental probability abstinent	Incremental costs per quitter
Six months' observed CEA results					
CAU	324	0.17	—	—	—
MT-CAU	538	0.18	214	0.01	21.400
MTC-CAU	770	0.17	446	0	Dominated
MTC-MT	770	0.17	232	0	Dominated
Twelve months' simulated CEA results					
CAU	914	0.13	—	—	—
MT-CAU	1126	0.15	212	0.02	10.600
MTC-CAU	1359	0.11	445	-0.02	Dominated
MTC-MT	1359	0.11	233	-0.04	Dominated

CAU, care as usual; MT, multiple tailoring; MTC, multiple tailoring and counseling; CEA, cost-effectiveness analysis.

Simulated results for the cost-effectiveness at 12 months (Table V) showed higher costs and lower effects, compared with 6 months' cost-effectiveness. Cost per quitter was €12,355 within MTC, €7507 within MT, and €7031 for participants receiving CAU. Again, MTC was dominated by CAU and the MT intervention. The incremental costs per quitter for MT versus CAU were €10,600. The simulated CEA showed that until a threshold value for the WTP of €10,600 per abstinent respondent, CAU was probably the most efficient treatment.

3.4. Uncertainty analyses

Bootstrap analyses took into account the sampling uncertainty around the estimates of the trial-based 6 and 12 months' cost-effectiveness results. For the 12 months' simulated results, probabilistic sensitivity analysis was employed to analyze the robustness of the aforementioned findings. The cost-effectiveness probabilities regarding a range of WTP thresholds for the observed 6 months and observed and simulated 12 months of results are visually displayed in the CEACs (Figures 4 and 5). The probability of MT being cost-effective was 88% with a WTP threshold of €18,000 in the observed, trial-based CEA versus 53% in the present study. The additional sensitivity analyses regarding the assumptions made for the categories containing 0 or 1 participant in the trial data showed an increased probability of MT being cost-effective in the simulated model (58%, 57%, and 65%).

The bootstrap results of the cost and effects for MT versus CAU for both the observed and simulated 12 months results are displayed in Figure 6. The cost-effectiveness plane of the simulated CEA shows that the uncertainty regarding the cost-effectiveness of MT versus CAU has increased considerably compared with the bootstrap results of the observed, trial-based CEA.

4. DISCUSSION

The aim of this study was to model cognitive parameters into a cost-effectiveness model of a behavioral intervention in order to explore the feasibility and validity of incorporating intermediate behavioral change based on cognitions in future CEAs. Data from the PAS study (Smit *et al.*, 2010) were used to re-analyze a CEA with addition of intermediate behavioral change estimates based on 6 months' smoking status and self-efficacy measures. Results of this model-based, simulated approach were compared with the observed, trial-based results of Smit *et al.* (2013). The findings of our study showed comparable results as those found by Smit and colleagues: the most intensive intervention (MTC) showed higher costs and lower effects compared to both the less intensive intervention (MT) and CAU in both the observed and simulated CEA. MT showed higher costs compared with CAU; however, effects were also somewhat better. Assuming a WTP of €18,000, MT is the most cost-effective intervention for both the trial-based and model-based approach. Based on these findings, it could

