RESEARCH PAPER

Effects of practitioner education, practitioner payment and reimbursement of patients' drug costs on smoking cessation in primary care: a cluster randomised trial

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Objective: To evaluate new strategies to enhance the promotion of smoking cessation in general practice.
Design: Cluster randomised trial, 2×2 factorial design.
Setting: 82 medical practices in Germany, including 94 general practitioners.
Participants: 577 patients who smoked at least 10 cigarettes per day (irrespective of their intention to stop smoking) and were aged 36–75 years.
Interventions: Provision of a 2-h physician group training in smoking cessation methods and direct physician payments for every participant not smoking 12 months after recruitment (TI, training+incentive); provision of the same training and direct participant reimbursements for pharmacy costs associated with nicotine replacement therapy or bupropion treatment (TM, training+medication).
Main outcome measure: Self-reported smoking abstinence obtained at 12 months follow-up and validated by serum cotinine.
Results: In intention-to-treat analysis, smoking abstinence at 12 months follow-up was 3% (2/74), 3% (5/144), 12% (17/140) and 15% (32/219) in the usual care, and interventions TI, TM and TI+TM, respectively. Applying a mixed logistic regression model, no effect was identified for intervention TI (odds ratio (OR) 1.26, 95% confidence interval (CI) 0.65 to 2.43), but intervention TM strongly increased the odds of cessation (OR 4.77, 95% CI 2.03 to 11.22).
Conclusion: Providing cost-free effective drugs to patients along with improved training opportunities for general practitioners could be an effective measure to achieve successful promotion of smoking cessation in general practice.

To make optimal use of the large potential for smoking cessation promotion in general practice is of primary importance to public health. In particular, barriers related to the structure of the healthcare system and strategies to overcome these barriers have to be identified. Surveys conducted among general practitioners in different countries disclosed similar obstacles to smoking cessation promotion, such as the lack of time, inadequate reimbursement of costs involved in promotion of smoking cessation and lack of training in smoking cessation methods.[1–5] For example, in the German healthcare system, no reimbursement is provided to general practitioners for specific counselling in smoking cessation; added to this, drugs that are proved to be effective in supporting smoking cessation are not covered by health insurance. Thus, patients will have to pay for nicotine replacement therapy (about €20 per week, over several weeks) and bupropion (about €130 for a pack of 60 pills) themselves, which may hinder the use of these drugs.

The aim of this study was to evaluate whether and to what extent structural changes could enhance promotion of smoking cessation in general practice. In particular, we aimed to investigate the effect of the following strategies on smoking cessation rates: (1) specific training of general practitioners in methods of promoting smoking cessation and a financial incentive to general practitioners for each recruited patient who successfully quits; and (2) specific training of general practitioners in promotion of smoking cessation and the cost-free prescription of drugs proved effective in supporting smoking cessation.

METHODS

Study design and participants

We conducted a cluster randomised trial among smoking patients of general practitioners in the Rhine–Neckar region, located in southwest Germany. Among 248 general practitioners who participated in a survey on promotion of smoking cessation and reported initial interest in the study,[5] 174 who reported to have conducted at least 30 general health screening examinations in the past 3 months were invited to participate in patient recruitment, and 94 general practitioners from 82 practices eventually agreed to participate. Owing to the nature of the interventions, the unit of randomisation was the medical practice. Practices were randomly allocated to one of four intervention arms in a 2×2 factorial design crossing two interventions, with the "usual care" arm serving as the reference group. Randomisation was performed centrally at the German Center for Research on Ageing, Heidelberg, Germany, using PROC PLAN in SAS.[6]

From October 2002 to September 2003, patients visiting the practices were recruited by the participating general practitioners. Patients aged 36–75 years who smoked at least 10 cigarettes/day were eligible irrespective of their intention to stop smoking. Written informed consent was obtained for each patient. The study was approved by the ethics board of the University of Heidelberg, Heidelberg, Germany, and by the Ethics Board of the medical association of the State of Baden–Wuerttemberg, Germany.

