

Guideline
Treatment of tobacco dependence



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Treatment of tobacco dependence

Colophon

This guideline is the translation of the Dutch guideline 'Behandeling van tabaksverslaving'. Some of the tables in this English version are adapted with new data.

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The mission of the Dutch Institute for Healthcare CBO, in Utrecht, is to support individual practitioners, their professional associations and healthcare institutes in the improvement of patient care. By means of programmes and projects, CBO provides support and supervision in the systematic and structured measuring, improving and safeguarding of the quality of patient care.

Guideline

Treatment of tobacco dependence

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Royal Dutch Organisation of Midwives [Koninklijke Nederlandse Organisatie van Verloskundigen, KNOV]

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Netherlands Institute of Psychologists [Nederlands Instituut van Psychologen, NIP]

Dutch Society for the Advancement of Dentistry [Nederlandse Maatschappij tot bevordering der Tandheelkunde, NMT]

The Dutch Society of Practitioners for Lung Disease and Tuberculosis [Nederlandse Vereniging van Artsen voor Longziekten en Tuberculose, NVALT]

Netherlands Society of Cardiology [Nederlandse Vereniging voor Cardiologie, NVVC]

Dutch Association of Doctors' Assistants [Nederlandse Vereniging van Doktersassistenten, NVDA]

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Netherlands Association for Paediatrics [Nederlandse Vereniging voor Kindergeneeskunde, NVK]

Netherlands Society for Obstetrics and Gynaecology [Nederlandse Vereniging voor Obstetrie en Gynaecologie, NVOG]

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Foreword

This guideline focuses on the treatment of smoking patients in medical practice and the health professionals involved with this. This guideline forms part of a broader action aimed at reducing smoking in the Dutch population. With 28% of the Dutch population smoking and an annual death toll due to tobacco use of more than 19,000, smoking is a major health problem (STIVORO for a smokefree future, annual report 2002).

General measures are necessary within the framework of the tobacco reduction policy to reduce the number of smokers. In the present policy these measures focus on the protection of non-smokers and preventing tobacco use by young people. Primary prevention is particularly important for young people, as the expected health gain is then considerable. However, this guideline focuses on the treatment of tobacco dependence.

A third spearhead in this policy is supporting smoking cessation by smokers. This guideline is relevant to this aim. The support of quit attempts focuses on influencing individual behaviour and it therefore falls within the area of individual care. Smokers often have an implicit or explicit desire to stop smoking and many smokers greatly appreciate the advice of a physician with respect to this. Within the healthcare system, there are a considerable number of contacts with smokers, whether or not this is the consequence of smoking-related complaints and disorders. In this guideline these contacts are considered to be possible opportunities to encourage individuals to make a quit attempt. The proposed short opportunistic advice scarcely costs any time and it is a very effective and cost-effective intervention at a population level.

The guideline describes a method that can be used in every healthcare sector, irrespective of the specialisation of the health professional and the nature of the health problems for which the smoking patient is being treated. The guideline presents a coherent and consistent approach to smokers in healthcare and is the product of a large number of disciplines in primary and specialised care (see list of disciplines involved). No less important is the signal that this sends to society: the medical, paramedical and dental professions are concerned about tobacco use and consider it their duty to help those who cross their paths and who want to quit. In this respect the guideline has a highly idealistic character. With this, the guideline deliberately chooses a different perspective: not that of the smoker who is responsible for his own behaviour, but that of an addiction for which help is necessary. The guideline details how this can be achieved in practice among the various categories of patients. The specific points of focus in dental practices and general practices, where smokers are seen irrespective of their health problems, are different from those in the cardiology or pulmonology practice where there are many patients with smoking-related diseases. For the preoperative patient and the pregnant woman, there is a clear short-term effect in addition to the effect of stopping permanently. It is essential that all fields within healthcare follow the same approach.

In view of the considerable importance for public health, it is important to reach as many smokers as possible and to motivate them to stop. On the basis of this, a stepped care approach has been developed which incorporates the diagnostics (of smoking status and motivation to stop) and intervention (advising, support, supervision). This approach from the healthcare sector means that every smoker is at least made aware of the negative effects of this habit, is encouraged to stop and is offered support during the cessation process. Support with nicotine replacement therapies or other medication is important, but only if the smoker is actually motivated to stop and has a degree of nicotine dependency (more than 10 cigarettes per day). Motivating interventions are the essence of the guideline. Health professionals who only focus on this in their contacts with smokers, already make a significant contribution to reducing tobacco use. With this it is possible to bridge the gap between present practice and optimising the care for smokers within routine healthcare, the aim of this guideline.

However, in reality it must be realised that the problem of smoking is strongly coloured by *persistent smokers* for whom a one-off advice and a one-off encouragement to stop is frequently not enough. Therefore, a smoker's persistence is pragmatically defined on the basis of previous attempts to stop. Persistent smokers often require a more intensive form of treatment. A step-by-step approach is advocated for the implementation of the guideline for selecting patients who want this more intensive care. With this, the guideline classifies interventions on the basis of their intensity and calls for the development of more intensive interventions and the testing of these. Specialised care facilities should be used for more intensive interventions.

The guideline agrees with the principle of one-off and brief supportive interventions and the model of 'stages of change'. The minimal intervention strategy (MIS) has a certain tradition in the Netherlands as a practical method for providing smoking cessation advice: various available programmes are based on this. However in the guideline, the MIS is considered to be a method and a different classification is used than in the traditional version of the MIS: What in 'MIS terms' is referred to as a minimal intervention, is considered in this guideline to be more than minimal and is placed in the category brief supportive intervention or in some cases in the category intensive treatment.

An important starting point in guidelines for medical practice is the optimal use of *available* facilities. This is also the case in this guideline with respect to a consistent motivating intervention for smokers. However, a special point in this guideline is the positioning of specialised facilities. These well-known facilities in the United Kingdom and United States are only available on a limited scale in the Netherlands. With the launching of this guideline it is argued that such facilities should be made available on a larger scale, despite the limited scientific evidence for this. The more widespread availability of these facilities will considerably enhance the efforts of realising a reduction in tobacco use by means of individual interventions.

Chapter 1

General introduction

Reason

Smoking causes considerable damage to the health. In their daily practice, health professionals regularly see smokers and can help them to give up smoking. At present only a limited number of health professionals see a role for themselves in encouraging smokers to quit smoking. Health professionals often do not know which interventions, at which moments, for which patient groups are worthwhile and effective. This guideline provides recommendations with respect to this.

Objective

The aim of this guideline is to reach as many smokers as possible by reminding curative health professionals about their intermediary function. This objective is prompted by the following considerations:

- Smoking cessation requires a change in health behaviour at the individual level.
- Recommendations from health professionals are more effective than those from non-professionals.
- Many smokers have contact with the curative medical care sector.
- Each smoker often has several such contacts.

This last point is the reason for a stepped care approach and also forms the challenge to offer the same approach across various disciplines. Therefore the guideline assumes an initial advice, such as that between an initial contact between the smoker and the health professional. However, many smokers have previously received the advice to stop smoking. For this group it is pointless starting from scratch.

Target group

The conclusions and recommendations in this guideline are in principle relevant to all health professionals. *Chapter 7* provides extra information on practice and profession-specific issues, in so far as these were available and in so far as the professional group or groups were represented in the guideline working group.

Composition of the working group

In June 2002 the multidisciplinary working group of 33 people was appointed. Three sub-working groups were formed: one for one-off and brief supportive interventions (including telephone counselling and self-help materials), one for pharmacological support and one for intensive interventions. A steering group was formed by the chairs of the sub-working groups for coordinating purposes. The sponsor of the guideline was the Partnership on smoking cessation [Partnership Stop met Roken], in cooperation with a large number of scientific associations and other professional organisations active within the field of healthcare. The project also received financial support from the Dutch Society of Medical Specialists [Orde van Medisch Specialisten]. Methodological and secretarial support were provided by the Dutch Institute for Healthcare CBO [Kwaliteitsinstituut voor de Gezondheidszorg CBO].

During the setting up of the working group, due consideration was given to ensuring a balanced representation of the various associations, 'schools' and academic backgrounds. The working group members acted independently and were mandated by their association.

Methodology working group

Although different parts of the text were prepared by individual working group members or sub-working groups, this document is very much written on behalf of the entire working group. The working group members systematically searched the literature and assessed its quality and content. They then wrote their texts for the draft guideline, into which they incorporated the literature assessed. During meetings they clarified their own texts and gave feedback on the other chapters. The collected texts formed the draft guideline, which was presented to all of the relevant groups and professional groups on 1 September 2003 via the CBO website. The comments received were incorporated into the guideline before the final version was published. The following people and organisations were invited by the working group to comment on the guideline: the Dutch College of General Practitioners [Nederlands Huisartsen Genootschap], the Dutch Society for the Advancement of Dentistry [Nederlandse Maatschappij tot bevordering der Tandheelkunde], STIVORO for a smokefree future, Dutch Association of Youth Healthcare Physicians [Artsen (vereniging) Jeugdgezondheidszorg Nederland] (AJN), Dutch Pharmacists' Scientific Institute [Wetenschappelijk Instituut Nederlandse Apothekers] (WINAp), Royal Dutch Organisation of Midwives [Nederlandse Organisatie van Verloskundigen] (KNOV), Dutch Association of Doctors' Assistants [Nederlandse Vereniging van Doktersassistenten]. At their own initiative, various individual health professionals from different disciplines sent in comments, as did the pharmaceutical company GlaxoSmithKline.

Literature and searching strategy used for the guideline

Wherever possible, the guideline is based on data from published scientific research. The basis is formed by guidelines for smoking cessation which have been developed in the United States and the United Kingdom and the systematic reviews published within the Cochrane Library (see below). Therefore most of the data has been obtained from systematic reviews and/or meta-analyses. Where possible this was supplemented with more recent literature and studies that were specifically carried out in the Netherlands.

The following information sources were used:

- The *Cochrane database* of systematic reviews of the *Cochrane Library* up to and including 2003, 'issue 3'. All systematic reviews with the subject 'smoking cessation' were used.
- Raw M, McNeill A, West R. Smoking cessation guidelines for health professionals. *Thorax* 1998;53(Suppl 5, Part 1):S1-18.
- Raw M, McNeill A, West R. Smoking cessation guidelines for health professionals. *Thorax* 1998;53(Suppl 5, Part 2):S2-3.
- West R, McNeill A, Raw M. Smoking cessation guidelines for health professionals: an update. *Thorax* 2000;55:987-99.
- Fiore MC, Bailey WC, Cohen SJ, Dorfman SF, Goldstein MG, Gritz ER, et al. Treating tobacco use and dependence. Clinical Practice Guideline. US: Rockville, MD. Department of Health and Human Services. Public Health Service; 2000.
- Health Education Board for Scotland. Smoking cessation guidelines for Scotland. Edinburgh, 2000.
- The journals *Addiction* and *Tobacco Control* from 1998 until May 2003 were screened by hand. All of the articles concerning smoking cessation were selected.
- For some subjects additional searches were performed in *Medline* and sometimes in *Embase* as well. This mostly concerned practice-specific and professional-specific parts of the guideline, especially when no information was available from the above mentioned sources.
- A separate literature study was performed on the subject of implementation, which is described in the relevant chapter.

The assessment of the various articles is detailed at the beginning of the section. The scientific basis is then summarised in a conclusion. The literature on which this conclusion is based, is stated with the conclusion and includes the 'degree of evidence'. Often, aspects other than the scientific evidence are also important in reaching a recommendation, for example: patient preferences, costs, availability (in different settings) and organisational aspects. These aspects are stated under the heading 'Other considerations'. The recommendation is the result of the available evidence and the other considerations.

Table 1 Classification of the support according to the degree of evidence in the conclusions

For articles concerning intervention (prevention or therapy)	
A1	systematic reviews which concern at least several studies from level A2, in which the results from the separate studies are consistent;
A2	randomised comparative clinical studies of good quality (randomised, double-blind, controlled studies) of sufficient size and consistency;
B	randomised clinical studies of moderate quality or insufficient size or other comparative studies (non-randomised, comparative cohort studies, patient follow-up studies);
C	non-comparative studies;
D	expert opinions, for example from the working group members.
For articles about diagnostics	
A1	studies into the effects of diagnostics on clinical outcomes in a prospectively followed and well-defined patient group, with a predefined policy based on the test results to be investigated, or operational research into the effects of diagnostics on clinical outcomes, in which the results of studies from level A2 used as the basis and sufficient consideration is given to the interdependency of diagnostic tests;
A2	studies with respect to a reference test, in which criteria for the test to be investigated and a reference test are defined beforehand, with a good description of the test and the clinical population investigated; it must involve a sufficiently large series of consecutive patients, use must be made of predefined cut-off values and the results of the test and the 'gold standard' must have been assessed independently. For situations in which multiple, diagnostic tests play a role, there is in principle an interdependency and the analysis should be adjusted for this, for example by using logistic regression;
B	comparison with a reference test, description of the test and population investigated, but not of the rest of the characteristics stated under level A;
C	non-comparative studies;
D	expert opinions, for example from the working group members.
Level of evidence of the conclusion	
1	one systematic review (A1) of at least two studies from level A1 or A2 carried out independently from each other;
2	at least two studies from level B carried out independently from each other;
3	one study from level A2 or B or one or more studies from level C;
4	expert opinion; for example from the working group members.