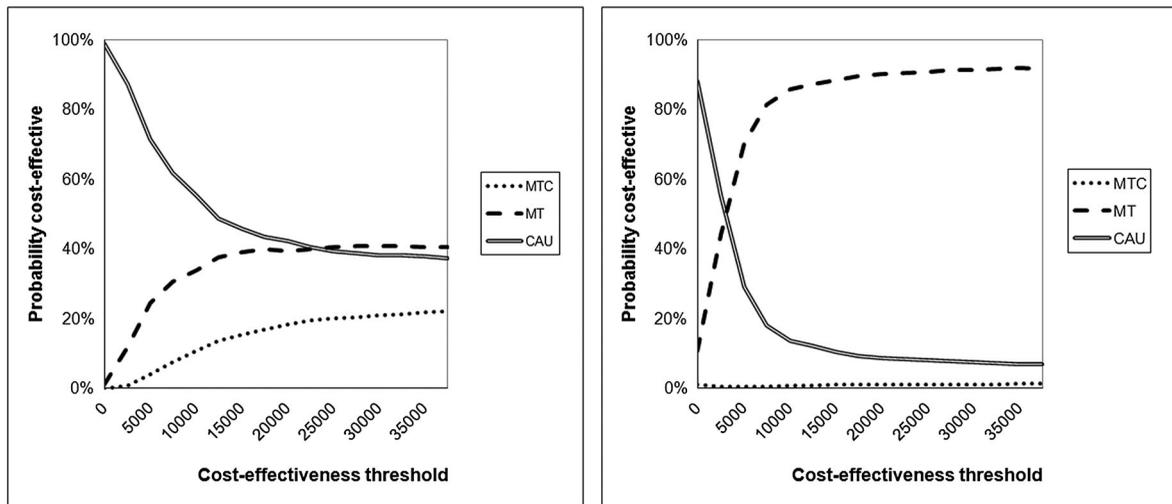


Figure 4. Six (left) and 12 months (right) of observed cost-effectiveness acceptability curves

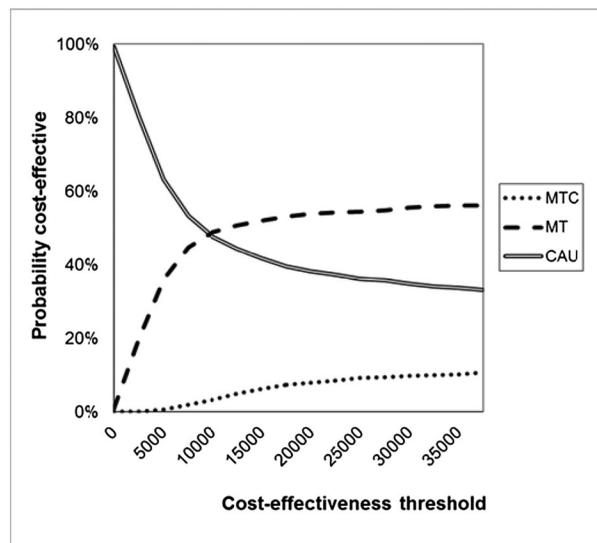


Figure 5. Simulated 12 months' cost-effectiveness acceptability curve

be concluded that modeling cognitive parameters in CEA can give a valid estimate of future cost-effectiveness at 12 months, based on 6 months' costs, effects, and cognitions. However, the results of the simulated CEA showed that uncertainty regarding data inputs was high. The probability of MT being cost-effective was 88% with a WTP threshold of €18,000 in the observed, trial-based CEA versus 53% in the present study.

In contrast to the earlier CEA study (Smit *et al.*, 2013), this study also modeled future behavior, which may be advisable for two reasons. First, many intervention studies have a relatively short follow-up period of 6 months or less. Delayed behavior change can occur after a study period ends, which may lead to biased (cost-)effectiveness results (Prenger *et al.*, 2012, 2013; Smith *et al.*, 2007; Wagner and Goldstein, 2004). When people attempt to change habitual behaviors, the likelihood of relapsing to their old habit after a while is high. Certainly in smoking cessation research, where the majority of attempts will fail, this is widely acknowledged