Intervention

Two interventions were provided to general practitioners within the trial: TI (training+incentive) and TM (training+medication).

Intervention TI included the provision of a 2-h cost-free group tutorial for general practitioners in methods of promoting smoking cessation, which covered issues such as the stages of change model, approaches for smoking cessation counselling

in general practice and the potential of pharmacological support for smoking cessation (nicotine replacement therapy or bupropion). Two sessions of this tutorial were offered shortly before the start of the recruitment period. Additionally, general practitioners were assured a financial remuneration of €130 after study completion for each study participant they recruited who was proved "smoke free" at 12 months follow-up.

Intervention TM included provision of the same group tutorial. Additionally, general practitioners could offer cost-free prescription of drugs proved effective in supporting smoking cessation—that is, nicotine replacement therapy or bupropion, to study participants during the follow-up period of 12 months. Participants had to purchase these drugs in pharmacies as usual, but costs were reimbursed up to a maximum of €130 per participant (which covers the costs of recommended treatment schemes) by the study centre after transmittal of prescription and bill.

Owing to the nature of the interventions, general practitioners and participants could not be blinded to the intervention.

Data collection

At the practice visit, a standardised self-administered questionnaire was handed out to participants, asking for information on current smoking status, nicotine dependence (by the Fagerström test),[7] stage of change for smoking cessation,[8] smoking history and demographics. In an active follow-up 12 months after recruitment, all participants were sent a standardised questionnaire asking for information on current smoking status, stage of change for smoking cessation and cessation attempts during the follow-up period. In this 12-month follow-up, participants were asked to visit their general practitioner for collection of a blood sample, and information on methods for promotion of smoking cessation used during follow-up was collected via a standardised form from the recruiting doctor. After completion of follow-up, a standardised questionnaire was sent to general practitioners, and information about the change in promotion of smoking cessation during the study was collected.

Laboratory analysis

Blood samples collected in the follow-up 12-months after recruitment were sent to a central laboratory, and cotinine levels in serum were determined in a blinded fashion by radioimmunoassay, according to the manufacturer's instructions (Immundiagnostik, Bensheim, Germany).

Statistical analysis

We compared the distribution of baseline characteristics of medical practices, general practitioners and participants in the different treatment arms. Next, we compared the frequency of the use of methods to support smoking cessation among participants during the follow-up period as reported by general practitioners.

The primary end point, point prevalence of smoking abstinence at 12 months follow-up, was determined according to the intention-to-treat approach: only those participants who reported to be smoke free and were cotinine negative (serum cotinine <15 ng/ml)[9] in 12 months follow-up were regarded as smoke free. All remaining participants were treated as continuous smokers, including those who reported to smoke, who were cotinine positive, or whose data on self-reported or cotinine-based smoking status were missing. Only those participants who had died during follow-up, who had moved to an untraceable address or who reported to be smoke free and to use nicotine replacement therapy at follow-up (which made validation of smoking abstinence by radioimmunoassay of serum cotinine impossible) were excluded from the statistical analysis.