Legal significance of guidelines

Guidelines are not legally-binding regulations, but evidence-based recommendations to which health professionals must commit themselves in order to provide good quality care. As the supporting literature for these recommendations is mainly based on the 'average patient', health professionals can deviate from the guideline on the basis of their professional autonomy. In certain situations this can even be necessary. In situations where the guideline is not adhered to, it is recommended that the arguments for this are documented.

Financial conflicts of interest/independence of working group members

A file containing declarations from working group members about possible financial conflicts of interest is held for inspection at the Dutch Institute of Healthcare CBO [Kwaliteitsinstituut voor Gezondheidszorg CBO]. This does not contain any conflicts of interest worth noting.

Review

In 2008, or earlier, the Partnership on smoking cessation [Partnership Stop met Roken] will determine whether or not this guideline is still current. If necessary a new working group will be appointed to review the guideline. The guideline's validity will expire earlier if new developments necessitate an earlier review process.

Definitions used

Smoking is understood to mean all forms of tobacco use, but the majority of the literature focuses on smokers of cigarettes, because this is by far the largest group of smokers. Somebody who smokes more than 10 cigarettes a day is considered to be a 'heavy smoker' in this guideline.

Definitions of other terms used in the guideline are:

- C-MIS: minimum intervention strategy for cardiological hospital patients.
- Behavioural interventions:
 - (a) One-off advice: brief intervention which takes place during a normal care contact. It consists of 'ask' (ask if somebody smokes), 'assess' (established motivation to stop), 'advise' (indicate that help can be given), 'assist' (behavioural and/or pharmacological support) and 'arrange' (make agreements about the favourable change and subsequent contact).
 - (b) Brief supportive intervention, whether or not with pharmacological support, that is spread over at least two contacts. It consists of 'ask' (ask if somebody smokes), 'assess' (establish motivation to stop), 'advise' (indicate that help can be provided), 'assist' (behavioural and/or pharmacological support) and 'arrange' (make agreements about the behavioural change and subsequent contact).

(c) Intensive intervention, with or without pharmacological support. Intensive interventions vary from three to four contacts of at least 10 minutes over a period of several weeks to ten or more contacts over a period of several months.

- H-MIS: minimum intervention strategy for general practice.
- L-MIS: minimum intervention strategy for the pulmonary outpatients' clinic, consultants or nursing consultants, of at least two face-to-face contacts and telephone contact for a period of 12 months. In the event of relapse a new treatment trajectory is started as soon as possible.
- L-MIS plus: the same as L-MIS, but with pharmacological help included.
- Minimum intervention strategy (MIS): MISs are previously developed protocols to support smoking cessation in various medical practices. The majority belong to the category brief supportive interventions and some to the category intensive interventions.
- NNT number needed to treat: the number of people that needs to be treated for one person to stop smoking.
- P-MIS: minimum intervention for cardiological patients during outpatients' follow-up after admission.
- Relapse prevention: actively anticipating possible relapses into the former smoking behaviour. Within the framework of this guideline, relapse prevention is considered to be a concrete part of the intervention/treatment (see also *appendix 3, Relapse prevention*). A distinction can be made between the physical dependence which mostly lasts about three weeks, and the mental dependence which can persist for much longer.
- USDHHS: United States Department of Health and Human Services.
- V-MIS: minimum intervention strategy for midwives.

Chapter 2

The harm done by tobacco

2.1 Introduction

One of the first and extensive descriptions of the harm done by tobacco dependence in the Netherlands was written by van Proosdij.¹ It is not new information that smoking is harmful to health and that nicotine dependence causes habituation and withdrawal symptoms. His advice then was 'to smoke less, not to inhale and to smoke pipe or cigar instead of cigarettes.'¹ The first attempts by the Dutch government to reduce smoking also originated from those days.

The harm done by smoking is related both to the number of cigarettes smoked and to the number of years of smoking, but of these two factors, the duration of smoking has the greater impact. For some diseases, such as lung cancer, the risk remains relatively low for the first 20 years of smoking, but then rises exponentially with increased duration of smoking.² As a result, smoking-attributable deaths from lung cancer tend to occur 20 to 30 years after changes in population smoking prevalence. Persistent smokers run a 1 in 2 risk of dying from cigarette smoking, losing, on average, 8 years of life.² One half of these deaths occur before the age of 69, bringing in this case an average loss of 20-25 years of life. About 20% of all cancer deaths worldwide are caused by smoking.³ Smoking causes 80% to 90% of lung cancers with a relative risk in men of over 20 and in women of over 10.⁴ Smoking is responsible for most cancers of the upper respiratory and alimentary tracts (lip, tongue, mouth, pharynx and larynx) and for a smaller fraction of cancers of the bladder, pancreas, oesophagus and kidneys. Over 80% of chronic obstructive lung disease can be attributed to smoking with a relative risk in both male and female smokers of about 10. The relative risk for cardiovascular disease is about 10 in smokers aged 30-50 years, but this risk declines with increasing age as death rates from heart disease rise in non-smokers.⁵ Across all ages, about 20% of cardiovascular deaths can be attributed to smoking. However, because cardiovascular disease is so common in the population, smoking attributable deaths from cardiovascular diseases (ischaemic heart disease, aortic aneurysm, and stroke) outnumber smoking-attributable deaths from all other causes, including lung cancer.

Smoking is a cause of peripheral vascular disease, cataracts, Crohn's disease, gastric and duodenal ulcers, hip fracture in the elderly, and periodontitis, the major cause of tooth loss in adults.⁶ Smoking is a major cause of adverse pregnancy outcomes, including perinatal death, an increased risk of spontaneous abortion, and a doubled risk of ectopic pregnancy.⁷ Babies of smoking mothers weigh on average 150g to 250g less at birth than do babies of non-smoking mothers. Smoking is casually associated with sudden infant death syndrome, although it is uncertain whether prenatal or postnatal exposure is more important.^{8,9}

The relative risks, the absolute risks per 100,000 people per year, and the proportion of all deaths due to smoking related diseases, or the incidence of some smoking related diseases, are presented in *Table 1, 2 and 3*.

Table 1 Smoking related mortality among male British doctors²

Disease		Relative risk*	Absolute risk per 100,000 men per year**	Attributed to smoking (%) ***
Cancer	Lung	15.0	195	81
	Upper respiratory track	24.0	23	87
	Bladder	2.3	17	28
Cardiovascular disease	Ischaemic heart disease	1.6	320	15
	Cerebrovascular disease	1.3	51	8
	Dilation of aorta	4.1	4	48
Respiratory disease	COPD	12.7	117	78

* Standardised death per 100,000 male per year among current smokers, divided by the standardised death of never smokers.

** Standardised death per 100,000 male per year among current smokers minus standardised death of never smokers.

*** The proportion of all deaths caused by smoking related diseases, assuming that 30% of the male adult population smokes and all extra risks are caused by smoking.

Table 2 Smoking related mortality among males and females of 35 years and older

Disease			Relative risk*	Absolute risk per 100,000 people per year**	Attributed to smoking (%)***
Cancer	Lung	M	22.4	513	87
		F	11.9	195	77
	Upper respiratory track	M	24.5	26	89
		F	5.6	8	58
	Bladder	M	2.9	35	36
		F	2.6	13	32
Cardiovascular disease	Ischaemic heart disease	M	1.9	470	22
		F	1.8	302	19
	Cerebrovascular disease	M	2.2	181	27
		F	1.8	198	20
	Dilation of aorta	M	4.1	74	48
		F	4.6	41	52
Respiratory disease	COPD	M	9.7	339	72
		F	10.5	195	74

* Standardised death per 100,000 people per year among current smokers, divided by the standardised death of never smokers.

** Standardised death per 100,000 people per year among current smokers minus standardised death of never smokers.

*** The proportion of all deaths caused by smoking related diseases, assuming that 30% of the adult population smokes and all extra risks are caused by smoking.

Table 3 Some selected non fatal diseases related to smoking

Disease	Relative risk*	Absolute risk per 100,000 people per year**	Attributed to smoking (%)***
Peripheral vascular diseases (age 45-74 years) ¹¹	2.0	150	23
Stomach ulcer (age 20-61 years) ¹²	3.8	165	45
Crohn's disease ¹³	2.1	10	25
Inflamed gums (age 19-40 years) ¹⁴	3.0	44,500	38
Hip fracture (age > 64 years) ¹⁵	1.3	134	8
Cataract (male age 40-84 years) ¹⁶	2.2	296	26

* Standardised rate per 100,000 people per year among current smokers, divided by the standardised rate of never smokers.

** Standardised rate per 100,000 people per year among current smokers minus standardised rate of never smokers.

*** The proportion of all smoking related diseases, assuming that 30% of the adult population smokes and all extra risks are caused by smoking.

For the year 2000, 27% of male deaths and 10% of female deaths are due to smoking.¹⁷ The average is higher than that of 15 European countries, respectively 22% and 7%. The increase of smoking related deaths among women is one of the highest in the European Union.

Smoking cessation benefits health at any age, the more so the younger the smoker is when he or she stops. In the British doctors' study, those who gave up smoking by their mid-thirties had a life expectancy indistinguishable from never smokers.² Even those who gave up smoking in their late 60s lived significantly longer than continuing smokers.

In the year 2000, the prevalence of smoking adults in higher socio-economic groups was 27%, and was 39% among adults in lower socio-economic groups (table 4). As people in lower socio economic groups smoke more than people in higher groups, so smoking related deaths are higher in lower than higher socio-economic groups. Smoking causes at least half of the socio-economic differences in overall mortality rates.^{18,19}

Table 4 Aspects of lifestyle related to education level, corrected for age differences and standardised to the Dutch population in 2000

	Percentage to education level					Relative Index of Inequality (RII) [*]		
	LO	LBO, MAVO	HAVO, VWO, MBO	HBO, University	Total	Male	Female	Total
Smoking (now)**	46.2	37.8	32.6	15.2	34.1	2.8	3.0	2.6 (2.3-2.8)
Alcohol (>3 drinks per day)**	16.8	14.9	14.5	12.7	14.7	2.4	0.8	1.7 (1.4-2.0)
Alcohol (>once per week > 6 drinks)	14.2	13.6	12.7	10.7	12.6	1.9	1.3	1.3 (1.1-1.5)
Physical activity (<3.5 hrs per week)***	58.7	46.2	45.8	42.0	46.9	1.2	2.1	1.6 (1.5-1.8)
Physical activity (<3.5 hrs per week of which <2 hrs heavy)***	93.5	86.3	82.6	80.6	85.1	2.3	2.9	2.7 (2.3-3.2)
Not regular walking**	44.8	41.8	28.6	33.7	39.8	2.0	2.0	2.0 (1.8-2.2)
Not regular biking**	55.7	50.0	48.1	46.7	49.2	1.6	1.6	1.7 (1.5-1.8)

* RII can be interpreted as the factor that shows the difference between the lowest and highest socio-economic group.

