204 European Journal of Public Health

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Effectiveness of pharmacotherapy in behavioural therapeutic smoking cessation programmes

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Background: In 2011, pharmacotherapy as a part of smoking cessation treatment was reimbursed through the basic health insurance in the Netherlands. We examine the (cost)-effectiveness of pharmacotherapy added to behavioural therapy. Methods: An observational study was conducted using data from the suppliers of the smoking cessation programmes together with information on costs from health insurance company Achmea. National suppliers, general practitioners and healthcare centres offered four different programmes. (i) Behavioural support (=therapy); (ii) Behavioural support combined with nicotine replacement therapy (NRT); (iii) Behavioural support combined with smoking cessation aids (=medication) (SCA); (iv) Behavioural support combined with NRT and SCA. The primary independent variable was the programme type, and the primary outcome was whether someone quitted smoking. To examine the effectiveness of the different programmes logistic regression and logistic multilevel analyses were performed. Bootstrapping was used to evaluate cost-effectiveness. Results: The results indicate that behavioural support combined with SCA has more guitters than the reference programme of behavioural support alone, and it also seems the most cost-effective programme for general practitioners and healthcare centres. Behavioural therapy combined with NRT had also more guitters, although the difference with the reference programme was smaller. Conclusion: Behavioural support combined with SCA seems the most successful programme. However, as we performed an observational study, firm conclusions about the differences in effectiveness between the programme types cannot be made. Future research should consider the type of smoker (smoking history, amount of cigarettes per day).

Introduction

Worldwide 5 million people die each year due to the direct and indirect consequences of smoking, which equals one death per 6 s.¹ In the Netherlands, 19 000 people died in 2012 due to smokingrelated diseases.² Smokers lose an average of 4.1 life years and 4.6 healthy life years in comparison with non-smokers.³ This high loss in healthy life years is mainly caused by the higher risks of chronic obstructive pulmonary disease, several types of cancer (particularly lung cancer) and cardiovascular diseases.⁴ Besides, smokers also have an increased risk of non-fatal diseases like osteoporosis, periodontal disease, impotence, male infertility and cataracts.⁵

Studies showed that most smokers want to stop although attempts to quit smoking fail frequently.^{2,6} In 2010, 25% of the Dutch smokers tried to quit, though the percentage of successes varied between 4 and 10%.^{2,7} Most quitters try to give up smoking on their own, without any help.^{8,9} However, cessation based on willpower alone without professional help has an effectiveness of only 3–5%.¹⁰ Several studies demonstrated that the use of smoking cessation programmes increases

the rate of successful attempts. $^{11-16}$ Thereby, smoking cessation programmes show a better cost-effectiveness than many other life-preserving medical interventions. 17

Unfortunately, smoking cessation programmes are relatively expensive and research showed that costs are a threshold for people who want to stop smoking.^{18,19} A Cochrane review of nine trials, found that financial reimbursement caused a 1.29 (95% confidence interval (CI): 1.05–1.59) times higher rate of quitting attempts while a 2.45 (95% CI: 1.17–5.12) times higher rate of abstinence was found.¹⁹ Also implementation of reimbursed smoking cessation programmes led to an increased use of it.²⁰

Since January 2011, different types of smoking cessation aids were included in the basic health insurance in the Netherlands and health insurance company Achmea subsequently contracted diverse suppliers: general practitioners, healthcare centres and national providers.²¹ Due to a revision of the Dutch government pharmaco-therapy as part of smoking cessation programmes was removed from the basic health insurance in January 2012 and only behavioural therapy was included.²² The partnership 'Stoppen met Roken'

advised health insurance companies to include pharmacotherapy in the additional health insurance.²³ Health insurer Achmea decided to first examine the effectiveness and the cost-effectiveness of the various smoking cessation programmes so they can decide whether it is worthwhile to add pharmacotherapy to smoking cessation programmes or not. Health insurance company Achmea initiated this scientific research project, to obtain interesting insights about the effectiveness of the smoking cessation programmes.

In this study, the effectiveness and cost-effectiveness of the programmes that included a form of pharmacotherapy will be compared with the reference programme of behavioural support alone.

Methods

Setting, participants and design

An observational study was conducted using data delivered by the suppliers of the smoking cessation programmes together with information on costs from Achmea. Dutch people insured by Achmea were included in the sample. Because more than a quarter of the Dutch population are insured with Achmea, we expect that in a cross section the smokers among the Achmea clients are also a representative group for all smokers in the Netherlands.²⁴ However, we do not know the smoking status of our clients.