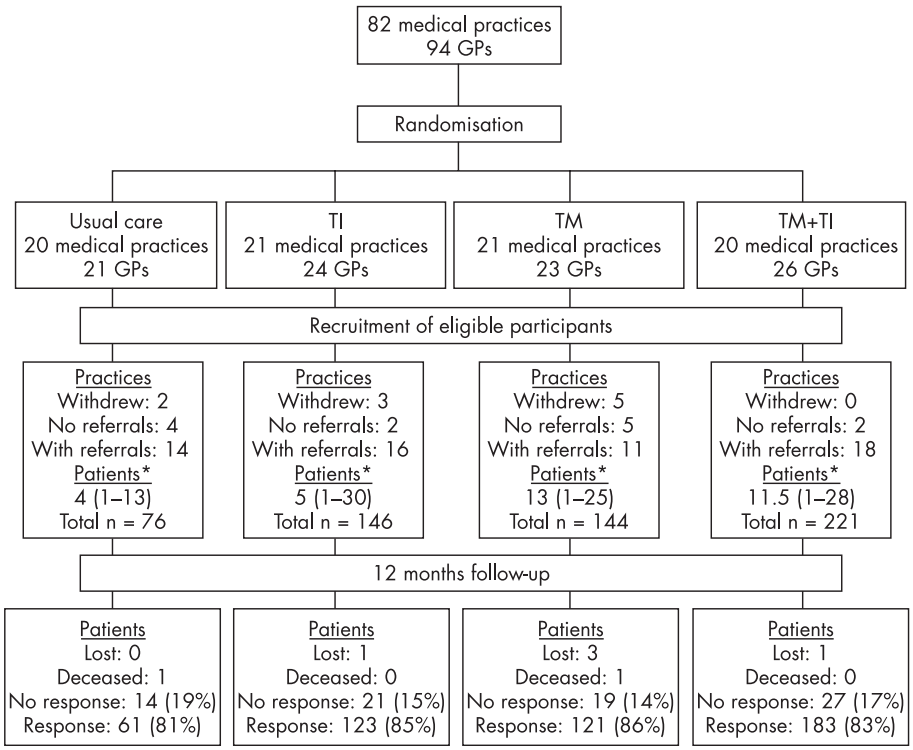

Figure 1 Flow of practices and patients through the trial. GP, general practitioner; TI, training and incentives; TM, training and medication. *Values are median (range) per practice.

Table 1 Baseline characteristics of participants by intervention arm (n = 587)

	Usual care n = 76	TI n = 146	TM n = 144	TI+TM n = 221	p Value*
Sex					
Female	38 (50)	74 (51)	71 (49)	121 (55)	0.73
Age (years)					
<45	30 (39)	55 (38)	59 (41)	95 (43)	
45–54	24 (32)	63 (43)	44 (31)	86 (39)	
⩾55	22 (29)	28 (19)	41 (28)	40 (18)	0.16
Nationality					
German	67 (92)	131 (91)	127 (90)	188 (88)	0.70
School education (years)					
<10	47 (64)	77 (57)	81 (58)	118 (55)	
10–11	17 (23)	37 (27)	30 (22)	48 (22)	
12–13	9 (12)	22 (16)	28 (20)	48 (22)	0.46
Family status					
Married or registered partnership	45 (63)	93 (67)	93 (67)	137 (64)	0.84
Cigarette consumption per day					
10–19	16 (23)	42 (29)	35 (26)	55 (26)	
20–29	28 (39)	67 (47)	48 (35)	84 (40)	
⩾30	27 (38)	35 (24)	53 (39)	73 (34)	0.21
Nicotine dependence (FTND)†					
Minimal (0–3)	13 (20)	33 (24)	30 (24)	32 (17)	
Moderate (4–6)	32 (50)	72 (53)	52 (42)	105 (56)	
Strong (7–10)	19 (30)	30 (22)	42 (34)	50 (27)	0.17
Stage of change for smoking cessation					
Pre-contemplation	28 (39)	64 (44)	25 (18)	32 (15)	
Contemplation	39 (54)	70 (48)	101 (72)	139 (65)	
Preparation	5 (7)	11 (8)	15 (11)	42 (20)	<0.001

FTND, Fagerström test for nicotine dependence
Values are n (%).
TI, training+incentive; TM, training+medication.
*Derived from the Mantel–Haenszel χ^2 statistic.
†Score of the FTND.

The point prevalence of abstinence at 12 months follow-up was determined separately for each treatment arm. The effect of both interventions on smoking abstinence at 12 months follow-up was assessed simultaneously in a mixed logistic regression model accounting for cluster randomisation—that is, including a random effect for medical practice in the model, using PROC NLMIXED in SAS, V.8.1.[10] In addition to a bivariate analysis, we conducted a multivariate analysis in which we adjusted for all baseline factors that were unequally distributed between intervention arms, as assessed by Mantel–Haenszel χ^2 ($p<0.05$).