** Estimates based on figures of POLS 1995-1999, 20 years and older.

*** Estimates based on figures from MORGEN 1993-1997, 20-59 years.

Source: Lucht F van der, Picavet HSJ. Sociaal economische verschillen in leefstijl. In: olksgezondheids Toekomst Verkenning, Nationaal Kompas Volksgezondheid. Bilthoven: RIVM (www.nationaalkompas.nl Demografische en sociaal-economische kenmerken\Sociaal-demografische gezondheidsverschillen\Sociaal-economische gezondheidsverschillen, 14 februari 2003)

2.2 Smoking is a dependence

Tobacco is a dependence producing drug due to its nicotine content.^{1,20-23} Nicotine has been shown to have effects on brain dopamine systems similar to those of other drugs such as heroin and cocaine.²⁴ With appropriate reward schedules it functions as a robust reinforcer.²⁵ Dependence on nicotine is established early in teenagers' smoking careers.²⁶ Much adult smoking behaviour is motivated by a need to maintain a preferred level of nicotine intake, leading to the phenomenon of nicotine titration, or compensatory smoking in response to lowered nicotine yields.²⁷ People seeking treatment for heroin, cocaine, or alcohol dependence rate cigarettes as hard to give up as their other drug of dependence.²⁸ The cost of nicotine withdrawal is an important factor underlying the failure of many attempts at cessation.²⁹

2.3 Neuropsychiatric disorders

Smokers perceive that smoking helps alleviate negative mood states, but the available evidence suggests that the only negative mood state so alleviated is that resulting directly from dependence on nicotine itself.²² Thus, the nicotine in tobacco relieves nicotine withdrawal symptoms, but does not have any mood enhancing properties in non-addicted individuals. Although relatively few smokers report that they smoke primarily to help them think and concentrate, the evidence suggests that nicotine can improve certain aspects of cognitive performance, although the size of the effect is small.²⁹

Although previous studies had suggested an inverse relationship between smoking and Alzheimer's dementia, more recent studies have in fact suggested either no relationship³⁰ or a positive relationship.³¹ Depression has consistently been linked with smoking. A history of major depression is associated with a greater prevalence of smoking and less success in smoking cessation.³² There is evidence for an inverse dose-response relationship between smoking and the risk of Parkinson's disease.³³ People with schizophrenia have a much higher smoking rate than people with other mental disorders, an association which has been postulated as "self-medication".³⁴

2.4 Cancers

Tobacco smoke contains more than 100 carcinogens and mutagens, many of which are classified as carcinogens based upon human and animal studies.³⁵ If a regular smokers quits, then the risk of cancer decreases, but the risk of cancer in former smokers does not decrease to the level of never smokers. A dose response relationship between cigarette smoking and lung cancer exists for both men and women.³⁶ Both daily smoking amounts and duration of smoking are important contributors to risk. An earlier age of initiation is associated with increased risk. The depth of inhalation is association with increased risk. The British doctors' study found a cumulative risk for lung cancer by age 75 among continuing male smokers of 15.9%. The cumulative risk was 9.9%, 6.0%, 3.0% and 1.7% for those who stopped at about 60, 50, 40 and 30 years of age respectively.³⁷ For women, the cumulative risk for lung cancer by age 75 among continuing smokers was 9.5%,

compared with 5.3% and 2.2% among women who stopped at about 60 and 50 years of age respectively. After about 20 years of quitting, the risk reduction is found to plateau, remaining slightly above that of never smokers (*see table 5*).

There is a dose response relationship between cigarette smoking and the risk of oropharyngeal cancers (cancers of the oral cavity, tongue, pharynx and larynx).³⁶ Stopping smoking reduces the risk of oropharyngeal cancers, with most reductions in risk apparent as soon as five years after cessation.³⁸

There is a dose response relationship between cigarette smoking and risk of bladder cancer, related to both the duration of smoking and the number of cigarettes smoked per day.³⁶ An immediate decrease in risk of bladder cancer is observed for those who give up smoking, although, even after 25 years, the decrease in risk does not reach the level of never smokers.³⁹

2.5 Cardiovascular diseases

Smoking significantly increases the risk of myocardial infarction, sudden coronary death, stroke, peripheral vascular disease and abdominal aortic aneurysms. The risk of coronary heart disease is substantially and relatively rapidly reversible on cessation of smoking. One year after quitting, the risk of coronary heart disease decreases by 50%, and within 10 years, the relative risk of dying from coronary heart disease for an ex-smoker approaches that of a never smoker.

There is a dose response relationship between cigarette smoking and risk of coronary artery disease, such that the risk increases with the number of cigarettes smoked daily, the extent of inhalation, and the number of years of smoking.³⁶ The risk of coronary heart disease is more than doubled in cigarette smokers as a group. Middle-aged men who smoke have a tenfold greater risk of sudden cardiac death and a 3.6-fold increased risk of myocardial infarction than non-smokers.⁴⁰

Smoking promotes acute coronary events by having an immediate effect on increasing heart muscle oxygen demand, through a rise in blood pressure, heart rate and heart muscle contractility.³⁶ Smoking causes vasoconstriction and reduced flow in the coronary arteries. Oxygen delivery is reduced to heart muscle cells. An increase in fibrinogen and platelet activity increases the risk of thrombosis. After eight weeks, smoking cessation normalizes elevated blood viscosity and plasma fibrinogen levels.³⁸

At all ages, the risk of ischaemic heart disease in individuals without known coronary heart disease decreases after cessation, particularly in the first two to three years.⁴¹ Thereafter the rate of decline decreases, so that it may take up to ten years for former smokers to reach the same risk level as never smokers. The risk for the first myocardial infarction declines quickly to reach that of never smokers by the third or fourth year.^{42,43} For smokers who already have coronary heart disease, cessation is also very effective in reducing the risk of further acute coronary events.

Smoking increases the risk of cerebrovascular disease in a dose response manner, for both subarachnoid haemorrhage and cerebral infarction, which occurs in conjunction with an increase in atherosclerosis of the carotid arteries.⁴⁴ The increased relative risk

Table 5 Incidence and deaths of lung cancer in the Netherlands, 1989-2003⁸⁹

Year diagnosis/ death	Incidence				Death (CBS)							
	Number of new cases		ESR**		Number of deaths		ESR**					
	Total	M	F	Total	M	F	Total	M	F			
1989	8,572	7,268	1,304	63.1	109.2	16.9	8,550	7,318	1,232	62.4	109.8	14.9
1990	8,750	7,391	1,359	63.1	109.0	17.2	8,241	7,011	1,230	59.1	103.6	14.7
1991	9,033	7,541	1,492	64.3	109.7	18.9	8,420	7,148	1,272	59.6	104.0	15.2
1992	9,072	7,507	1,565	63.4	107.4	19.3	8,512	7,097	1,415	59.0	101.4	16.6
1993	8,989	7,238	1,751	61.8	102.2	21.3	8,616	7,071	1,545	58.9	100.0	17.8
1989-93	44,416	36,945	7,472	63.1	107.5	18.7	42,339	35,645	6,694	59.8	103.8	15.8
1994	9,017	7,226	1,791	61.1	100.6	21.6	8,566	6,934	1,632	57.7	96.5	18.9
1995	9,078	7,159	1,919	60.2	97.7	22.6	8,651	6,920	1,731	56.9	94.3	19.5
1996	9,078	7,089	1,989	59.2	95.2	23.3	8,571	6,770	1,801	55.4	91.1	19.7
1997	9,116	6,955	2,161	58.4	91.8	25.0	8,619	6,730	1,889	54.9	88.9	20.9
1998	9,078	6,804	2,274	57.1	88.3	26.0	8,646	6,665	1,981	53.9	86.5	21.2
1994-98	45,367	35,233	10,134	59.2	94.7	23.7	43,053	34,019	9,034	55.8	91.5	20.0
1999	8,967	6,671	2,296	55.3	84.7	25.8	8,725	6,589	2,136	53.3	83.9	22.7
2000	8,999	6,521	2,478	54.4	81.4	27.5	8,559	6,297	2,262	51.2	78.5	23.9
2001	8,920	6,343	2,577	52.8	77.4	28.2	8,748	6,403	2,345	51.3	78.2	24.4
2002	9,211	6,455	2,756	53.4	77.1	29.6	8,920	6,388	2,532	51.1	76.4	25.8
2003	9,014	6,126	2,888	51.1	71.6	30.5	8,862	6,158	2,705	49.3	71.7	27.0
1999-2003	45,111	32,116	12,995	53.4	78.4	28.3	43,814	31,883	11,930	51.2	77.7	24.8
EAPC** 89-03 (p-value)				-1.6%	-3.1%	4.3%				-1.5%	-2.8	4.5%
				(0.00)	(0.00)	(0.00)				(0.00)	(0.00)	(0.00)

* ESR = European Standardized Rate

** EAPC = Estimated Annual Percentage Change

for cerebrovascular disease is lowered by smoking cessation to that of a non-smoker by about five years.^{45,46}

Smoking markedly accelerates atherosclerosis in the abdominal aorta and occlusive disease in its branches.⁴⁷ Aortic aneurysm, peripheral vascular disease and renal artery stenosis are increased in smokers.⁴⁸ Cigarette smoking is an independent risk factor in the development of atherosclerosis in the internal pudendal and penile arteries of young men with impotence.⁴⁹ Smoking cessation reduces the risk of peripheral artery occlusive disease compared with continued smoking.⁵⁰ Among patients with peripheral artery disease, smoking cessation improves exercise tolerance, reduces the risk of amputation after peripheral artery surgery, and increases overall survival.

2.6 Respiratory diseases

Numerous respiratory diseases are strongly related to cigarette smoking.⁵¹ Cigarette smoking is estimated to contribute to over 80% of cases of chronic obstructive pulmonary disease (COPD), and the amount and duration of cigarette smoking directly influence the progression of COPD. Asthma and respiratory infections are not caused by tobacco smoke but are worsened by exposure to cigarette smoke.

Cigarette smoking is associated with a lower forced expiratory volume in 1 second (FEV₁), a measure of lung function impairment, and with an accelerated decline in FEV₁ over time.^{52,53} Both the duration of smoking and the amount smoked are significant predictors of lung function impairment. The Lung Health Study found a reduced rate of decline in lung function and fewer respiratory symptoms in those who remained quitters over the five year duration of the trial.^{54,55} The benefit was seen also in heavy smokers, older smokers and smokers with poor baseline lung function.

2.7 Gastrointestinal diseases

Cigarette smokers have an increased risk of peptic ulcer disease with relative risks of between 3.0 and 3.4, increased rate of relapse after treatment, and increased risk of the complications associated with ulcer development.⁵⁶ Ulcer healing and the risk of recurrence improve with cessation.⁵⁷

Cigarette smoking leads to a three to fivefold increased risk of developing Crohn's disease.⁵⁸ Smokers with Crohn's disease have an increased risk of developing severe disease, and have a greater risk of requiring surgery and of having post surgical complications.⁵⁹ Smoking cessation leads to a decreased risk of developing Crohn's disease, and a decrease in the need for surgery amongst those with Crohn's disease and a decrease in recurrence after surgery.³⁶

In contrast, smoking has been shown to have a protective effect for ulcerative colitis and a better course for those with ulcerative colitis.⁶⁰

2.8 Diabetes

There is some evidence for a dose response relationship between cigarette smoking and the risk of non-insulin dependent diabetes mellitus.^{36,60,61} There is also the suggestion that smoking is an independent risk factor for increased insulin resistance. Smoking increases the risk of cardiovascular diseases with patients suffering from diabetes⁶² and an increases risk of retino- and nephropathy. The risk profile of patients suffering from diabetes type 2 should be assessed, and adequate interventions are required.

2.9 Renal disease

Cigarette smoking is associated with a two to three fold increased risk of microalbuminuria and proteinuria and an increased rate of progression to diabetic nephropathy and end stage renal disease in individuals with diabetes.^{63,64} In individuals without diabetes, there is a dose response relationship between cigarette smoking and several measures of abnormal renal function, including high-normal albuminuria, microalbuminuria and abnormal glomerular filtration rates.⁶⁵ Smoking cessation was associated with only microalbuminuria, suggesting some degree of reversibility with quitting.

2.10 Reproductive and developmental effects

Smoking among women of reproductive age is a critical risk factor for reproductive health problems, including foetal and infant mortality and impaired foetal development. Cigarette smoking increases the risks of fertility impairment in women and vascular erectile dysfunction, but not fertility impairment in men.³⁶ Cigarette smoking increases the risks of spontaneous abortions, low birth weight, pre-term delivery, perinatal morbidity, placental complications and sudden infant death syndrome.^{36,66} Among pregnant smokers, the risk of low birth weight babies is doubled compared to non-smokers.⁶⁷ The effect of smoking is particularly prominent with exposure after the first trimester. Women who stop smoking during pregnancy have significantly increased birth weights compared to women who continue to smoke.³⁶ Some relation between smoking mothers and children born with hare lip has been found.^{68,69} The risk of sudden infant death syndrome increases two- to four- fold among infants of mothers who smoke during pregnancy, and the risks increase even further when combined with postnatal exposure to tobacco smoke.⁷⁰

2.11 Post-operative complications

Smokers have an increased risk of intra-operative and post-operative complications, including pulmonary, circulatory and infectious complications, impaired wound healing and post-operative need for intensive care.³⁸ A randomized controlled trial of a smoking intervention program in Denmark found that smoking cessation 6 to 8 weeks before surgery led to fewer wound-related complications, tended to reduce cardiovascular complications and the need for secondary surgery, and led to a shorter hospital stay.⁷¹

The long term risk for myocardial infarction, operation or death after coronary bypass surgery is increased by smoking.⁷²

2.12 Oral disease

Cigarette smoking is a major risk factor for periodontal disease, with a dose response relationship.⁷³ Smoking cessation improves gingival health, and there is evidence of a decrease but not a complete reversal in the severity and prevalence of periodontitis among former smokers.