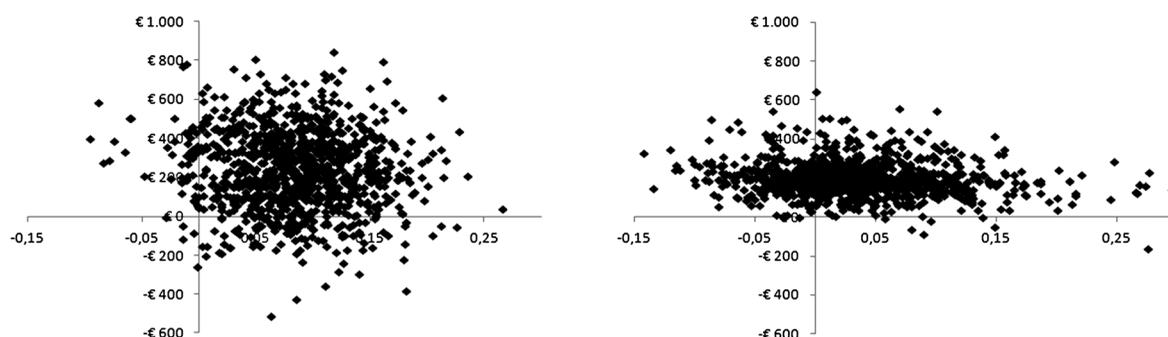


Figure 6. Cost-effectiveness planes for observed (left) and simulated (right) incremental costs and effects at 12 months for multiple tailoring versus care as usual

(Hughes *et al.*, 2004; Piasecki, 2006). The issue here, therefore, is not whether delayed behavior change will occur after a follow-up of less than 12 months but rather to what degree this occurs and more specifically whether this occurs differentially depending on a particular intervention. The present study indeed revealed these differences. The observed CEA at 6 months suggested that with a WTP of €18,000, CAU was the most cost-effective. Yet, from the observed 12 months' cost-effectiveness results using the same threshold for the WTP, the results suggested MT to be the most cost-effective. Oldenburg *et al.* (1995) also demonstrated varying cost-effectiveness results comparing short-term (<6 months) with long-term behavior change (>6 months). These results imply that MT either more effectively may prevent relapse in the second half of the year following the quit attempt and/or increased chances of a renewed quit attempt. In conclusion, when trying to account for delayed behavior change, simulated CEA may be useful for examining the cost-effectiveness of an intervention over longer periods of months or even years.

Second, modeling of future behavior change by means of cognitive parameters provides a way to deal with missing behavioral endpoints for CEA research. For example, CEAs of interventions aimed at prevention in health promotion are scarce (e.g., van den Berg *et al.*, 2008; Van den Berg and Schoemaker, 2010; Vijgen *et al.*, 2008) mostly because of missing endpoints of the intended behavior. Often, the aim of these interventions is to change cognitions associated with the behavior to be altered. As changes in cognitions are assumed to lead to changes in behavior, modeling these parameters can contribute to an approximation of future (cost-) effectiveness. Furthermore, effectiveness data from existing trials that were not originally developed with the aim of a CEA are often unsuitable for CEAs because of a lack of adequate behavioral endpoints. Potentially, substituting behavioral endpoints by cognitive measures, which are often available, can make many more health promotion programs available for health economists to evaluate on their cost-effectiveness.

Obviously, the predictive value of the cognitive parameters should be high and empirically supported as this is a prerequisite for valid (cost)-effectiveness prediction. Which specific cognitive parameters should be chosen might depend on the behavior to be predicted. Moreover, time variations should be taken into account as well. In the present study, Cox regression analyses with time-varying covariates were applied to examine the association of cognitions and smoking status at multiple measurements over time. Several studies found changes in cognitions to be relevant for the prediction of future behavior change (e.g., Baldwin *et al.*, 2006; Gwaltney *et al.*, 2005, 2009; Shiffman, 2005). Therefore, solely focusing on a single point in time to predict future behavior may ignore important timing information and may consequently lead to biased predictions. The present study showed a univariately explained variance of approximately 25% of time-varying self-efficacy to smoking cessation. In addition, tests of the PH assumption implied that the HR could be assumed to be constant over time. In combination with information regarding smoking status, changes in self-efficacy from 6 weeks to 6 months could therefore be extrapolated to the prediction of 12 months' smoking behavior.