As a secondary end point, continuous abstinence for at least 6 months (183 days) at 12 months follow-up was determined. Participants were categorised as ''at least 6 months abstinent'' if they were smoke free at the 12 months follow-up (validated by serum cotinine) and, according to self-report, had stopped smoking at least 6 months before the date of follow-up. The effect of both interventions on continuous abstinence for at

Table 2 Methods used to support smoking cessation during follow-up by intervention arm, as reported by general practitioners

	Usual care n = 54	TI n = 114	TM n = 110	TI+TM n = 153	p Value*
Written material	8 (15)	37 (32)	34 (31)	36 (24)	0.39
Individual counselling	32 (59)	83 (73)	74 (67)	100 (65)	0.94
Nicotine replacement therapy	4 (7)	15 (13)	33 (30)	34 (22)	0.16
Nicotine gum	2 (4)	8 (7)	8 (7)	14 (9)	
Nicotine patch	2 (4)	9 (8)	25 (23)	22 (14)	
Nicotine nasal spray	0 (0)	0 (0)	0 (0)		
Nicotine lozenge	0 (0)	4 (4)	4 (4)	4 (3)	
Bupropion	2 (4)	3 (3)	26 (24)	18 (12)	0.03
Nicotine replacement or bupropion	6 (11)	17 (15)	55 (50)	47 (31)	0.003

Values are n (%).
TI, training+incentive; TM, training+medication.
*p Value for the difference in distribution between intervention arms derived in mixed logistic regression.

Table 3 Point prevalence of smoking abstinence at 12 months follow-up by intervention arm

	Usual care	TI	TM	TI+TM
Smoking abstinence, self-reported				
Not abstinent	71 (96)	134 (93)	119 (85)	181 (83)
Abstinent	3 (4)	10 (7)	21 (15)	38 (17)
Smoking abstinence, validated				
Not abstinent	72 (97)	139 (97)	123 (88)	187 (85)
Abstinent	2 (3)	5 (3)	17 (12)	32 (15)
p Value*		0.75	0.046	0.02

TI, training+incentive; TM, traing+medication.
Values are n (%).
*Compared with the usual care group, retrieved in mixed logistic regression.

least 6 months was again evaluated in a bivariate and an adjusted mixed logistic regression model.

The effect of drug use during follow-up, as recorded by general practitioners, was evaluated in a bivariate mixed logistic regression model.

Sample size calculation

Initial power calculations were based on the expected point prevalence of abstinence of 5% in usual care, 10% in interventions TI and TM, and 15% in the intervention TI+TM in a 12-month follow-up. With an intended number of 720 patients recruited from 80 practices, a difference of the expected size between usual care and the TI+TM arm would have been detected at the 5% level of significance (two sided) with a power of >85%. Power calculation did not account for intraclass correlation, which was expected to have a minor effect on the required sample size.

RESULTS

Of the 82 practices, 20, 21, 21 and 20 were randomised to the usual care, TI, TM and TI+TM arms, respectively. In 12 practices two general practitioners participated in the trial, leading to a total of 94 participating doctors. We found no significant differences between the four groups of general practitioners with respect to the number of general practitioners per practice ($p = 0.13$), location ($p = 0.62$), sex ($p = 0.38$), age ($p = 0.19$) or smoking status ($p = 0.21$). About two thirds of general practitioners invited to the training in methods of promoting smoking cessation did participate, and participation rates were similar in the respective intervention arms. During the recruitment period, 13 general practitioners (10 practices) withdrew their participation and another 13 had no referrals of eligible patients (fig 1). In the remaining 59 practices, 587 eligible participants were recruited: 76, 146, 144 and 221 participants were recruited in the usual care, TI, TM and TI+TM arms, respectively.

Participants did not differ substantially at baseline by intervention arm, except regarding the stage of change for smoking cessation: in arms TM and TI+TM, the proportion of participants in the pre-contemplation stage—that is, participants with no concrete intention to stop smoking—was lower, and the proportion of participants in both the contemplation and preparation stages was higher than in the usual care and TI arms (table 1).