2.13 Joint and bone disease

Cigarette smoking seems to increase the risk of development of rheumatoid arthritis⁷⁴ although it is not certain whether smoking plays a casual role in the aetiology or the progression of rheumatoid arthritis. The Iowa Women's Health Study found that current smokers and those who had stopped within 10 years, were at increased risk of rheumatoid arthritis, whereas those who had stopped for more than 10 years were not at increased risk.⁷⁵ Cigarette smoking has been linked to adverse orthopaedic consequences including osteoporosis, hip fracture and delay in bone healing, with some evidence of a dose response relationship.³⁶ Reversal of the risk for hip fractures has been described 10-20 years post cessation.⁷⁶

2.14 Eye disease

Cigarette smoking is associated with numerous diseases of the eye, including ischaemic diseases such as amaurosis fugax, retinal infarction and anterior ischaemic optic neuropathy.^{77,78} There is a dose response relationship between cigarette smoking and risk and severity of cataracts, with a doubling of risk for nuclear type cataracts and a two to four fold increase in the rate of cataract surgery.⁷⁹ The risk of cataract formation appears to be related to lifetime cumulative cigarette dose, with less reduction in risk found among heavy smokers compared to moderate and light smokers after cessation.⁸⁰

2.15 Skin diseases

There is a dose response relationship between cigarette smoking and wrinkling independent of age, gender and sun exposure and of psoriasis.⁸¹

2.16 Environmental tobacco smoke

Cigarette smoke not only causes harm to the smoker, but also to those surrounding the smoker through environmental tobacco smoke. A non-smoker inhales side stream smoke from the burning tip of the cigarette as well as mainstream smoke breathed out by the smoker. In addition to the unpleasant smell and irritation to the eyes, environmental

tobacco smoke increases the risks of lung cancer and cardiovascular and respiratory diseases.

Analyses have suggested that the relative risk of lung cancer among non-smokers is between 16% and 24% higher for women having a husband who smokes, relative to non-smokers whose husbands are also non-smokers.⁸² It is estimated that between 110 and 270 people die of passive smoking annually in the Netherlands.⁸³ Pooled results of epidemiological studies indicate a 20% excess coronary disease death rate among non-smoking spouses of smokers.⁸³ Results from California calculated for the Dutch situation, show that about 3,000 ischemic heart diseases occur annually.⁸⁶

It appears that even a small exposure to second hand smoke has a large effect on heart disease, with further exposure having a relatively small additional effect. The increased risk has almost all gone after two years of non-exposure to second hand smoke.

Although it is unclear whether or not environmental tobacco smoke increases the risk of chronic obstructive pulmonary disease or asthma in adults, there is evidence that environmental tobacco smoke increase the risk of impaired lung function, asthma, and lower respiratory infections in children.³⁶

Conclusion

Over 19,000 deaths each year, or 54 deaths per day, are caused by smoking (*see table 6*). Of the 48,451 deaths occurring in adult men and women (aged 20 years and older) for four smoking related illnesses in the year 2004, it is estimated that 40% of these (19,415) were caused by smoking.

Table 6 Mortality caused by smoking related diseases in 2004 (adults, 20 years and older)

Disease	Total deaths		Deaths caused by smoking	
	M	F	M	F
Lung cancer	6,468	2,855	5,913	2,120
COPD	3,410	2,320	2,855	1,594
Coronary heart disease	7,965	6,115	2,263	806
Stroke	4,331	6,743	906	672
Heart failure	2,366	3,759	426	215
Oesophagus cancer	949	390	753	249
Larynx cancer	173	43	138	35
Oral cavity cancer	350	214	323	119
Total per sex	26,012	22,439	13,605	5,810
Total	48,451		19,415 (40.1%)	

Source: http://www.rivm.nl/vtv/data/kompas/determinanten/exogeen/roken/roken_gevolg.htm⁸⁷

Chapter 3

Summary of recommendations

Recommendations Behavioural support

4.1 One-off and brief supportive interventions

In view of the considerable health risk posed by smoking in the Dutch population and the proven effectiveness of one-off and brief advice, health professionals should, if possible, systematically record the smoking behaviour of a patient/client in the medical records. This could lead to an increase in the number of interventions by health professionals.

Although more intensive advice or smoking cessation programmes are more effective than a one-off advice, it is vitally important that all health professionals give at least a one-off advice to each new patient/client who is found to smoke. In the case of smokers who are not motivated to stop, this should be repeated regularly, for example each year.

As more intensive interventions are more effective than one-off advice, the most intensive form of supervision is preferred. If this is not feasible, the preference is for the most intensive intervention available in the existing situation within a reasonable timeframe; a 'stepped care' approach can also be chosen (*see under 'Stepped care' in section 4.3.4*).

There are no convincing indications for a direct relationship between the effectiveness of one-off and brief interventions and the degree to which smokers indicate their willingness to undertake a quit attempt. However, more intensive interventions should clearly not be used in the case of smokers who are not motivated. Therefore in applying the guideline, a distinction can be made between three types of smokers/patients:

(a) Smokers who are prepared to undertake a quit attempt

For each contact with a health professional in which smoking plays a relevant role, it is important to ask if the person smokes ('ask'), assess the willingness to stop ('assess'), give advice to stop smoking ('advise'), to assist with the undertaking of an attempt to stop ('assist') and finally to take measures for relapse prevention and follow up ('arrange'). This process of the five As has been designed to be carried out in 3 to 10 minutes (*appendix 1, The five As*).

There is a lot of overlap between the MIS and the five As model and the MIS also contains elements of relapse prevention (five Rs).

(b) Smokers who are not prepared to undertake a quit attempt at present

For smokers who indicate that they are not motivated to undertake an attempt to stop, a brief supportive intervention can be given with the objective of increasing the motivation. The lack of motivation can have various causes, such as anxiety/uncertainty about the stopping or previous, unsuccessful attempts. Such smokers could benefit from an intervention aimed at increasing the motivation, which is structured according to the strategy of the five Rs: 'relevance', 'risks', 'rewards', 'roadblocks', 'repetition' (*appendix 2, The five Rs*). The MIS also contains elements of relapse prevention (five Rs), as a result of which this method can be used for both group a and group b.

(c) Recently stopped smokers

The failure of an attempt to stop usually occurs during the initial period (3 months) after the start of a stop attempt. Yet a relapse can also occur years later. Therefore relapse prevention by health professionals over a long period of time is important.² Relapse prevention can be subdivided into two categories:

- **Minimal practice intervention:** intended for every recently stopped smoker who attends a consultation with a health professional during the first 3 months of the attempt to stop. It consists of:
 - expressing appreciation of the attempt and encouraging the patient to keep going;
 - a consultation with open questions about the advantages of smoking cessation;
 - celebrating the success of the stopped smoker and listing problems that he/she experiences due to stopping.
- **Anticipatory relapse prevention:** intended for the stopped smoker who indicates that he/she is experiencing problems in not relapsing. This consists of a specific response to the problem that the stopped smoker reports, for example in the area of social support, depressive feelings, withdrawal symptoms, weight increase, decreased motivation (*appendix 3, Relapse prevention*). A distinction can be made between the physical dependence, which mostly lasts about three weeks, and the mental dependence, which can persist for much longer.

4.2 Telephone counselling

4.2.1 Reactive telephone counselling

- Reactive telephone counselling is recommended as a method for advising and supporting smokers during smoking cessation.
- Offering more intensive telephone counselling which consists of several conversations is effective. The conversations contain at least the following types of counselling: problem-solving skills and social support.

4.2.2 Proactive telephone counselling

- Proactive telephone counselling is recommended as a method for advising and supporting smokers during smoking cessation.

4.3 Intensive interventions

4.3.1 Effectiveness

- As there is evidence for a dose-response relationship and the working group considers heavy smoking to be an addiction that should be taken seriously, intensive forms of intervention within a research setting are recommended because, even though there is no scientific evidence for specific intensive treatment forms of tobacco addiction, intensive interventions have achieved positive effects with other types of addiction. Scientific research will need to demonstrate whether the large-scale use of intensive interventions is worthwhile.
- Smokers who want intensive treatment and smokers who have made several unsuccessful attempts to stop with help – but who are prepared to stop – must be given the possibility of receiving more intensive support. An intensive treatment can be recommended at an earlier stage to certain target groups, such as pregnant women and patients with smoking-related conditions.

4.3.2 Certain categories of smokers/patients

- **Adolescents and young people**
The effect of intensive smoking cessation interventions among young people still needs to be investigated further. In doing so it is wise to give as much consideration as possible to the individual characteristics and preferences of the smoker concerned.

- **Pregnant women**

In view of the importance of smoking cessation for mother and child, intensive interventions for pregnant women can be recommended if a less intensive intervention has not worked.

- **Patients admitted to hospital**

- When smokers are admitted to a hospital, there is a unique opportunity to provide them with intensive support during smoking cessation.
- When patients are admitted, the hospital staff must determine whether or not they smoke, advise smokers to stop and in the case of those who want to stop, provide intensive help if this is wanted. Patients must be informed about the smoking ban in the hospital before they are admitted.

- **Other special target groups**

Intensive treatment must be used as much as possible in the case of persistent smokers. If this proves to be too expensive then the choice can be made to treat risk groups. Thought must be given to ways of making nicotine replacement therapies more available to smokers from the lowest income groups. For example, these could be provided for a lower price or free of charge.

4.3.3 Setting, discipline and training

- There need to be enough locations in the Netherlands where intensive interventions can be provided. The following are eligible for this: primary healthcare (general practitioner), public healthcare (home assistance services, municipal health services), outpatients' departments of general hospitals, addiction care, telephone counselling and e-learning programmes via the Internet.
- Intensive interventions are preferably carried out by a physician ('ask', 'assess', 'advise' and the prescription of supportive medication) and/or a nurse, and with a behavioural therapist ('assist', 'arrange'; behavioural supervision and training).
- Good supportive courses should be developed for professionals and given to professionals. These courses should be accredited by the professional groups.

4.3.4 Influence of method, form and size on the effectiveness of intensive interventions

Method

It is recommended that those carrying out intensive interventions are trained in a motivating approach and in methods for behavioural, affective and social support. Intensive interventions should preferably be combined with nicotine replacement therapies.

Form

Intensive interventions in the area of smoking cessation can be just as well organised in a group context.

Size: number and duration of sessions

- An intensive intervention should consist of at least four sessions of 10-20 minutes, spread over one month, plus follow-up visits.
- There are indications that the effectiveness of the intensive intervention increases for a total contact duration of up to 90 minutes. A possible additional effect above this limit has not yet been demonstrated.
- On the basis of smoking cessation modules already developed in the Netherlands, as well as the experiences in the care of addicted people, the working group recommends distinguishing intensive smoking cessation interventions in several subcategories of intensity that are parallel with the intensity gradations used by interventions for other substances in addiction care, namely:
 - **Shorter ambulant training:** Interventions with a size of 4 to 6 contacts of 20 minutes to 1 hour per contact (analogous to addiction care lifestyle training brief individual and group protocol).
 - **Longer ambulant training:** Interventions with a size of 10 to 15 contacts of 20 minutes to 1 hour per contact (analogous to addiction care lifestyle training long individual and group protocol – for example Grab your chance [Pakje Kans] of STIVORO for a smokefree future), possibly followed by several follow-up contacts.
 - **Short clinical + long ambulant training:** An intervention in which smoking cessation takes place in a clinical setting, as part of an intervention as described for longer ambulant training.

Stepped care

- For all patients who report to physical healthcare and addiction care services (and the mental health service), the use of tobacco is one of the issues raised. All regular smokers receive the advice to stop.
- For all of those who are not insensitive to this advice and for those in whom the health complaints are clearly associated with smoking, the offer is made to further support the smoking cessation in one or more follow-up consultations (less intensive intervention). This can be pharmaco-therapeutically supported.
- Relapsed smokers are offered a more intensive intervention that, if possible, is supported pharmaco-therapeutically.
- Persistent relapsed smokers and smokers under the addiction services receive a more intensive intervention which is provided in a specialist setting, and if possible is supported pharmaco-therapeutically.

Recommendations Pharmacological support

5.1 Nicotine replacement therapies

5.1.2 Safety and side effects

- For each form of support given to smokers who smoke 10 or more cigarettes per day, information about pharmacotherapy should be given. Nicotine replacement therapies are safe and effective resources for helping people to stop smoking, particularly for people who ask for such help themselves. All available nicotine replacement therapies increase the chance of a successful attempt to stop smoking in the longer term by a factor of 1.5-2 (NNT of nicotine replacement therapies compared to placebo is about 14).
- The choice between the various nicotine replacement therapies can be based on the personal preference of the user, the side effects profile (see *appendix 7*, Dosages and contraindications for the pharmacological treatment of tobacco addiction) and the price. There is little difference in effectiveness.
- Nicotine replacement therapies can be used by 'risk groups' such as people with cardiovascular diseases but also by addicted young people aged 12 years or older. For pregnant or breastfeeding women nicotine replacement therapies can be considered when smoking cannot be stopped using any other approach and when the advantages of using nicotine replacement therapies weigh up against the risks of smoking (see also *section 7.3.3*).
- There is no evidence that the approach used for smokers from different socio-economic groups in the population or for different types of smokers (heavily as opposed to moderately addicted) should substantially differ.