In 2011, Achmea reimbursed smoking cessation programmes offered by contracted suppliers. In total 886 suppliers: 5 national suppliers and 881 of both general practitioners and healthcare centres were contracted. Each Achmea client who applied at a contracted supplier was automatically participant of the research project. Eventually, we had a total of 9422 participants that could be evaluated. The study was observational, as we only had clinical data from the patients dossiers of the suppliers and the smoking cessation programmes were not influenced by the investigators.

Protocol

In practice, smokers who participated in a smoking cessation programme decided together with their therapist in which programme they would participate:

- (1) Behavioural support.
- (2) Behavioural support combined with nicotine replacement therapy (NRT).
- (3) Behavioural support combined with smoking cessation aids (SCA). Bupropion, varenicline and nortryptiline were available for reimbursement.
- (4) Behavioural support combined with NRT and SCA.

Therapists provided smoking cessation support according to existing Dutch guidelines. In these guidelines, it is advised to use a combined programme of behavioural and pharmacological support (programmes 2–4) when the client smokes more than 10 cigarettes a day or when the patient prefers to use them or the therapist thinks it is necessary. NRT is preferred to SCA because of safety. Smoking cessation aids can be used when the client rather wants to use SCA or when he is contraindicated for NRT or when the therapist thinks it is necessary.^{25,26}

In practice, the type of behavioural support varied between suppliers and could consist of face-to-face meetings, telephone coaching or a group programme. The frequency and duration of the meetings were determined in consultation. In our study, we took over the aforementioned grouping for evaluation.

Outcomes

Data were collected by the therapists and was completed in a fixed format. All suppliers received a single reminder for this contractual obligation. We only included the patients whose full report was available. All healthcare providers delivered data on the type of programme (main independent variable), whether or not the patient quitted smoking (main outcome, measured with a 'yes or no'-question) and some additional variables. We compared the programme types within each of the suppliers and therefore included per supplier the useful variables in our study. For the general practitioners and healthcare centres we used: whether someone finished the programme and total amount of treatment time. We added the total amount of patients per provider and the costs per programme to this data. For the national providers the following additional variables were used: birth date, gender, relevant diseases and reason of ending the programme. The suppliers collected the information about the therapy during the programme. At the end they called their patients to ask whether or not they quitted smoking.

Cost data were extracted from the databases of Achmea. All suppliers received a fixed amount for behavioural support, although this amount could vary between suppliers. For most suppliers, the pharmacotherapy was declared separately by the client's pharmacy. To calculate the total costs per patient the mean costs for the use of NRT and/or SCA were added to the fixed amount for behavioural therapy. Mean costs were used because it was not possible to link the pharmaceutical declarations with the other anonymous patient data. Some national providers agreed to declare the behavioural and pharmacological support together, for these providers this rate was used as total amount.

Statistical analysis

Comparison of the amount of quitters within each type of provider between the reference programme and the different forms of combined therapy was done using logistic-regression for the national providers and multilevel analysis for the general practitioners and healthcare centres. Multilevel analysis was used because the data were hierarchical (patient-level and supplierlevel). For the same reason multilevel analysis was not suitable for the data of the national providers. A cost-effectiveness analysis was also performed for the different programme types of behavioural and pharmacological support relative to behavioural support alone.

Statistical Package for the Social Sciences (SPSS) 17.0 was used to describe the baseline characteristics of the research population. Odds ratios (ORs) of logistic regression analysis with corresponding 95% CI were estimated to compare pharmacological support combined with behavioural support with the reference programme of behavioural support only. The ORs were adjusted for age, gender, contact time and relevant diseases of the client. Effect modification was verified for the following variables: age, gender and relevant diseases. A variable was considered an effect modifier when the interaction term was significant.

To examine the association between the type of programme and its effectiveness for healthcare centres and general practitioners logistic multilevel analyses were performed in MlwiN 2.25. ORs with corresponding 95% CI were estimated to compare the programme types in which behavioural support was combined with pharmacotherapy with the reference programme. The multilevel analyses corrected for the different suppliers by including them in the analysis, thereby the following potential confounders were included as covariates: amount of patients and total amount of contact time. A significance level of 5% was used in this study.