Some limitations have to be noted. First, the reliability of the social modeling construct was not sufficient but did appear to contribute significantly to the time-varying model of smoking cessation. This effect may

therefore be a result of measurement error. However, this parameter was not included in the predictive model and could therefore not have affected these results. Second, some states that were distinguished in the predictive model were empty, and consequently, assumptions regarding the probabilities had to be made. Analyses of different scenarios following these assumptions show variations in uncertainty but did not influence the result of MT being the most cost-effective intervention in this study. Potentially, larger datasets could have estimated these probabilities more accurately. Also, it should be noted that for psychological constructs, often, 5-point Likert scales are used, which are in principle considered to produce ordinal data. These states are thus not categorical or qualitatively different, which consequently increases the chance on 'empty' states. There appears to be a consensus in methodological literature that analyses based on 5-point scales in general result in findings similar to data obtained with interval scale and may therefore be accepted in such analytical techniques (Gregoire and Driver, 1987; Rasmussen, 1989; Jenkins and Taber, 1976).

The probability of MT being cost-effective was 88% with a WTP threshold of €18,000 in the observed, trial-based CEA versus 53% in the present study. We added extra parameters to the decision analytic model and thus introduced more uncertainty in the model. Obviously, conclusions drawn on the basis of the present study are less certain, compared with the observed, trial-based modeling study. Nonetheless, this study has provided preliminary evidence that when true endpoints are missing in a behavioral intervention and a conventional CEA would not be possible, the theory-based simulation methodology presented here provides a promising approach. Third, the focus of this study was on effectiveness data applied in CEAs. Of course, whether the same methodology can be used in cost-utility analyses, which are often based on quality-adjusted life years (QALY) as their outcome measure, remains to be explored. As a behavioral outcome measure, such as smoking cessation, could in turn be considered an intermediate outcome of QALY, this does seem worthwhile. However, a discussion on the implications of methods needed to predict QALY outcomes based on cognitive intermediate outcomes is beyond the scope of this paper. Fourth, the primary outcome of this study was self-reported abstinence in the past 7 days. Unfortunately, self-reported quit rates in smoking cessation programs are likely to be biased and tend to overestimate program effectiveness. Cost-effectiveness may therefore also be overestimated in the PAS study. However, the purpose of this study was to compare simulated with observed cost-effectiveness results. As, in both the simulated and observed models, the same self-reported outcome was used, a bias will affect both models similarly. Consequently, it is unlikely that the self-reported abstinence outcome measure impairs the validity of our results. Furthermore, as with many Internet-based studies (Shabab & McEwen, 2009), the PAS study suffered from missing data. However, the current study accounted for attrition by including a missing-data category for both smokers and quitters in the decision analytic model. Although this method may seem unconventional, the alternative of simply ignoring those participants who dropped out of the study would certainly have biased the results. By including a missing-data category, the participants remain in the study as being smokers, which makes this procedure comparable with imputation of missing outcomes. Lastly, not all significant cognitive parameters of smoking cessation found in the multivariate Cox regression model were included in the predictive model, as this would reduce parsimoniousness and applicability of the presented method.

Many decision analytic models exist in health economic research. As models are a simplification of reality, uncertainty will always be present. Uncertainty is pervasive in CEAs and exists because we can never perfectly predict what the mean costs and outcomes associated with the use of a particular treatment will be (Bojke *et al.*, 2009). Moreover, reliance on solely intermediate outcomes may both overestimate and underestimate final outcomes (Gold *et al.*, 1996). Nonetheless, the present study showed promising results for dealing with problems as delayed behavior change and missing endpoints by including intermediate behavior change in CEA. More information on additional cognitions and demographics in the model would probably imply less uncertainty but also comes with more complexity and data requirements.

In conclusion, the model-based 12 months' CEA showed results largely similar to that of the observed CEA, in spite of the models' uncertainty. Our predictive CEA model was therefore validated by the true data. The present study showed promising results for dealing with problems as delayed behavior change and missing endpoints by including intermediate behavior change in CEA. Using a cognitive parameter to enhance the

estimation of the true behavioral outcome seems not only a feasible but also valid way to estimate future cost-effectiveness outcomes. As this is the first validation study of this kind in the field, the present study contributes uniquely to research in this domain.

CONFLICT OF INTEREST

No conflicts of interest are reported.

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