5.2 Bupropion

5.2.2 Safety

- In view of the side effects profile it is recommended that the treatment with bupropion should be accompanied by at least two appointments with a physician. The first appointment is to check for contraindications (for example, pregnancy) and to provide an explanation about the drug, and the second is for a follow-up consultation with the smoker and if need be to issue a further prescription. The pharmacist can also provide information in this phase.
- Although bupropion appears to be safe for schizophrenic smokers, it is recommended that it is not prescribed as the drug of first choice due to the relatively frequent occurrence of side effects, such as headache, insomnia and memory problems.

5.3 Nortriptyline

5.3.2 Safety

- The possibility of using nortriptyline can be discussed with all smokers who want to stop smoking.
- The presence of one or more contraindications should be checked before the advantages and disadvantages of using nortriptyline are discussed. Other drugs should be considered first in the case of pregnant women.
- The slight difference in effectiveness and the considerable difference in price between bupropion and nortriptyline makes nortriptyline an attractive drug. It is however not registered for smoking cessation.

5.8 Conclusion: choosing a pharmacological therapy

- For all smokers who smoke more than 10 cigarettes per day and who are considering an attempt to stop, the use of one of the nicotine replacement therapies during this attempt should be considered. These drugs can also be recommended in the case of a second attempt to stop.
- For all smokers who smoke more than 10 cigarettes per day and who want to stop, and for whom nicotine replacement therapies are not or are no longer an option, the use of bupropion or nortriptyline can be considered.

Recommendations Practice settings and target groups

7.1 General practice

7.1.4 Practice assistants or doctor's assistants

- When the general practice has to set priorities with respect to the investment of time, the practice staff can best focus on smokers with a high motivation. Such smokers particularly deserve attention if they have (or have a high risk of) smoking-related complaints.
- General practitioners should actively give a smoking cessation advice to smokers with smoking-related complaints and from risk groups (cardiovascular diseases, COPD and pregnant women).
- In order to promote the implementation and satisfactory use of one-off and brief smoking cessation advice in the general practice (in general practice often according to the H-MIS, see *appendix 8*), general practitioners, doctor's assistants and practice assistants should receive sufficient practical support and training.

- General practitioners (or the practice assistant or doctor's assistant) should assess the smoking behaviour and motivational level of smokers, and then use a brief supportive intervention for motivated smokers, for example according to the H-MIS method.
- A smoker should preferably be given a smoking cessation advice once a year during a visit to the general practice, irrespective of whether he/she requests an intervention.
- In the case of smokers who are not motivated to stop, a one-off advice is sufficient; for smokers who are motivated to stop, the motivation and the factors which are obstacles and stimulants are discussed, a stop date and follow-up consultation are agreed upon and a leaflet is given to the patient (preferably Dutch College of General Practitioners – Dutch acronym: NHG [Nederlands Huisartsen Genootschap] Patient letter). If necessary this can take place with pharmacological support (see also H-MIS, *appendix 8*).
- The general practitioner can partly or completely delegate the intervention to a trained doctor's assistant or practice assistant. The cooperation of health professionals is recommended. The use of a longer investment of time (up to 90 minutes) and as many contacts as possible per smoker seem to be worthwhile and cost-effective.
- The ideal is a practice assistant who, after special training, provides intensive individual counselling during special hours outside of the normal provision of care.

7.2 Dental practice

7.2.3 Dentists' smoking policy

- In view of the added value of their stop advice, dentists should be involved in smoking cessation campaigns.
- It must be established whether the existing educational material for dentists and patients is sufficient. Courses for the training of dentists should be developed and offered.
- A charge should be introduced for a smoking cessation consultation in order to encourage the implementation of smoking cessation advice by dentists.
- It is recommended that courses are not only organised for dentists, but also for other practice staff.

7.3 Midwifery practice (all disciplines)

7.3.1 Effectiveness of brief smoking cessation interventions for pregnant women

- Due to the considerable risks of smoking during pregnancy for both the mother and child, all smoking pregnant women must receive the urgent and clear advice to stop smoking. Smoking cessation interventions should preferably go further than a brief supportive advice.
- Although smoking cessation at the start of the pregnancy provides the most benefits, stopping at any moment during pregnancy is favourable. Smoking cessation interventions should therefore be offered at least once each during pregnancy, preferably during the initial consultation.
- Midwives, gynaecologists and general practitioners should note the smoking behaviour and motivation level of pregnant women and then give a brief advice to motivated smokers. The V-MIS is an effective method for this purpose, at least in the short-term. The smoking cessation advice to pregnant smokers could adopt the following form (Melvin 2000).¹⁵
- ASK-1 minute:
Ask the patient to indicate which of the following statements best describes her:
 - A I have NEVER smoked or have smoked less than 100 cigarettes in my entire life.
 - B I stopped smoking BEFORE I discovered I was pregnant and I do not smoke now.
 - C I stopped smoking AFTER I discovered I was pregnant and I do not smoke now.
 - D I still smoke occasionally but I reduced the number of cigarettes when I discovered that I was pregnant.
 - E I smoke regularly, about the same as BEFORE I knew that I was pregnant.

In the case of B or C, congratulate the woman with her decision to stop and encourage her to keep this up both during and after the pregnancy.

In the case of D or E, record her smoking status in the records and apply a one-off or brief supportive intervention according to the 5 As model ('assess', 'advise', 'assist' and 'arrange', see *appendix 1*.) The five As are intended for every smoker who wants to stop.
- For motivated smokers it is worthwhile devoting attention and support to smoking cessation throughout the course of the pregnancy (therefore during several consultations).
- As good experiences have been gained with the educational programme 'Smoking? Not when the little one is around' [Roken? Niet waar de kleine bij is], this can be used as a good example for reducing passive smoking by children.

7.3.3 Pharmacological support

- For pregnant women or breastfeeding women, nicotine replacement therapies can be considered when smoking cannot be stopped using any other approach and when the advantages of stopping weigh up against the risks of nicotine replacement therapies (see also *section 7.3.3*). It is recommended that further clinical research be carried out into the effectiveness and safety of nicotine replacement therapies for pregnant smokers. The use of bupropion is contraindicated. The risks of using nicotine replacement therapies at the same time as smoking must be emphasised (risk of lower birth weight).

7.3.4 Relapse prevention among pregnant women

- Women who have stopped smoking during pregnancy must also be offered support after childbirth. The care provided by midwives ends one week after childbirth, and is then followed by a one-off check up at six weeks after childbirth. The effect of an intervention aimed at relapse prevention can possibly be increased by clearly transferring this task from the midwife or gynaecologist to the infant welfare centre, the general practitioner or possibly the paediatrician.

7.4 Parents of newborns and young children

7.4.2 Effectiveness

- Paediatricians, general practitioners, infant welfare centre doctors, school doctors and other health professionals should include a one-off advice and a brief supportive intervention about smoking cessation in their policy for each new patient/parent contact, for example according to the MIS approach.
- Children with respiratory complaints suffer more from passive smoking. For this group of children in particular, paediatricians, general practitioners, infant welfare centre doctors, school doctors and other health professionals involved in the care of children should be particularly vigilant in offering systematically given one-off advice and brief supportive interventions, for example according to the MIS approach.

7.5 Teenagers

- In view of the considerable health risks of smoking for teenagers, paediatricians, general practitioners, infant welfare centre doctors, school doctors and other health professionals should encourage teenagers to stop smoking. It is not clear which intervention or combination of interventions is particularly effective for this target group. There is no reason to treat this group in a fundamentally different manner, but it is important to relate as much as possible to the outlook of young people.

7.6 Patients with smoking-related complaints

7.6.1 Cardiovascular diseases

- Cardiologists and the nurses involved should record the smoking behaviour and motivational level of their patients with a smoking-related disorder and then support motivated smokers in their attempt to stop. This should also include attention and support for the period following discharge from the hospital. Patients who are not motivated to stop smoking should first of all be motivated. The C-MIS is a method that can be used for this. For longer-lasting and greater effects a more intensive intervention is recommended, with follow-up care following discharge from hospital and attention for relapse prevention.

7.6.2 Chronic lung diseases

- Pulmonologists and the nurses involved should record the smoking behaviour and motivational level of the patients with a smoking-related disorder and then support motivated smokers in their attempt to stop, and in so doing, attention and support should also be devoted to the period following discharge from the hospital. Patients who are not motivated to stop smoking should first of all be motivated. The L-MIS is a method that can be used for this. For longer-lasting and greater effects a more intensive intervention is recommended, with follow-up care following discharge from hospital and attention for relapse prevention.

7.8 Psychiatric smoking patients and multiple addiction smokers

7.8.3 Treatment

- Patients with psychiatric clinical pictures can benefit just as much from the positive effects of smoking cessation as other smokers.
- The person treating a psychiatric patient will need to be aware that smoking cessation can have consequences for both the pattern of the symptoms as well as the effect and side effects of medication. It might be necessary to change medication dosages after the patient has stopped smoking.
- In view of the side effects profile and the possible interactions with other medicines, prescribing bupropion to patients with psychiatric disorders is less preferable than treatment with nicotine replacement therapies. As nicotine can have a positive effect in the case of some psychiatric clinical pictures, nicotine replacement therapies would also seem to be the most suitable option.

- For serious, chronic psychiatric patients there might be reasons why treatment of the nicotine addiction is not possible, for example because their ability to realise a problem and exercise self-control has been damaged. If these patients are dependent on residential care institutes for a longer period of time, the quality of life should take centre stage, with due consideration to the handicaps present.

Recommendations Starting points of implementation

8.5 Expertise centres

- In line with the Health Facilities Board [College van Zorgvoorzieningen], the working group recommends that smoking cessation interventions that have been demonstrated to be effective are reimbursed.⁸
- It is recommended that general practices can call upon a sufficient level of practice support for the use of the H-MIS.⁸
- Accredited training must be further developed and should be offered to trainee health professionals.
- Practice-oriented screening, intervention protocols and resources must be further developed and disseminated among all primary care and hospital health professionals, including pharmacists and dentists, with instructions for usage.
- All cost-effective, evidence based, behavioural and pharmacological forms of support must be reimbursed for all smokers who make use of these and all health professionals who offer these.
- Smoking cessation treatment centres must be developed and implemented with one such centre per 500,000 head of population. Expertise centres with a link to treatment centres must be commissioned to provide the treatment centres with scientific support.

Chapter 4

Behavioural support

As the intensity of the behavioural intervention is important, a distinction is made in this chapter between: (a) a one-off advice (two As), with or without pharmacological support on request (particularly for smokers of more than 10 cigarettes per day), (b) a brief supportive intervention (two to five As), with or without pharmacological support (particularly for heavy smokers and patients in risk groups), and (c) an intensive intervention, with or without pharmacological support.

In the Netherlands, the manner in which the brief supportive intervention is carried out is known as the *minimum intervention strategy (MIS)*. This refers to an intervention which is split over at least two contacts and contains at least the five As described in *appendix 1*. As indicated under the definitions in the general introduction, a series of MIS protocols have been developed for the Dutch healthcare system, which differ from each other in certain aspects, for example in terms of intensity, due to differences between the practice situations. A section on telephone counselling has also been included. As this can take the form of a one-off advice (reactive counselling) or an intensive advice (proactive counselling) this method is discussed separately (see *section 4.2*).

4.1 One-off and brief supportive interventions

One-off, brief advices during normal care contacts are probably the most relevant for health professionals in primary care, but there is no reason why most health professionals in specialised care cannot use these.

In a review¹ about advice provided in general practice, in which the advice is mostly given by a general practitioner and supported by written material, it was found that:

- one-off advice has a positive effect: OR: 1.27 (95% CI: 1.11-1.45), equivalent to an absolute difference between intervention and control groups of 2.1%:
- a brief supportive intervention (more than one contact) has a positive effect: OR: 1.96 (95% CI: 1.18-1.80), equivalent to an absolute difference of 4.4%.

Another meta-analysis revealed that advice given by a physician is effective: OR: 1.3 (95% CI: 1.1-1.6), equivalent to an absolute difference of 2.3%. (95% CI: 0.6-4.1).² Finally a review of studies which mostly took place in primary healthcare revealed that³:

one-off advice or a brief supportive intervention has an OR of 1.69 (95% CI: 1.45-1.98) equivalent to an absolute difference of 2.5%. Intensive intervention has an OR of 2.11 (95% CI: 1.74-2.54). However, this result is not reliable due to the heterogeneity between the studies ($p = 0.005$) (no absolute difference percentage stated).

In Dutch general practice, use of the MIS had a positive effect compared to ‘usual care’: OR: 3.04 (95% CI: 1.7-5.6) and an absolute difference of 5.1%. The success in the intervention group was 8.2%. In the intervention group 9.3% of smokers received a prescription for nicotine gum.⁴ In this study the MIS consisted of establishing the motivation level and the nicotine dependence (1), increasing the motivation (2), discussing barriers (3), agreeing a stop date (4), offering a self-help guide (5), advising pharmacotherapy (6) and offering a follow-up consultation (7).

