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A randomized controlled trial to assess the effects of reimbursing the costs of smoking cessation therapy on sustained abstinence

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ABSTRACT

Aims We studied whether reimbursement for smoking cessation treatment (SCT) can increase prolonged abstinence from smoking up to 2 years. **Setting, participants and design** From the general population, we recruited smokers and assigned them randomly to a control group ($n = 634$) or an intervention group ($n = 632$). For 6 months, participants in the intervention group could apply for reimbursement and received information regarding the reimbursed SCT. Participants in the control group received no reimbursement or information. **Measurements** In this follow-up study, prolonged abstinence from smoking was defined as reported being abstinent from at least 7 days before the end of reimbursement until the follow-up assessment 6 months or 2 years later. **Findings** At 6 months after the end of reimbursement, 18 participants in the control group (2.8%) and 35 participants (5.5%) in the intervention group reported sustained abstinence for at least 6 months [odds ratio (OR) = 2.0, 95% confidence interval (CI) 1.1–3.6]. Two years after the reimbursement period, 10 participants in the control group (1.6%) and 27 participants in the intervention group (4.3%) still reported sustained abstinence (OR = 4.1, 95% CI 1.7–10.2). The overall effectiveness of SCT increased with reimbursement and was 22% in the intervention group and 8% in the control group after 2 years. **Conclusions** Reimbursement may be an effective strategy to increase the prolonged abstinence rate even after 2 years.

Keywords Prolonged abstinence, reimbursement, smoking cessation treatment.

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INTRODUCTION

Smoking is the main risk factor for developing respiratory and cardiovascular diseases [1]. Stopping smoking is most essential for treatment and prevention; however, the success rates of smoking cessation interventions are low [2,3].

From the literature, it is known that smokers who use smoking cessation treatment (SCT) have a higher probability of being a successful quitter after 1 year [4,5]. Despite this knowledge, few quitters use these treatment methods [6]. An opportunity to promote the use of SCT and to increase the success rate of a quit attempt is to offer reimbursement for all proven effective treatment methods.

Currently, in the Netherlands no reimbursement is offered for SCT. Nicotine replacement therapy is available over the counter, and bupropion is available at pharmacies and can be obtained with a prescription from a health-care provider. Smoking cessation interventions offered by health-care community centres or health-care providers have to be paid for by the smokers themselves. If a smoker already has a smoking-related disease, then smoking cessation interventions given by health-care providers are often reimbursed. Some health insurance companies offer reimbursement privately for smoking cessation group interventions and alternative treatment methods, such as acupuncture and laser therapy.

To evaluate the potential effects of a reimbursement system in the general Dutch population, we previously

conducted a randomized controlled trial [7]. In this trial, for a period of 6 months, participants in the intervention group were offered full reimbursement for all proven effective and currently available treatments in the Netherlands, i.e. nicotine replacement therapy (NRT), bupropion, behavioural counselling, including smoking cessation interventions given by health-care providers, or any combination of these interventions. The control group received care as usual and was not offered reimbursement for SCT. The results showed that at the end of a 6-month period of financial reimbursement, the use of smoking cessation treatment increased from 4.1% to 10.8% and the 7-day point prevalence abstinence rate increased from 2.8 to 5.5% [7].

In the follow-up study presented in this paper, we examined primarily the effects of reimbursement for SCT on prolonged abstinence from at least 7 days before the end of reimbursement until 6 months and 2 years later.

Furthermore, the concern was that if SCT is available free of charge then the effectiveness of the treatment methods would decline, i.e. smokers could be less motivated to quit. To evaluate this assumption, we related the cessation methods that were used during the reimbursement period to the self-reported prolonged abstinence outcomes at 6-month and 2-year follow-up.

METHODS

Setting, participants and design

The setting, recruitment of participants, study design and intervention have been described previously [7]. To summarize, a general sample of 1320 smokers, who were insured at the same regional health insurance company, gave oral consent for participation in a study concerning smoking, smoking cessation and the use of SCT and were randomized to the intervention or control groups. Participants did not have to be motivated to quit smoking. After randomization, 54 participants were excluded as they were ineligible [7].