Two participants died during the follow-up period and five participants could not be located. Also, three participants in whom smoking abstinence could not be validated as a result of current use of nicotine replacement therapy were excluded, leaving 577 patients for the analysis. For 431 (76%) of these participants, information by general practitioners was available on methods used during follow-up to support smoking cessation (table 2). Individual counselling was most commonly reported, followed by the use of written material, and prescription of nicotine replacement therapy and bupropion. Nicotine replacement therapy and bupropion were prescribed more often in the arms where the reimbursement for costs of these drugs was offered (TM and TI+TM) than in the arms with no such offer.

In the 12 months follow-up, of the 487 participants who provided self-reported data, 72 reported themselves to be smoke free. Nine of those participants had positive cotinine values and seven did not provide a blood sample, leaving 56 participants

Table 4 Effect of the interventions on point prevalence of smoking abstinence at 12 months (results of the mixed logistic regression model)

	Total n (column-%)	n abstinent (row-%)	Crude OR (95% CI)	Adjusted OR (95% CI)*
TI: training+financial incentive for GP				
Not abstinent	214 (37)	19 (9)	1.00†	1.00†
Abstinent	363 (63)	37 (10)	1.26 (0.65 to 2.43) p=0.50	1.13 (0.60 to 2.12) p=0.70
TM: training+cost-free drugs				
Not abstinent	218 (38)	7 (3)	1.00†	1.00†
Abstinent	359 (62)	49 (14)	4.77 (2.03 to 11.22) p<0.001	4.31 (1.87 to 9.93) p=0.001
Intracluster correlation coefficient			<0.042	<0.015

TI, training+incentive; TM, training+medication.
GP, general practitioner.
*Adjusted for baseline stage of change; 13 observations were excluded because of missing values in this variable.
†Reference category.

who both reported to be smoke-free and were cotinine negative. The point prevalence of smoking abstinence 12 months after recruitment was 3%, 3%, 12% and 15% in the usual care, TI, TM and TI+TM arms, respectively (table 3). Differences between the TM and TI+TM arms and the usual care arm were significant (p = 0.046 and 0.02, respectively).

Table 4 gives the results regarding the effect of both interventions on smoking abstinence 12 months after recruitment, obtained from a common mixed logistic regression model. Intervention TI was not significantly associated with the point prevalence of abstinence at 12 months follow-up (odds ratio (OR) 1.26, 95% confidence interval (CI) 0.65 to 2.43), whereas intervention TM was associated with a strong increase in prevalence of abstinence (OR 4.77, 95% CI 2.03 to 11.22). Adjusting for baseline stage of change for smoking cessation of participants did not materially alter the estimates of effects.

Of the 56 patients abstinent at follow-up, 33 reported to have stopped smoking at least 6 months earlier. Similar to the point prevalence of being smoke free, continuous abstinence for at least 6 months was higher in the TM (13/140, 9%) and TI+TM (17/219, 8%) arms than in the usual care (1/74, 1%) and TI (2/144, 1%) arms. In the mixed logistic regression model, we observed no effect of intervention TI, but a strong significant effect of intervention TM in both crude analysis (OR 6.13, 95% CI 1.65 to 22.68) and adjusted analysis (OR 5.43, 95% CI 1.48 to 19.84).

With respect to drug use alone (as reported by general practitioners), the provision of nicotine replacement therapy or bupropion was associated with an increased point prevalence of abstinence (OR 3.33, 95% CI 1.78 to 6.20). After study completion, 41%, 88%, 64% and 76% of the 71 general practitioners participating in our post-trial survey in the usual care, TI, TM and TI+TM arms, respectively, reported that they now give smoking cessation advice more often, and 6%, 16%, 50% and 43% in the usual care, TI, TM and TI+TM arms, respectively, reported that they thought they had been more successful in promoting smoking cessation.