An overview of the studies used can be found in *tables 1 and 2 (appendix 5)*.

Type of intervention

Motivating counselling was not significantly more effective than a brief advice: OR: 2.00 (95% CI: 0.59-6.72) (studies mostly took place in primary healthcare). However, a small positive effect of follow-up was reported for a minimum intervention.³

A health professional offering personal supervision (OR: 1.3 (95% CI: 1.1-1.6)), discussion and resolving of obstacles (OR: 1.5 (95% CI: 1.3-1.8)) and giving an advice to gain support from the social network (OR: 1.5 (95% CI 1.1-2.1)), are effective.²

Adding an intervention to increase the support from a partner has no extra effect compared to interventions without this extra intervention. The partner support does not or scarcely seems to increase as a result of the intervention.⁵

There is limited evidence that stage-based interventions are more effective than other interventions or the usual provision of care.⁶ This last study does not contain a meta-analysis and consequently the small studies had a relatively large effect on the conclusions. An overview of the studies used can be found in *tables 3 and 4 (appendix 5)*.

Duration and intensity

In a direct comparison between a one-off advice or a brief supportive intervention, the OR was not significant: 1.07 (95% CI: 0.88-1.29).¹ However, a meta-analysis revealed that the effectiveness of interventions increases if the intervention is more intensive, lasts longer or contains more contact moments.² In a direct comparison of an intensive intervention as opposed to one-off advice or a brief supportive intervention the OR was 1.44 (95% CI: 1.23-1.68). However, there was a significant heterogeneity between the studies ($p = 0.040$). Adding follow-up consultations was more effective than no follow-up: OR 2.66 (95% CI: 2.06-3.45) as opposed to 1.59 (95% CI: 1.33-1.90). Upon direct comparison the OR was 1.60 (95% CI: 1.10-2.33).³ Adding a telephone follow-up to a face-to-face intervention has no additional effect: OR 1.08 (95% CI: 0.87-1.34).⁷

An overview of the studies used can be found in *tables 5 to 8 (appendix 5)*.

Self-help materials

Adding resources to an advice as a reward, such as a video, self-help guide, or a telephone card was not clearly more effective (OR 1.95 (95% CI: 1.54-2.45)) than an advice without a resource (OR 1.88 (95% CI: 1.63-2.18)).

Adding a telephone follow-up to a face-to-face intervention has no additional effect: OR 0.97 (95% CI: 0.78-1.21).⁸ In another meta-analysis the addition of self-help materials to face-to-face advice was found to have a minimal effect.² An overview of the studies used is given in *tables 9 and 10 (appendix 5)*.

Characteristics of the smoker

A direct comparison between intensive as opposed to one-off advice or a brief supportive intervention gave an OR of 1.23 (95% CI: 1.02-1.49) for unselected smokers and 1.82 (95% CI: 1.44-2.29) for smokers with a high risk of smoking-related complaints.³

A meta-analysis of different forms and intensities of treatment revealed that the effect of treatment is not dependent on whether the smoker requests treatment or the treatment is offered without being requested. Sex, race and ethnicity were also found to have no effect. Treatment of the elderly was also found to be effective.²

Table 7 Variables associated with abstinence rates²

Variables which are associated with high abstinence rates	
Variable	Example
High motivation	Smoker indicates motivation to stop
Ready for change	Smoker is ready to stop within one month
Average to high self-efficacy	Smoker has confidence in his/her attempt to stop
Supportive social network	A smoke-free environment at work and at home; friends who do not smoke in the presence of the smoker who has stopped
Variables associated with lower abstinence rates	
Strong nicotine dependence	Smoker experienced serious withdrawal symptoms during previous attempt to stop, smokes a lot (> 20 cigarettes/day), and/or smokes his/her first cigarette of the day within 30 minutes of waking up
Psychiatric history	Smoker has a history of depression, schizophrenia, alcohol dependence, or other chemical dependence
High stress level	Stressful circumstances and/or recent large changes in everyday life (for example divorce, new job, moved house)

Logistic regression revealed that low nicotine dependence was correlated with more quitters after 12 months.⁴

There is no evidence that interventions without pharmacotherapy are effective among patients with COPD.⁹

Interventions for smoking cessation among pregnant women are effective: OR (reductions in number of women who smoke): 0.53 (95% CI: 0.47-0.60), equivalent to an absolute difference of 6.4%.¹⁰ For interventions with a very high intensity the OR (reductions in number of women who smoke) was 0.54 (95% CI: 0.46-0.63), equivalent to an absolute difference of 7.9%. Pharmacotherapy was not used in these interventions. Another meta-analysis also revealed that extra attention for smoking cessation among pregnant women was more effective than usual care: OR: 2.8 (95% CI: 2.2-3.7).²

An overview of the studies used can be found in *tables 2 and 11 (appendix 5)*.

Conclusions

Level I	<p>Personal supervision by the health professional, discussion of the obstacles and increasing the support from the social network, all have a weak positive effect.</p> <p><i>A1 Silagy 2002³; A1 Fiore 2000²; A1 Park 2002⁵</i></p>
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Type of intervention

Level I	<p>Adjusting the intervention to the patient's stage of change increases the possible effect, but the evidence for this is limited.</p> <p><i>A1 Riemsma 2003⁶</i></p>
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Duration and intensity

Level I	<p>Offering follow-up consultation(s) increases the effect of the advice.</p> <p><i>A1 Silagy 2002³; A1 Fiore 2000²</i></p>
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Level I	<p>There is a dose-response relationship between the total duration of contacts and the effect.</p> <p><i>A1 Silagy 2002³; A1 Fiore 2000²</i></p>
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Self-help materials

Level I	<p>Self-help materials do not increase or scarcely increase the effect of brief supportive interventions.</p> <p><i>A1 Silagy 2002³; A1 Lancaster 2002⁸; A1 Fiore 2000²</i></p>
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Characteristics of the smoker

Level I	<p>Interventions are probably more effective in the case of a well-motivated smoker, low nicotine dependence, a lack of stress and psychiatric problems and a high risk for or the presence of smoking-related conditions. Unsolicited advice is also effective.</p> <p><i>A1 Silagy 2002³; A1 Fiore 2000²; Pieterse 2001⁴</i></p>
Level I	<p>Interventions among pregnant women are effective.</p> <p><i>A1 Fiore 2000²; A2 Lumley 2003¹⁰</i></p>

Other considerations

- Smoking is a serious health risk for the Dutch population; therefore offering interventions with a marginal effectiveness to a large number of people is still relevant and cost-effective.
- The time that health professionals have for consultations is limited. Smokers can also be reticent with respect to participating in intensive programmes. It would be good if the time invested by health professionals were compensated. Thirty percent of general practitioners receive help from a practice assistant; this person can develop into a specialist for intensive or less intensive smoking cessation interventions.
- Due to anxiety of failure, quitters sometimes seek no general or social support. Anxiety of failure possibly exists because people underestimate their self-efficacy (the confidence that an attempt to stop can be maintained). Accordingly they do not know how to cope without a cigarette, as they are afraid that they will be unable to resist the urge to smoke with a cup of coffee and/or alcohol, or that they will put on weight.

Recommendations

In view of the considerable health risk posed by smoking in the Dutch population and the proven effectiveness of one-off and brief advice, health professionals should, if possible, systematically record the smoking behaviour of a patient/client in the medical records. This could lead to an increase in the number of interventions by health professionals.

Although more intensive advice or smoking cessation programmes are more effective than a one-off advice, it is vitally important that all health professionals give at least a one-off advice to each new patient/client who is found to smoke. In the case of smokers who are not motivated to stop, this should be repeated regularly, for example each year.

As more intensive interventions are more effective than one-off advice, the most intensive form of supervision is preferred. If this is not feasible, the preference is for the most intensive intervention available in the existing situation within a reasonable timeframe; a ‘stepped care’ approach can also be chosen (*see under ‘Stepped care’ in section 4.3.4*).

There are no convincing indications for a direct relationship between the effectiveness of one-off and brief interventions and the degree to which smokers indicate their willingness to undertake a quit attempt. However, more intensive interventions should clearly not be used in the case of smokers who are not motivated. Therefore in applying the guideline, a distinction can be made between three types of smokers/patients:

(a) Smokers who are prepared to undertake a quit attempt

For each contact with a health professional in which smoking plays a relevant role, it is important to ask if the person smokes (‘ask’), assess the willingness to stop (‘assess’), give advice to stop smoking (‘advise’), to assist with the undertaking of an attempt to stop (‘assist’) and finally to take measures for relapse prevention and follow up (‘arrange’). This process of the five As has been designed to be carried out in 3 to 10 minutes (*appendix 1, The five As*).

There is a lot of overlap between the MIS and the five As model and the MIS also contains elements of relapse prevention (five Rs).

(b) Smokers who are not prepared to undertake a quit attempt at present

For smokers who indicate that they are not motivated to undertake an attempt to stop, a brief supportive intervention can be given with the objective of increasing the motivation. The lack of motivation can have various causes, such as anxiety/uncertainty about the stopping or previous, unsuccessful attempts. Such smokers could benefit from an intervention aimed at increasing the motivation, which is structured according to the strategy of the five Rs: ‘relevance’, ‘risks’, ‘rewards’, ‘roadblocks’, ‘repetition’ (*appendix 2, The five Rs*). The MIS also contains elements of relapse prevention (five Rs), as a result of which this method can be used for both group a and group b.

(c) Recently stopped smokers

The failure of an attempt to stop usually occurs during the initial period (3 months) after the start of a stop attempt. Yet a relapse can also occur years later. Therefore relapse prevention by health professionals over a long period of time is important.² Relapse prevention can be subdivided into two categories:

- **Minimal practice intervention:** intended for every recently stopped smoker who attends a consultation with a health professional during the first 3 months of the attempt to stop. It consists of:
 - expressing appreciation of the attempt and encouraging the patient to keep going;
 - a consultation with open questions about the advantages of smoking cessation;

- celebrating the success of the stopped smoker and listing problems that he/she experiences due to stopping.
- Anticipatory relapse prevention: intended for the stopped smoker who indicates that he/she is experiencing problems in not relapsing. This consists of a specific response to the problem that the stopped smoker reports, for example in the area of social support, depressive feelings, withdrawal symptoms, weight increase, decreased motivation (*appendix 3, Relapse prevention*). A distinction can be made between the physical dependence, which mostly lasts about three weeks, and the mental dependence, which can persist for much longer.

4.2 Telephone counselling

Telephone counselling can be offered on either a reactive or a proactive basis. In reactive counselling the smoker calls a helpline for advice on stopping and support. In proactive counselling smokers are called to receive advice on stopping and support at previously agreed upon times according to a predetermined protocol. Therefore this form of support always consists of several conversations.

Telephone counselling can be offered as the sole intervention but also in addition to, for example, a self-help method. Telephone counselling can vary in the number of conversations that take place and the duration of these.

In the Netherlands, telephone counselling is also referred to as telephone coaching and is available from STIVORO for a smokefree future. This national helpline provides both reactive and proactive support consisting of a 30 minutes initial conversation and six follow-up conversations with an average duration of 15 minutes. The telephone number for this helpline has been provided on cigarette packets since 1 May 2002.

4.2.1 Reactive telephone counselling

It is not possible to compare reactive telephone counselling, in which smokers have an acute request for help, with no intervention in a randomised study design, due to the ethical objections of withholding help from smokers. Therefore evidence for the effectiveness of this approach is limited. In the Cochrane database one study is discussed in which the combination of self-help materials with the offer of help via a telephone helpline was compared with just self-help materials. Telephone counselling in addition to self-help materials was found to be a more effective intervention (OR: 1.72; 95% CI: 1.13-2.63). However, two other studies with a similar design found that offering the possibility of calling a helpline had no significant effect.

Three non-randomised studies have been carried out into the effectiveness of reactive 'quit lines' which reveal high success rates. The point prevalence of stopping after 12 months was 24%,¹ 29% and 16% (*table 13, appendix 5*).² Due to the lack of a control group it is not known how many would have stopped if no telephone help had been offered.

Effective components

In the Cochrane database two studies are discussed in which several telephone conversations were compared with a single telephone conversation. One study showed a significant effect (OR: 1.36; 95% CI: 1.01-1.83). The other study revealed an almost significant effect (OR: 1.40; 95% CI: 1.00-1.96). These results are in keeping with the American guideline in which a positive correlation was found between intensity and effect.³ The best results are achieved with conversations that last more than 10 minutes, support that consists of eight or more sessions and in counselling where the following techniques are used: skills training, offering social support, and supporting smokers in obtaining social support outside of the intervention.