Only smokers in the intervention group were told that they participated in a study that assessed the effects of reimbursement for SCT. Participants were not encouraged to stop smoking. Participants in the intervention group received by mail a letter about the reimbursement offered as well as a leaflet describing which SCT reimbursement was available and how they could be reimbursed. No reimbursement or information was offered to participants in the control group. For example, 12 weeks' treatment with bupropion including two visits to a general practitioner would cost €0 in the intervention group and €250 in the control group.

As we expected that participants in the control group might change their behaviour because they were disappointed, we used a double randomized consent design in order to blind them for the intervention group. The study was approved by the Medical Ethics Committee of the Dutch Trimbos Institute.

Assessments

Figure 1 shows the timing of the different assessments. To evaluate the long-term effects of the intervention, data were collected after the 6-month period of reimbursement and followed-up at 6 months and 2 years after the reimbursement period had ended. Smoking status at the end of the reimbursement period and at 6-month follow-up was assessed by self-report and validated by carbon monoxide breath tests 2 months later. Two years later, we attempted to contact all respondents who reported being prolonged abstinent from smoking until 6-month follow-up and asked them about their smoking behaviour between the follow-up assessment at 6 months and at 2 years.

Outcomes

At baseline we collected data concerning age, gender, nicotine dependence, education and airway complaints. The level of nicotine dependence was measured by the six-item Fagerström Test for Nicotine Dependence (FTND), with scores ranging from 0 to 10 [8]. A score higher than 5 corresponds to a high level of nicotine dependence. Educational level was defined as low for primary and lower vocational school, middle for lower secondary and intermediate vocational school and high for secondary and higher vocational school or university.

The primary outcome measure was prolonged abstinence from smoking. At 6-month follow-up, prolonged self-reported abstinence was defined as reported being abstinent for at least 7 days preceding the end of the reimbursement period and not having smoked until the

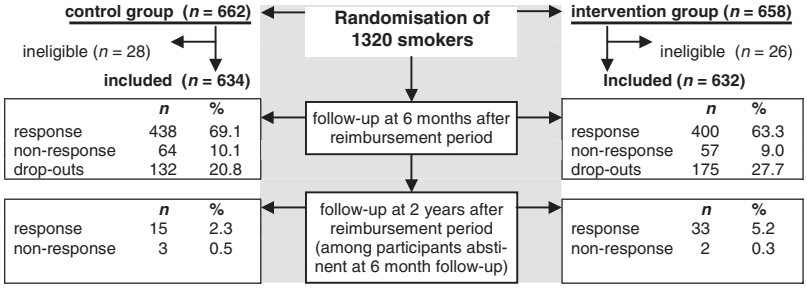

Figure 1 Recruitment, study design, assessments and participants' flowchart

questionnaire 6 months later. Prolonged biochemical validated abstinence was defined as prolonged self-reported abstinence combined with an expired air carbon monoxide level lower than 7 parts per million (p.p.m.) at both the end of the reimbursement period and 6-month follow-up [9]. Prolonged abstinence at 2 years was defined as self-reported abstinence since 7 days preceding the end of the reimbursement period and not having smoked until the follow-up assessment 2 years later.

As smokers could be less motivated to quit if SCT is available free of charge, we examined the possibility that with reimbursement the effectiveness of SCT would decline. For that reason, we linked the cessation methods that participants had used during the reimbursement period to the self-reported prolonged abstinence outcomes at 6-month and 2-year follow-up. The cessation methods used were registered by questionnaire at the end of the reimbursement period. We did not assess the compliance of using SCT.

Statistical analysis

All eligible and randomized participants were included in the intention to treat (ITT) analyses, in which non-responders or dropouts were considered smokers. For the demographic variables and smoking characteristics, descriptive statistics were presented and χ^2 tests and *t*-tests were performed. Risk differences (RD) (i.e. absolute change in risk attributable to intervention) and odds ratios (OR) with corresponding 95% confidence intervals (CI) were calculated to determine the difference between the control and intervention group on abstinence from smoking. The level of significance was set at $\alpha < 0.05$ (two-tailed).