An incremental cost-effectiveness analysis (CEA) was performed in Stata 12.0. Incremental cost-effectiveness ratios (ICERs) were calculated as the difference in mean costs between the programme types of behavioural and pharmacological support and the programme type of behavioural support alone divided by the mean difference in quitters. The ICER gives the costs per additional quitter gained from the pharmacotherapy combined with behavioural support relative to the programme of only behavioural support. The cost-effectiveness of the smoking programmes was modelled using bivariate regression models. These models made it possible to correct costs and effects separately for possible confounders. The uncertainty around the cost differences and ICERS was estimated using non-parametric bootstrapping with 5000 replications.²⁷ The distribution of the 5000 bootstrap samples were used to estimate acceptability curves representing the probability that an intervention is cost-effective in comparison with the reference treatment for a range of cost-effectiveness thresholds.²⁸ The costs were not discounted, as the timeframe of the study was limited to 1 year.

Results

Baseline data

Of a total of 886 contracted suppliers, 212 suppliers delivered data over the whole year (192 general practitioners, 15 healthcare centres and 5 contracted national providers. This resulted in a total of 9422 participants. Different types of suppliers delivered different patient data, general practitioners and healthcare centres were asked to deliver only a few important variables. National practitioners were asked to deliver more extensive data.

For general practitioners the mean treatment time was almost 70 min (SD 44.5), and they treated 4622 patients. The healthcare centres treated 1342 patients. Their mean treatment time was a bit longer than the general practitioner (82.5 min with an SD of 47.8).

National providers treated 3458 patients. The patients had a mean age of 46.7 years (SD12.8) and 48% were men. Fifty-five percentage of the patients had a relevant disease. Cardiovascular diseases (23%) and Chronic Obstructive Pulmonary Disease (COPD) (18%) were most often reported as current relevant diseases.

Participants per programme

The number of people who participated in each programme, and the percentages of the people who completed the programme and who quitted smoking are presented in table 1. We did not find a strong correlation between completing the programme and quitting. The number of participants in each programme ranged from 102 (behavioural support at a healthcare centre) to 1763 (behavioural support combined with SCA at a general practitioner). The percentages of people who completed each programme were highest for national providers.

Costs

Table 1 shows that the costs per programme differed between €90 for behavioural support at a general practitioner and €501 for behavioural support combined with NRT and SCA at a national provider. The average costs of each programme are shown in table 1.

Outcome analyses by programme type

(1) National providers

Table 2 shows the results of the effectiveness analyses. The programme of behavioural support combined with SCA seems to give more quitters than behavioural support alone (OR = 1.92; 95% CI = 1.15-3.21). All other programmes did not give significantly more quitters.

(2) General practitioners

All programmes in which behavioural therapy is combined with pharmacotherapy (NRT and/or SCA) gave more quitters than behavioural support alone.

(3) Healthcare centres

Table 2 presents that the programme type in which behavioural therapy is combined with NRT gave more quitters than behavioural support alone (OR = 1.80; 95% CI = 1.04-3.12). Behavioural therapy combined with SCA also resulted in a higher proportion of quitters

| | | Nat | National provider | | | Ū | General practitioner | er | | Health | Healthcare centre | |
|--|--------------------------------|--------------------------------|---------------------------------|---------------------------------------|-------------------------------|--------------------------------|----------------------------------|--|------------------------------|-------------------------------|--------------------------------|--|
| | BS (<i>n</i> = 290) | BS + NRT (<i>n</i> = 1048) | BS+SCA (<i>n</i> = 1200) | BS + NRT + SCA (<i>n</i> = 95) | BS (<i>n</i> = 801) | BS + NRT (<i>n</i> = 1094) | BS + SCA (<i>n</i> = 1763) | BS + NRT + SCA (<i>n</i> = 558) | BS (<i>n</i> = 102) | BS + NRT (<i>n</i> = 304) | BS + SCA (<i>n</i> = 684) | BS + NRT + SCA (<i>n</i> = 126) |
| Programme completed Quitted smoking Mean costs per patient | 129 (83%) 136 (61%) €233 | 370 (41%) 563 (57%) €363 | 1011 (95%) 709 (63%) €368 | 59 (67%) 51 (55%) €501 | 366 (46%) 328 (43%) €90 | 570 (53%) 567 (55%) €195 | 1033 (59%) 1109 (67%) €289 | 285 (52%) 285 (56%) €388 | 39 (40%) 35 (38%) €135 | 90 (45%) 105 (54%) €240 | 282 (60%) 309 (68%) €334 | 531 (54%) 46 (52%) €388 |

Table 1 Percentages of participants who completed the programme and quitted smoking and the mean costs per patient for the different programmes and providers

aids;

cessation

smoking

with

combined

support

BS + SCA = Behavioural

with nicotine replacement therapy;