Characteristics of smokers

A Dutch study revealed that the smokers who make use of telephone counselling (compared to the general population of smokers) are older, frequently women, have a low income, underestimate their own capacities to be able to stop (low estimates of self-efficacy) and were more addicted to nicotine.⁴

Conclusions

Level 3	<p>There are indications that reactive telephone counselling is an effective method for permanent smoking cessation.</p> <p><i>C1 Stead 2003⁵</i></p>
Level 3	<p>A successful telephone counselling consists of several contacts.</p> <p><i>A2 Stead 2003⁵</i></p>
Level 1	<p>There is a strong dose-response relationship between the intensity of the telephone counselling and success: the more intensive the intervention, the greater the chance of success. Interventions can be made more intensive by increasing the length of the individual sessions and the number of sessions. The best results are achieved with eight or more sessions.</p> <p><i>A1 Fiore 2000³</i></p>
Level 1	<p>Three types of counselling result in higher abstinence rates: skills training, providing social support, and support in obtaining social support.</p> <p><i>A1 Fiore 2000³</i></p>

Recommendations

- Reactive telephone counselling is recommended as a method for advising and supporting smokers during smoking cessation.
- Offering more intensive telephone counselling which consists of several conversations is effective. The conversations contain at least the following types of counselling: problem-solving skills and social support.

4.2.2 Proactive telephone counselling

According to the American guideline³ proactive telephone counselling is more effective than no intervention (OR: 1.2; 95% CI: 1.1-1.4; *table 14, appendix 5*). Since the publication of the American guideline, much research has been carried out into the effectiveness of telephone counselling. This has been incorporated into an update (March 2003) of the Cochrane database (*table 14, appendix 5*).³ The American analyses included all of the studies concerning telephone counselling, even if they were combined with other components in the intervention. In the Cochrane analyses only the studies that directly measured the effect of telephone counselling were included. As a result of this they provide a less biased picture of the effectiveness of telephone counselling.

In the Cochrane review, 13 studies were examined in which proactive telephone counselling was compared with a minimum control intervention (self-help material in ten studies, no intervention in two studies and self-help materials combined with a 'hotline reminder' in one of the studies). As the studies were statistically heterogeneous, no pooled odds ratio could be calculated. Five of the 13 studies found a positive effect and eight found a non-significant difference. During the meta-analysis with the same studies in which the least intensive intervention was used as a control group (only self-help guide or no intervention), the heterogeneity disappeared. Then it was found that proactive telephone counselling gave rise to significantly more quitters than a minimum intervention (OR: 1.56; 95% CI: 1.38-1.77).

The difference was 2.51% and the pooled success in the intervention group was 9.36%. Four studies compared the addition of telephone counselling to a personal intervention and demonstrated no significant long-term effect (OR: 1.08; 95% CI: 0.87-1.33). Also no significant effect was found when telephone counselling was added to nicotine replacement therapies (OR: 1.08; 95% CI: 0.82-1.43).

In another meta-analysis of proactive telephone counselling it was found that this method seemed to be very effective as a supplement to smoking cessation programmes in cardiology departments.⁶ After discharge from the hospital, patients were supported on four to seven occasions over the telephone by a nurse to persist with not smoking. The pooled OR from three studies was 2.01 (95% CI: 1.47-2.74) at 12 months follow-up.

Conclusions

Level I	Proactive telephone counselling is effective. <i>A1 Fiore 2000³</i>
Level I	Proactive telephone counselling is more effective than self-help material or no intervention. <i>A1 Stead 2003⁵</i>
Level I	No evidence was found for the effectiveness of proactive telephone counselling as a supplement to a personal intervention or pharmacotherapy. <i>A1 Stead 2003⁵</i>
Level I	Proactive telephone counselling is effective in preventing the relapse of cardiology patients after smoking cessation. <i>A1 Lichtenstein 1996⁶</i>

Other considerations

- Research into the client perspective among ‘healthy’ smokers revealed that they were not familiar with STIVORO for a smokefree future and their telephone helpline.
- In addition to this it was found that telephone counselling has the advantage that it is easy and accessible. Furthermore, the anonymity is an advantage (if things are going less well), but also a disadvantage (because you do not build up a relationship). There is no preference for the smoker phoning (reactive) or being phoned (proactive).

Recommendation

- Proactive telephone counselling is recommended as a method for advising and supporting smokers during smoking cessation.

4.3 Intensive interventions

The American guideline defines intensive to mean at least four sessions, each of which lasts at least 10 minutes. This chapter adopts the same principle. In the Dutch situation this can mean that variants of the minimum intervention strategy (MIS) are placed under the intensive intervention according to these criteria. This therefore applies to all interventions which in total last for at least 40 minutes and take place in at least four

sessions or contacts. For the sake of convenience the term ‘less intensive interventions’ will be used in this chapter for all interventions with a shorter duration. A second prior comment concerns the nature of interventions. Unless otherwise stated we only discuss non-pharmacological interventions, in other words, all psychological or psychosocial forms of influencing behaviour.

4.3.1 Effectiveness

More intensive interventions for smoking cessation are more effective than less intensive interventions. The effect of more intensive interventions is 1.4 times greater than less intensive interventions, and 1.6 times greater if there is at least one follow-up.¹

Conclusion

Level 1

Intensive support of persons who want to stop smoking is more effective than less intensive support or no intervention.

A1 Fiore 2000²; A2 Silagy 2002¹

Other considerations

- Even though there is little evidence for specific intensive forms of treatment for tobacco addiction, the working group is of the opinion that the intensive forms should be investigated further and that the facilities for this should be expanded. Use can also be made of the smoking cessation modules already developed. For example, STIVORO for a smokefree future has developed the group training ‘Grab your chance’ [Pakje Kans], a training programme of nine sessions of 1.5 hours, based on cognitive behavioural therapy methods. The Jellinek clinic [Jellinek kliniek] has developed and tested an intensive treatment module based on the lifestyle courses for addicts developed there.³ The following arguments are given for using more intensive interventions in certain cases:
 - There is good evidence for a dose-response relationship as a result of which it is expected that a positive effect will occur. There is no evidence that more intensive interventions have no additional value.
 - The working group views heavy smoking as an addiction which should be taken seriously, and for other types of addictions the positive effects of more intensive interventions are known.
- At present health insurers do not usually reimburse the costs of intensive interventions, as a result of which the possibilities for intensive interventions are limited. Furthermore it should be borne in mind that not all smokers want an intensive intervention.
- Intensive supportive interventions differ in intensity and in form, for example interventions of between 4 and 6 contacts (group or individual), which in total last for no more than about 90 minutes, up to a brief clinical admission.

- Many ‘healthy’ smokers value the fact that a health professional offers help with smoking cessation in the case of a smoking-related condition. Many ‘healthy’ smokers experience an intensive course with expert supervision as ideal.
- A group approach is preferable to an individual approach, due to the stimulus that the group provides.

Recommendations

- As there is evidence for a dose-response relationship and the working group considers heavy smoking to be an addiction that should be taken seriously, intensive forms of intervention within a research setting are recommended because, even though there is no scientific evidence for specific intensive treatment forms of tobacco addiction, intensive interventions have achieved positive effects with other types of addiction. Scientific research will need to demonstrate whether the large-scale use of intensive interventions is worthwhile.
- Smokers who want intensive treatment and smokers who have made several unsuccessful attempts to stop with help – but who are prepared to stop – must be given the possibility of receiving more intensive support. An intensive treatment can be recommended at an earlier stage to certain target groups, such as pregnant women and patients with smoking-related conditions.

4.3.2 Certain categories of smokers/patients

Motivation

Behavioural interventions are frequently based on the transtheoretical model, which is also called the ‘stages of change’ model.⁴ This model distinguishes five motivational stages in the cessation process: precontemplation, contemplation, preparation, action and maintenance. Interventions are based on the idea that it is more effective to tailor the intervention to the motivational stage of the quitter than to use a ‘general’ intervention. A review of 23 randomised clinical trials revealed that there was limited evidence for the added value of motivational stage-specific interventions on the effectiveness of smoking cessation.⁵ However, in this review a diverse range of studies were compared with each other and in drawing this conclusion, the authors did not take this diversity into account.

For the time being, questions remain about the use of stage-related interventions and the grouping of smokers into various classifications. Methodologically sound research into this much-used model is clearly needed.

Degree of addiction

The American guideline states that there is no evidence for the differential effectiveness of intensive treatment for subpopulations, such as strongly dependent smokers.⁶

Patient groups

Adolescents and young people

Adolescents and young people are an important target group; the younger people can be persuaded to stop smoking, the greater the benefit gained. Further, young people also form a special group because it is particularly important to connect with their specific mentality. It is not known whether the intensive support of adolescent smokers who want to stop smoking is effective.⁷ Interventions might be more effective among adolescents and young people when these are adapted to their language and culture.² For young people, the advantages of smoking cessation must be credible and approachable (such as physical stamina and fitness), and visible in the short-term.⁸

Pregnant women

Intensive interventions during pregnancy affect the foetus, the mother and the family: reducing smoking during pregnancy reduces the number of children with a low birth weight and premature birth.⁹

By stopping smoking during pregnancy, women know what it is to stop. This experience must be used to ensure that these women do not relapse into their old pattern after the pregnancy. The parents of newborn children should be supervised by other disciplines (infant welfare centre doctors, school doctors, paediatricians) with respect to smoking cessation.

Patients admitted to hospital

Intensive interventions among patients admitted to hospital (smokers and recently stopped smokers with smoking-related conditions) during their admission and a follow-up for at least one month after discharge, increases the chances of stopping. Whether this effect is just due to the intervention in the hospital is not clear.¹⁰

Compared to standard care, the C-MIS for admitted patients with cardiovascular complaints is effective.¹¹

Other special target groups

Intensive smoking cessation interventions are also effective for smokers who belong to special target groups, such as psychiatric patients, the elderly, ethnic minorities and smokers from poorer backgrounds. However, it has not been demonstrated that they are more effective for these groups than for other smokers.²

Psychiatric patients run a greater risk of relapse.²

Smokers aged 65 years and older can successfully quit and benefit from it: the risk of cardiovascular conditions and lung cancer decreases. Furthermore, there is an improvement in both the recovery from smoking-related diseases and the cerebral circulation.²

Ethnic minorities also benefit from the usual effective interventions. Sometimes translations should be used. Both men and women benefit from the interventions.²

Conclusions

Level 1	<p>There is limited evidence that interventions linked to the motivational stages of the smoker are more effective than interventions that are not related to smoking stages.</p> <p><i>A1 Riemsma 2003⁵</i></p>
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Level 3	<p>Intensive treatments are equally effective for all smokers, irrespective of the level of addiction.</p> <p><i>B Cromwell 1997⁶</i></p>
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Adolescents and young people

Level 3	<p>The effectiveness of intensive interventions among adolescents who want to stop smoking has not been sufficiently demonstrated.</p> <p><i>C Moolchan 2000⁷</i></p>
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Pregnant women

Level 1	<p>Intensive interventions combined with supportive educational materials that are offered by smoking cessation specialists to pregnant women who want to stop smoking, are effective. However, it has not been demonstrated that these women do not smoke again after the pregnancy.</p> <p><i>A1 Lumley 2003⁹</i></p>
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Patients admitted to hospital

Level 1	<p>It has been demonstrated that intensive interventions are effective among all patients who were admitted to a hospital.</p> <p><i>A1 Rigotti 2002¹⁰</i></p>
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Other special target groups

Level 1	<p>Intensive smoking cessation interventions are also effective for smokers who belong to particular target groups.</p> <p><i>A1 Fiore 2000²</i></p>
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Other considerations

For smokers from poorer backgrounds the costs associated with the intensive intervention and/or pharmacological support can form a barrier. An intensive treatment can be used for everybody, but on the basis of pragmatic considerations a choice can be made for risk groups (people with smoking-related conditions, pregnant women, etc.).

Recommendations

Adolescents and young people

The effect of intensive smoking cessation interventions among young people still needs to be investigated further. In doing so it is wise to give as much consideration as possible to the individual characteristics and preferences of the smoker concerned.

Pregnant women

In view of the importance of smoking cessation for mother and child, intensive interventions for pregnant women can be recommended if a less intensive intervention has not worked.

Patients admitted to hospital

- When smokers are admitted to a hospital, there is a unique opportunity to provide them with intensive support during smoking cessation.
- When patients are admitted, the hospital staff must determine whether or not they smoke, advise smokers to stop and in the case of those who want to stop, provide intensive help if this is wanted. Patients must be informed about the smoking ban in the hospital before they are admitted.

Other special target groups

Intensive treatment must be used as much as possible in the case of persistent smokers. If this proves to be too expensive then the choice can be made to treat risk groups. Thought must be given to ways of making nicotine replacement therapies more available to smokers from the lowest income groups. For example, these could be provided for a lower price or free of charge.