RESULTS

Participants

Of the 1266 smokers included, the mean age was 39.7% [12.8 standard deviation (SD)] and 55.3% were male. Of the participants, 25.7% had a low education level, 19.8% a middle education level and 18.8% a high level of education (35.7% were missing). The mean score on the FTND was 3.4 (2.1 SD) and on average people smoked 13.7 cigarettes (9.3 SD). At 6-month follow-up, questionnaires were completed and returned by 400 participants from the intervention group (63%) and by 438 participants from the control group (69%) (Fig. 1). Non-responders and dropouts were compared with those who returned the questionnaire. There were no significant differences, except for age. The non-responders and dropouts had a mean age of 38.0 years (13.6 SD) and the responders had a mean age of 40.4 years (12.5 SD) ($t = 3.1$, df = 1190, $P < 0.01$). Of the participants who were still abstinent at 2-year follow-up, the mean age was 41.7 years (14.7 SD), 62.2% were male, 32.4% had a low education level, 54.1% had a middle educational level and 13.5% had a high educational level. At baseline, the mean score of the FTND was 2.9 (2.0 SD) and smoked on average 12.9 cigarettes (6.9 SD).

Prolonged abstinence at 6-month follow-up

Six months after the reimbursement period, 18 participants in the control group (2.8%) and 35 participants in the intervention group (5.5%) reported abstinence for at least 6 months. Table 1 shows that significantly more quitters were abstinent in the intervention group (OR = 2.0, 95% CI 1.1–3.6).

The smoking status of six of the 18 self-reported quitters in the control group (33.3%) and 24 of the 35 self-reported quitters in the intervention group (68.6%) was validated biochemically at both the end of the reimbursement period and 6-month follow-up. Table 1 shows that the validated biochemically 7-day point prevalence at 6-month follow-up and the 6-month sustained abstinence rate was significantly higher in the intervention group when compared with the control group.

Five smokers in the control group and three smokers in the intervention group, who reported abstinence at the end of the reimbursement period *or* at 6-month follow-

Table 1 Effects of reimbursement on abstinence from smoking at 6-month and 2-year follow-up.

	Controlgroup n (%)	*Intervention group n (%)*	*RD (95% CI)*	*OR* (95% CI)*
Point prevalent abstinence				
6-month self-reported	44 (6.9)	62 (9.8)	2.9 (–0.1–5.9)	1.5 (1.0–2.3)
6-month biochemically validated	18 (2.8)	34 (5.4)	2.5 (0.3–4.7)	1.9 (1.1–3.5)
Prolonged abstinence				
6-month self-reported	18 (2.8)	35 (5.5)	2.7 (0.5–4.9)	2.0 (1.1–3.6)
6-month biochemically validated	6 (0.9)	24 (3.8)	2.9 (1.2–4.5)	2.8 (1.3–5.8)
2-year self-reported	10 (1.6)	27 (4.3)	2.7 (0.8–4.5)	4.1 (1.7–10.2)

*Corrected for age and gender.

Table 2 Use and effectiveness on self-reported prolonged abstinence of SCT in the control and intervention group.

Group	*Follow-up*	*Smoking status*	*Total use, n (%)*	*Effectiveness,%*
Control group	6 months	Smokers ($n = 616$)	22 (4)	15
		Quitters ($n = 18$)	4 (22)	
	2 years	Smokers ($n = 624$)	24 (4)	8
		Quitters ($n = 10$)	2 (20)	
Intervention group	6 months	Smokers ($n = 597$)	51 (9)	25
		Quitters ($n = 35$)	17 (49)	
	2 years	Smokers ($n = 605$)	53 (9)	22
		Quitters ($n = 27$)	15 (56)	