BS+NRT+SCA=Behavioural support combined with nicotine replacement therapy and smoking cessation aids.

combined

support

BS + NRT = Behavioural

BS=Behavioural support;

| | | National provider | | | General practitioner | | | Healthcare centre | |
|----------------------------------|---|---|---|---|--|--|---|---|-------------------------------------|
| | BS + NRT | BS + SCA | BS + NRT + SCA | BS + NRT | BS + SCA | BS + NRT + SCA | BS + NRT | BS + SCA | BS + NRT + SCA |
| OR (95% CI) ICER | 1.36 (0.81–2.31) 1120 | 1.92 (1.15–3.21) 1617 | 0.74 (0.34–1.62) 1766 | 1.54 (1.24–1.91) 1062 | 2.92 (2.34–3.62) 878 | 1.44 (1.10–1.90) 3381 | 1.80 (1.04–3.12) 760 | 3.10 (2.59–3.61) 733 | 1.19 (0.59–2.40) 2983 |
| The ORs for tl provider are a | he general practition djusted for age, ger | The ORs for the general practitioner and healthcare centre are corrected for the different suppliers, the amount of patients and the total amount of contact time. The ORs for the national provider are adjusted for age, gender, contact time and relevant diseases of the client. BS=Behavioural support; BS+NRT=Behavioural support combined with nicotine replacement therapy; | entre are corrected id relevant diseases | for the different s_{U} of the client. BS = B | d for the different suppliers, the amount of patients and the total amount of contact time. The ORs for the national ss of the client. BS=Behavioural support; BS+NRT=Behavioural support combined with nicotine replacement therapy; | of patients and the BS+NRT=Behaviour. | total amount of co al support combined | ontact time. The ORs d with nicotine repla | for the national cement therapy; |

Table 2 The OR's and ICERSs of the different programme types

BS + NRT + SCA = Behavioural support combined with nicotine replacement therapy and smoking cessation aids

BS + SCA = Behavioural support combined with smoking cessation aids;

(OR = 3.10; 95% CI = 2.59-3.61). The most intensive programme of behavioural support combined with NRT and SCA did not result in a higher percentage of quitters.

Comparison of costs by programme type

(1) National providers

Table 2 shows the ICERS of the various programmes compared with the reference programme. The ICER shows the costs of one extra unit of effect (in this study one extra quitter). Figure 1 shows the CEA-curves for the different programmes in comparison with behavioural support alone. It can be seen that at a ceiling ratio of \in 1000 per additional quitter the probability that behavioural support combined with NRT is cost-effective in comparison with behavioural support alone is 0.38, that behavioural support combined with SCA is cost-effective is 0.13, and that behavioural support combined with NRT and SCA is cost-effective 0.051. At a ceiling ratio of \in 5000 per additional quitter these probabilities are 0.98, 0.89 and 0.92, respectively.

(2) General practitioners and healthcare centres

Table 2 shows the ICERS of the various programmes in comparison with behavioural therapy alone for both general practitioners and healthcare centres. Figure 2 shows the CEA-curves for general practitioners. The CEA-curves for healthcare centres are not shown. However, the course of the CEA-curves for healthcare centres is more or less similar to the CEA-curves for general practitioners.

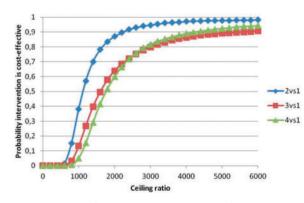


Figure 1 CEA-curve for the programme types of behavioural and pharmacological support vs. behavioural support alone, national providers. The graph shows the probability that the different programmes are cost-effective for different ceiling ratios

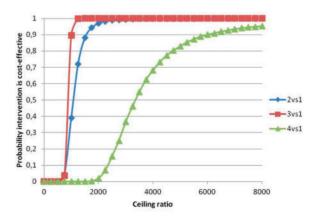


Figure 2 CEA-curve for the programme types of behavioural and pharmacological support vs. behavioural support alone, general practitioners. The graph shows the probability that the different programmes are cost-effective for different ceiling ratios

The probability that behavioural support combined with NRT is cost-effective in comparison with behavioural support alone at a ceiling ratio of \in 1000 is 0.39 for general practitioners and 0.71 for healthcare centres. The probability that behavioural support combined with SCA is cost-effective for both 0.90 (at a ceiling ratio of \in 1000). The probability that behavioural support combined with NRT and SCA is cost-effective for general practitioners and healthcare centres is 0 and 0.0034, respectively. At a ceiling ratio of \in 5000 per additional quitter these probabilities are 1, 1 and 0.83 for general practitioners and 0.97, 1 and 0.71 for healthcare centres.