DISCUSSION

In our cluster randomised trial on strategies to promote smoking cessation in general practice, one of the interventions was highly effective. The cost-free provision of drugs to support smoking cessation for patients along with improved training opportunities for general practitioners in methods of promoting smoking cessation seems to strongly increase the success of promotion of smoking cessation in general practice. In conjunction with the enhanced reach of patients, indicated by higher recruitment numbers, these offers may serve as a powerful strategy to reduce smoking prevalence in the general population.

Our results are consistent with and extend the results of previous studies on the effects of training programmes for doctors in methods of promoting smoking cessation.[11 12] These studies often evaluated the effect of programmes on rates of advice in addition to the level of quit rates. Training programmes have been shown to have beneficial effects in terms of increased numbers of people whom health professionals identify as smokers, and increased numbers of people who are offered advice and support for quitting. However, an effect on quitting smoking could not be proved. In our study, it is difficult to disentangle the effect of the training and that of the incentive for general practitioners or the coverage of treatment, as a training-only arm was not included. However, the increased number of recruited patients and the (self-reported) increased rate of advice among doctors in all intervention arms offering the training programme may be regarded as an indicator for increased rate of advice caused by training. This and the observation of increased cessation rates only if cost-free drugs were offered seem to support earlier findings.

Coleman *et al*[13] evaluated the introduction of payment to doctors for the identification of patients who stopped smoking; they could not find an increase in smoking-related advice given by general practitioners. Explanations for the absence of effect were that payment did not overcome the major barriers to promotion of smoking cessation and that the payment (£15) was insufficient.[14] Our results do support these findings and show that even a much higher payment is not an effective measure to increase general practitioners' successful advice for smoking cessation.

In our trial, the decisive intervention leading to increased cessation rates was the provision of cost-free drugs along with improved training opportunities for general practitioners. Although the effectiveness of pharmacological smoking cessation support by nicotine replacement therapy or bupropion is beyond doubt,[15 16] utilisation of these products is low in many countries including Germany.[17] Low utilisation might be partly because of a lack of knowledge or lack of perceived effectiveness in smokers,[18] but the lack of reimbursement might be an additional obstacle. Some evidence, although not conclusive, suggests that at least self-reported prolonged abstinence is increased if full financial coverage is provided when compared with a partial or no coverage.[19]

In a longitudinal observational study comparing different insurance coverage plans in the US, the usage of smoking-cessation services, including nicotine replacement therapy, and the percentage of quitters increased with increasing coverage.[20] Likewise, in an individually randomised trial conducted in the US, those smokers who were offered cost-free smoking cessation treatment (nicotine replacement therapy and group behavioural cessation programmes) in addition to a self-help kit had higher rates of quit attempts, higher usage of nicotine gum or patch and higher quit rates after 12 months than smokers who were offered only the self-help kit.[21] However, smoking status in this study was only self-reported. Furthermore, interventions were not delivered to doctors but directly to smokers, and thus could not have an effect on physicians promoting smoking cessation.

Our findings underline the importance of insurance coverage for drugs to support smoking cessation. Besides the effect of higher rates of utilisation of prescribed drugs with lower co-payments, as reported in other trials, we observed an increase in prescriptions of drugs. This indicates an additional effect of the intervention on the general practitioners and their practice of promoting smoking cessation. General practitioners may also feel more comfortable initiating the topic of smoking cessation if they are able to provide some pharmacological support to their patients. This hypothesis is strengthened by our finding that, particularly in these study arms, the confidence of general practitioners in being successful in promoting smoking cessation increased. In the UK, effective aids to smoking cessation are available on National Health Service prescription, and this policy is widely accepted and used by general practitioners.[22]

Our study has the following limitations: owing to the inclusion of smokers irrespective of the intention to quit, the quit date could be any time within the follow-up period. Although continuous abstinence is the preferable outcome measure of a smoking cessation trial,[23] the absence of a common quit date made us focus on the percentage abstinent at a given time, which is a commonly used end point in so-called cessation-induction trials like ours.[24] However, the additional analysis of continuous abstinence for at least 6 months during the time of follow-up indicates the effectiveness of intervention TM also in the long run.