up, appeared to be smokers by biochemical validation. These smokers were not counted as self-reported quitters. No one who claimed prolonged abstinence was proved to be smoking by exhaled carbon monoxide. No appointment for biochemical validation at both the end of the reimbursement period and 6-month follow-up could be made with nine of the 18 self-reported quitters (50.0%) in the control group, one participant (5.6%) was in hospital and two participants (11.1%) declined to participate. Of the 35 self-reported quitters in the intervention group, no appointment could be made, at one or both occasions, with six self-reported quitters (17.1%) and five participants declined to participate (14.3%). Defining the participants who declined to participate in the biochemical validation as smokers, then the OR for 6-month sustained abstinence was 1.9 (95% CI 0.98–3.7) in favour of the intervention group.

Prolonged abstinence at 2-year follow-up

Of the 53 self-reported quitters, 48 could be contacted for the 2-year follow-up measurement. Two quitters in the intervention group (5.7%) and three quitters in the control group (5.6%) could not be reached (Fig. 1). Ten participants in the control group (1.6%) and 27 participants in the intervention group (4.3%) reported abstinence for at least 2 years (OR = 4.1, 95% CI 1.7–10.2) (Table 1). The mean time of abstinence was 26.7 months (1.9 SD) in the control group and 28.2 months (1.9 SD) in the intervention group ($t = 2.0$, df = 35, $P < 0.05$). The relapse rate after the 6-month follow-up assessment was 44% in the control group and 23% in the intervention group. This difference in relapse rate was not statistically significant ($\chi^2_{(1)} = 2.6$, $P = 0.1$).

The effectiveness of reimbursed SCT

Of the 68 participants who used SCT during the reimbursement period in the intervention group, 42 (61.8%) combined behavioural support and pharmacological treatment. In the control group, 10 (38.5%) of the 26 participants used both treatment methods. As the treatment methods were not mutually exclusive, we did not present the effectiveness per treatment method. At 6-month follow-up the overall effectiveness of SCT in the intervention group was 25%, i.e. 17 participants of the 68 participants who had used SCT were abstinent (Table 2). Two years after the reimbursement period, the overall effectiveness was 22%. In the control group, i.e. without reimbursement, the overall effectiveness of SCT was 15% at 6-month and 8% at 2-year follow-up.

Of the users of SCT in the intervention group, only 45 participants (66.2%) applied for reimbursement. Thirty-eight participants received reimbursement for pharmacotherapy (combined with visits to the general practitioner in 40% of the cases) and seven participants applied for reimbursement of health-care providers only. Eighty per cent of the applications were sent in the first 3 months of the reimbursement period. Participants who applied for reimbursement were older (47.9 years, 10.5 SD) and 44.4% had a low educational level. Both were not significantly different from the intervention group.

DISCUSSION

Sustained abstinence

In this follow-up study, we primarily assessed the effects of reimbursement for SCT on sustained abstinence. Results showed that with reimbursement significantly more participants were abstinent 6 months and 2 years after the reimbursement period had ended. The adjusted odds of being abstinent, controlling for age and gender, was two to four times higher when reimbursement was offered compared to no financial compensation. Only one other study reported the effects of reimbursement on prolonged abstinence, but in a study by Boyle *et al*. [10] no effect was found. In contrast to our study, participants in the study by Boyle *et al*. were not informed explicitly about the reimbursement offered and accordingly only 30% of the smokers in the benefit group were aware of the reimbursement. The suggestion that reimbursement for SCT is more effective when smokers are informed and aware of the coverage seems supported by US data [11–13].

The effects of full reimbursement versus no reimbursement for SCT on self-reported point prevalence abstinence after 6 months were studied by two controlled trials by Hughes *et al*. [14] and Schauffler *et al*. [15]. In a Cochrane Review, the point prevalence abstinence data [14,15] and the prolonged abstinence data [10] were pooled, which resulted in an odds of 1.48 (95% CI 1.17–1.88) in favour of offering reimbursement for SCT [16]. In addition, if comparing full with partial coverage, studies by Curry *et al*. [17] and Hughes *et al*. [14] demonstrate that more participants quit smoking at 6 months in the full coverage group (OR 2.49; 95% CI 1.59–3.90) [16].