Discussion

This study showed that behavioural support combined with NRT or SCA has more quitters than the reference programme of behavioural support alone. However the most intensive programme of behavioural support combined with NRT and SCA did not lead to a larger proportion of quitters, for the national providers this programme even tended to a smaller proportion of quitters. The programmes combining behavioural support with NRT or SCA seem more costeffective than the most intensive programme of behavioural support combined with NRT and SCA. However, the ceiling ratios are high, which means that a lot of money has to be invested to consider these programmes cost-effective.

The results of this study are largely in line with previous research. Although a study like this, comparing four types of smoking cessation programmes has never been done before, other studies did already examine the effectiveness of NRT and SCA in smoking cessation.¹⁵⁻¹⁷ These studies found large effects of pharmacotherapy when compared with placebo. Although in our study we compared an effective treatment instead of a placebo, a smaller effect was expected and indeed smaller ORs were found. We did not expect to find that behavioural support combined with NRT and SCA had no better results than behavioural support. Although there are no large RCT's examining the effects of NRT and SCA together, the effect was expected to be at least as high as the programme types of behavioural support combined with NRT or SCA alone. Moreover, Hughes et al.^{29¹} did find a somewhat larger effect for NRT combined with bupropion in comparison with NRT alone. The most plausible explanation is that in our study heavy smokers or smokers who already did some quit attempts are more likely to apply for the most intensive programme. However, information about these characteristics was not available in our study. Therefore, it was not possible to adjust for important characteristics like the number of quit attempts, the smoking history or the amount of cigarettes a smoker had per day. This would probably determine for the results.

The strength of this study is that the research population was large, and 9422 participants were included which enhanced the precision. Thereby the representativeness is greater because of the large research population.

Another strength of this research project is that the effects were observed in a naturalistic setting. The setting was not manipulated and therefore the estimates are more accurate. Thereby, it was a nationwide design, wherefore we were able to include costs. The naturalistic and nationwide setting gives a unique view on the effects of smoking cessation programmes. However, this naturalistic setting also has some limitations.

One of these limitations is the lack of randomization. Care providers decided, according to the Dutch guidelines, together with their patient in which programme the patient participated. The characteristics of the smokers could differ between the programmes. Due to lack of data on patient characteristics the differences between participants of the different programme types cannot be determined. In combination with the large study population, one could argue that the smokers were randomly scattered over the programme types. However, smoking history will have a bog influence on the effectiveness of smoking cessation, so we cannot draw firm conclusions about the differences in effectiveness and cost-effectiveness between the programme types.

Another limitation is that the data were collected by healthcare providers during the smoking cessation programme and therefore it is not sure whether some of the quitters started smoking again. Research has shown that the maintenance of cessation is difficult for people and relapses occur frequently.^{30,31} In this research, it was not possible to take these relapses into account. Thereby, smoking status was assessed by self-report and was not biochemically verified. However, we expect that a potential over reporting of smoking cessation would be independent of the programme type.

Besides, the number of participants and dropout rates varied among the different programme types. The differences in amount of patients make it more difficult to interpret some of the results. Whether or not someone completed the programme was not strongly related to the outcome (quitted smoking) so the differences in dropout rates did not influence our results.

A last limitation is that the behavioural support could consist of several different interventions. However, we assume that it did not differ between the types of programmes and therefore had no effect on the results. Moreover, the differences in behavioural support existed particularly between care providers and we corrected for differences between suppliers.

The findings of this study suggest that more people quit smoking when receiving behavioural support combined with SCA or NRT compared with behavioural support alone. It seems that combined therapies (behavioural support combined with SCA or NRT) need to be advised to potential quitters. For future research, it is highly recommended to collect patient characteristics and information about smoking history as well, to make conclusions on effectiveness possible.

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Conflicts of interest: None declared.

Key points

- More people quit smoking when receiving behavioural support combined with SCA (smoking cessation aids) or NRT (nicotine replacement therapy) compared with behavioural support alone.
- Behavioural support combined with NRT and SCA does not lead to a larger proportion of quitters than behavioural support alone.
- The programmes combining behavioural support with NRT or SCA seem more cost-effective than the most intensive programme of behavioural support combined with NRT and SCA.
- Pharmacotherapy should be added to behavioural therapy in smoking cessation programmes.

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