The general practitioners participating in this trial were not a random selection but a selected group recruited from participants of a survey on promotion of smoking cessation. This

What this paper adds

- Although the efficacy of measures to promote smoking cessation in general practice, such as counselling or nicotine replacement therapy, has been shown in numerous studies, the use and implementation of these measures is insufficient.
- Strategies that will help overcome barriers to implementation of these measures in general practice have to be identified.
- The provision of training opportunities for general practitioners in methods of promoting smoking cessation, along with the possibility to prescribe drugs free of cost for the support of smoking cessation for patients, strongly increases the extent and success of promoting smoking cessation in general practice.

group might be characterised by an increased commitment to the issue of smoking cessation and to improving their quality of cessation promotion. Thus, the uptake of training opportunities we observed may not be generalisable. However, among general practitioners with initially lower commitment to smoking cessation, the potential for improvement in promoting smoking cessation is particularly large, and thus interventions could have even stronger effects.

We were unable to obtain numbers of patients approached for the study from the recruiting general practitioners and thus cannot provide initial response rates. Previous research suggests that general practitioners tend to introduce some unplanned selection criteria in smoking cessation trials, and are more likely to enrol smokers with pre-existing disease or symptoms.[25] Whereas a limited representativeness would hamper generalisability to all smoking patients, internal validity would not necessarily be affected.

The selection of different types of patients at the different practices based on the intervention offered could have had a major effect on study results, particularly if the selection factor would be associated with quit rates. Therefore, the differential proportion of participants in the various stages of change, which is an indicator of motivation to quit smoking, has to be considered. Neither this differential proportion nor the differential number of participants recruited can be explained by differences in recruitment procedure: The patient information material in all groups was identical, with the exception of the particular intervention that was provided in the respective group, about which the participants had to be informed. Also, in all study groups, general practitioners received the same reimbursement for the recruitment of one participant.

The finding of higher numbers of smokers prepared to quit could, however, reflect an additional effect of the intervention rather than a source of selection bias: the intervention itself might have increased the rate of participation, in particular among smokers more ready to quit. Furthermore, participation itself might have initiated cessation intentions, as it might have been perceived as an opportunity to tackle the problem of smoking, causing an overall increased proportion of smokers in the contemplation and preparation stage of change in comparison to a recent random sample from the German population.[26] This effect on intentions of cessation might have been particularly strong in those study arms where smokers received co-payments for treatment and thus were able to spare up to €130 if they started a cessation attempt within the trial period. However, other explanations for the differential distribution of stages of change in the study groups, such as participating general practitioners might have selected patients who seemed to be more motivated to stop smoking in arms of the trial where free nicotine addiction treatments were available, cannot be excluded. To evaluate the magnitude of this possible bias, we performed an additional adjusted analysis. As results show, the differential distribution of stages of change accounted for a minor share of the effect of the intervention only on cessation rates, and a strong and statistically significant effect persisted even when differences in stages of change were accounted for in adjusted analysis.

From a health policy point of view, the combination of both an increased rate of participation in a programme that offers enhanced access to effective smoking cessation aids and an increased rate of quitting among participants can be considered to be a particularly desirable outcome of specified interventions.

In conclusion, our results support the hypothesis that the provision of cost-free drugs to patients to support smoking cessation along with improved training opportunities for general practitioners may be a promising strategy for the enhancement of promoting smoking cessation in general practice. In light of the still very high prevalence of smoking and the enormous health benefits of smoking cessation in many countries, coverage of treatment for smoking cessation by health insurance and provision of easy-to-reach and low-cost training opportunities for general practitioners can have a large effect on public health.

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Ethical approval: The study was approved by the ethics board of the University of Heidelberg and by the ethics board of the medical association of the State of Baden–Wuerttemberg.

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The Lighter Side

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Notes