Effectiveness of reimbursed SCT

Furthermore, we examined the effectiveness of reimbursed SCT. At 6-month follow-up, the overall effectiveness of SCT was 10% higher with than without reimbursement and 2 years after the reimbursement period the difference was 14% in favour of the reimbursement group. Concern that the effectiveness of the treatment methods would decline if SCT was available free of charge is not supported by our results. An explanation for an increased effectiveness with reimbursement might be that participants had to contact their health-care provider before they could obtain coverage. From the literature, it is known that personal contact with a health-care provider increases the abstinence rate [4,18]. Secondly, reimbursed participants may have used SCT for longer periods, which can also increase the success rate of a quit attempt.

The effectiveness of SCT on prolonged abstinence from smoking after 2 years in the intervention group (22%) is relatively high. Data from Cochrane Reviews show that the 12-month effectiveness in clinical studies was between 13 and 20% for the diverse treatment methods [19–21]. Because in this study only a small number of participants used SCT, no hard conclusions can be drawn; however, it may indicate that real-life effectiveness with reimbursement is no lower than in clinical studies.

Limitations

A limitation of this study concerns the validation of self-reported quitters. We measured expired air carbon monoxide, which is non-invasive and easy to use, but has a restricted time period and low sensitivity if smoking less than 10 cigarettes a day. Not all self-reported quitters could be validated biochemically and the number of participants with whom no appointment could be made was higher in the control group. Only 33% of the self-reported quitters in the control group could be validated biochemically at the end of the reimbursement period and 6-month follow-up and in the intervention group this was 69%. Less involvement in the study and less compliance could be an explanation for the difficulties that were present when making appointments for biochemical validation with participants in the control group. Because of this difference between the groups, the results of the biochemical validation should be interpreted with care. However, one should keep in mind that in the current study no reward or penalty was linked to smoking status. However, quitters could have been less than truthful about their smoking status. The same is true for the quitters at 2-year follow-up, i.e. no biochemical validation was performed with this assessment.

Concluding remarks

Taken these limitations into account, we conclude cautiously that reimbursement for SCT in combination with information may be effective in increasing prolonged abstinence rates, even after 2 years, and that reimbursement might increase the success rates of evidence-based SCT.

The impact of this study on the Netherlands and on other countries depends on the generalizability of the study results. Despite the fact that the study was conducted in one region with one local health insurance company, there is no reason to assume that the results are not generalizable to the general population. Moreover, as we tried explicitly to fit the real-life situation, the examined reimbursement system could be implemented almost directly into the Dutch health-care system. The generalizability of the results of this study to other countries depends on the differences in health-care systems between the countries, which is not easy to evaluate. However, a Cochrane Review [16] demonstrated that with full reimbursement the adjusted odds of being abstinent, controlling for age and gender, at 6 months was in general 1.5 times higher than without reimbursement, indicating that reimbursement for SCT is an effective strategy in other countries as well.

An extensive cost-effectiveness study showed that the mean costs per participant were €291 in the control group and €322 in the intervention group. If society is willing to pay €10 000 for an additional 6-month quitter or €18 000 for a quality-adjusted life year (QALY), it is likely that reimbursement for SCT would be a cost-effective intervention [22]. In addition, this study showed that reimbursement for SCT may increase the number of quitters by 2.7%. In the Netherlands, 28% of the population smokes. If implemented in the Netherlands, reimbursement could help 120 000 people to stop smoking for at least 2 years.

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Declaration of interest

C. P. van Schayck is a member of the International (Health Outcome) Advisory Board of GlaxoSmithKline. E. J. Wagena has been employed by Solvay Pharmaceuticals BV since March 2005. From January 2006, E.J. Wagena works for Astellas Pharma. Both membership and employment had no influence on this study or the views expressed in this paper.

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