4.3.3 Setting, discipline and training

Setting

It cannot be established from the literature that the use of the same interventions in different settings (addiction care, hospital, outpatients' clinic or other) affects the effectiveness of the intervention. It is more likely that the success is related to the intensity of the treatment.^{10,12} Interventions are effective in both primary care and hospitals. Smoking cessation works just as well in the work situation as in other environments.¹⁷

Nevertheless, it seems logical to treat seriously-addicted, relapsed smokers either partly or entirely in the addiction care setting. A recently completed 'pilot' study revealed that this is feasible and leads to reasonable results.³

Discipline of the person treating

Interventions by health professionals are significantly more effective than self-help or help provided by a non-professional. In terms of the professional discipline, physicians were found to be no more effective than non-physicians (OR: 2.2 versus 1.7).² This finding concerns interventions in general – in which no distinction is made in terms of intensity – and is therefore mainly based on studies of non-intensive interventions. The extent to which this does or does not apply to intensive interventions is not clear.

Advice given by physicians (not differentiated according to setting) is effective for smoking cessation.² Interventions by nurses in hospitals are effective as well; of these, more intensive interventions are not more effective than less intensive interventions.¹³

Interventions involving professionals from different disciplines have more effect than interventions carried out by professionals from a single discipline. However, this effect is not statistically significant (OR: 2.5 versus 1.8).²

This outcome is mainly based on research into non-intensive interventions.

The extent to which this does or does not apply to more intensive interventions is unclear.

It is interesting to note that in the American guideline² the non-significant difference found with respect to the nature of the discipline has not led to a recommendation in the guideline to use mainly physicians. The equally non-significant difference concerning the involvement of several disciplines did, however, result in the recommendation to deploy several disciplines.

Due to their key competencies, physicians can best assume responsibility for the initial steps of a short supportive intervention (ask, assess, advise), as well as the prescription of supportive medication, while the behavioural supervision and training (assist, arrange) can best be carried out by a behavioural therapist or a nurse trained for this purpose.

Training of the person providing the treatment

Various studies have revealed that intensive support via interventions provided by nurses in specialised clinics is only effective if they have been specifically trained for this task. If this is not the case then the effectiveness has not been demonstrated.¹⁴

A Cochrane review revealed that interactive workshops for health professionals can result in moderately large changes in professional practice.¹⁵ Another Cochrane review also revealed that the training of health professionals has a measurable effect on professional practice.¹⁶ No strong evidence was found to indicate that this affects smoking behaviour. For these reviews the findings are also mainly based on studies into non-intensive intentions. The extent to which these also apply to intensive interventions is unclear.

Conclusions

Level I	<p>Less intensive support can be offered in all cases.</p> <p><i>A1 Hulscher 2001¹²; A1 Rigotti 2002¹⁰; A1 Moher 2003¹⁷</i></p>
Level I	<p>There are no indications that the deployment of certain professional disciplines is more effective.</p> <p><i>A1 Fiore 2000²; A1 Rice 2002¹³</i></p>
Level I	<p>Intensive interventions should be provided for people who are specifically trained for this purpose.</p> <p><i>A1 Rice 2000¹⁴; A1 Thomson O'Brien 2001¹⁵; A1 Lancaster 2002¹⁶</i></p>

Recommendations

- There need to be enough locations in the Netherlands where intensive interventions can be provided. The following are eligible for this: primary healthcare (general practitioner), public healthcare (home assistance services, municipal health services), outpatients' departments of general hospitals, addiction care, telephone counselling and e-learning programmes via the Internet.
- Intensive interventions are preferably carried out by a physician ('ask', 'assess', 'advise' and the prescription of supportive medication) and/or a nurse, and with a behavioural therapist ('assist', 'arrange'; behavioural supervision and training).
- Good supportive courses should be developed for professionals and given to professionals. These courses should be accredited by the professional groups.

4.3.4 Influence of method, form and size on the effectiveness of intensive interventions

Method

There is some evidence that programmes which focus on increasing social skills (mostly important elements of relapse prevention) are more effective than programmes without these components.¹⁸

With the exception of social support and skills training, there is no evidence that a specific component will contribute to the effectiveness of interventions.¹⁸

A meta-analysis into the effectiveness of interventions for different types of counselling and behavioural support revealed that effective interventions consist of: a) practical counselling (focused on problem-solving skills/skills training), b) social support, and c) helping quitters to obtain social support.²

Studies into the effect of combined interventions consisting of interventions and exercise programmes (lifestyle physical activities and formal structured activities) revealed that there is not yet enough evidence to demonstrate that this affects behaviour during smoking cessation.¹⁹ Behavioural interventions supported by a partner, friend or another person of influence have no effect on the percentage of smokers who stop smoking.²⁰ Also the effectiveness of hypnotherapy, rapid smoking and other aversion methods, acupuncture, acupressure, laser therapy or electrostimulation for smoking cessation is still unknown.²¹⁻²³

Focus group interviews with two groups of smokers nevertheless revealed a considerable interest for alternative methods.³⁰

All commercially available forms of nicotine replacement therapies (gum, patches, nasal spray, inhaler, sublingual tablets and lozenges) are effective as a component of interventions. These can increase the chances of stopping by a factor of 1.5 to 2, irrespective of the setting in which the intervention takes place.¹ The use of nicotine replacement therapies in combination with behavioural interventions increases the chances of smoking cessation.^{2,13}

Pharmaceutical products should be expressly recommended in the case of risk groups. The courses in social and affective skills that have been investigated, varied in terms of their nature and content. Components which are frequently used here and elsewhere in addiction care are: motivating to stop, agreements about a stop date, listing of experiences with stop attempts and opposing and stimulating factors, training in social, affective and cognitive skills, encouraging and supervision of pharmacological support, stimulation of social support and relapse prevention.

Form

Group interventions offer smokers the possibility of learning behavioural techniques for smoking cessation. Group interventions are more effective than self-help programmes or less intensive individual interventions.

In terms of effectiveness, behavioural therapy group programmes are comparable with individual support of the same intensity: after 12 months 16%-48% have stopped.²⁴ As group therapy is often studied in combination with nicotine replacement therapies it is difficult to indicate the precise effect of the programme.

It has not yet been demonstrated which components in group training work better than others (for example, skills training or strengthening of the motivation). In the Netherlands the long-term effects of the regional 'Stop together' [Samen stoppen] courses were reported in 2001. The point prevalence of abstinence after 12 months was 25%.²⁵

Size: number and duration of sessions

For behavioural support there is a strong dose-response relationship between the duration and number of the sessions and the success rate.² In a study by Alterman the most intensive form of support with four sessions of advice and information, nicotine replacement therapies and 12 sessions of cognitive behavioural therapy gave the highest cessation rate (35% for 12 months continuous abstinence).²⁶

The American guideline found that behavioural support had a strong dose-response relationship with the total contact time and the abstinence rate. A contact time of 31-90 minutes leads to an abstinence rate which is significantly higher than 1-30 minutes. A total contact time of 90 minutes or longer does not lead to a further increase in the abstinence rate than a contact time of 31-90 minutes.²

The American guideline also states that treatments of more than 10 minutes are more effective than less intensive treatments.² The English guideline also found a dose-response relationship between the intensity of support and the number of quitters.²⁷

In the Cochrane review of Silagy this dose-response relationship is less strongly present. In this review, intensive interventions are only marginally more effective than less intensive interventions.¹ The less intensive intervention is defined here as less than 20 minutes and one follow-up visit; the intensive intervention has a contact time of more than 20 minutes and more than one follow-up visit. Follow-up visits and no follow-up visits compared to no advice whatsoever resulted in ORs of respectively 2.66 (95% CI: 2.06-3.45) and 1.59 (95% CI: 1.33-1.90). In the study of Gilbert, the addition of a follow-up visit to the less intensive intervention strategy led to a small increase in the number of quitters (OR: 1.60; 95% CI: 1.20-2.33).²⁸

After biochemical validation there was no significant difference between 2 or 4 follow-up visits.¹ The study of Miller²⁹ describes an intervention in the hospital followed by either one or four follow-up phone calls. The more intensive interventions increased the continuous abstinence from 14% to 19% compared to the less intensive intervention. This difference was just statistically significant.¹⁸

According to the English guidelines a smoking cessation treatment must consist of at least five sessions of about one hour.²⁷ The American guidelines indicate that an intensive treatment must contain at least four sessions of 10 minutes.

Yet there are several reasons for offering and continuing to offer longer interventions and for developing new ones. This should preferably take place within a scientific framework, so that the effects can be tested. First, all of the available methods have a very low effectiveness. This justifies looking for new and also more intensive interventions. In addition to this, it is also easier to carry out better relapse prevention via longer interventions. More intensive interventions relate better to the psychosocial interventions developed by the addiction services which have been put together on the basis of the available evidence about the treatment of alcohol and drug addiction in the literature. Recently a series of protocols (with manuals, workbooks and supervisory materials) were put together under the name 'Lifestyle courses' [Leefstijltrainingen] and published in various forms (individual and group, short duration and long duration). These contain cognitive behavioural therapy methods which have been found to be effective in addiction care. These can be useful as psychological co-morbidity is often present, so that tackling an addiction behaviour independent from other problems does not have enough effect. It should be noted that these lifestyle courses are aimed at addictive behaviours other than smoking (for example, alcohol and cannabis). In addition to this, STIVORO has developed a course for smoking cessation based on cognitive behavioural therapy principles Grab your chance [Pakje Kans].

‘Stepped care’ range of interventions

According to the American guideline and a recent review from Riemsma et al., stepped-care approaches do not result in significantly higher abstinence figures among smokers than a non-stepped-care approach.^{2,5}

However despite the lack of empirical evidence, there are still a number of considerations which make a stepped-care approach interesting:

- A stepped-care approach facilitates the acceptability and practical use of the guidelines and therefore increases the implementation of interventions.
- A stepped-care approach does not hinder the use of more intensive interventions on the basis of clinical insight.
- A stepped-care approach is probably cost-effective.
- Research from a client perspective reveals that ‘healthy’ smokers wanted to have the possibility of receiving intensive and extended support. However, they wanted to be able to determine the method used.³⁰

Conclusions**Method**

Level I	Programmes aimed at increasing social skills are more effective than programmes without these components. <i>A1 Stead 2002¹⁸; A2 Fiore 2000²</i>
Level I	The effect of exercise programmes and alternative therapies has not yet been sufficiently proven. <i>A1 Ussher 2002¹⁹; Park 2002²⁰; A1 Abbot 2000²¹; A1 Hajek 2002²²; A2 Willemsen 2003²³</i>
Level I	Intensive behavioural counselling combined with nicotine replacement therapies increases the chances of smoking cessation (see also <i>chapter 5</i>). <i>A1 Fiore 2000²; A1 Rice & Stead 2002¹³; A2 Silagy 2002¹</i>

Form

Level I	It has been demonstrated that group interventions are more effective than less intensive individual interventions. However, it is still not clear whether group interventions are more effective than intensive individual interventions. <i>A1 Stead 2002¹⁸; A2 Stead 2002²⁴</i>
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Size: number and duration of sessions

Level 1

Increasing the number of sessions as well as the duration of the sessions results in better success rates. The length of an intervention should be at least 4 sessions of 10 minutes spread over one month with follow-up visits.

A1 *Fiore 2000*²; A1 *Parrot 1998*²⁷; A1 *Silagy 2002*¹; A2 *Alterman 2001*²⁶

Stepped care

Level 1

There is not yet enough evidence that a stepped-care approach results in more abstinent smokers.

A1 *Fiore 2000*²; A1 *Riemsma 2003*⁵

Recommendations

Method

It is recommended that those carrying out intensive interventions are trained in a motivating approach and in methods for behavioural, affective and social support. Intensive interventions should preferably be combined with nicotine replacement therapies.

Form

Intensive interventions in the area of smoking cessation can be just as well organised in a group context.

Size: number and duration of sessions

- An intensive intervention should consist of at least four sessions of 10-20 minutes, spread over one month, plus follow-up visits.
- There are indications that the effectiveness of the intensive intervention increases for a total contact duration of up to 90 minutes. A possible additional effect above this limit has not yet been demonstrated.
- On the basis of smoking cessation modules already developed in the Netherlands, as well as the experiences in the care of addicted people, the working group recommends distinguishing intensive smoking cessation interventions in several subcategories of intensity that are parallel with the intensity gradations used by interventions for other substances in addiction care, namely:

Shorter ambulant training: Interventions with a size of 4 to 6 contacts of 20 minutes to 1 hour per contact (analogous to addiction care lifestyle training brief individual and group protocol).

Longer ambulant training: Interventions with a size of 10 to 15 contacts of 20 minutes to 1 hour per contact (analogous to addiction care lifestyle training long individual and group protocol – for example Grab your chance [Pakje Kans] of STIVORO for a smokefree future), possibly followed by several follow-up contacts.

Short clinical + long ambulant training: An intervention in which smoking cessation takes place in a clinical setting, as part of an intervention as described for longer ambulant training.

Stepped care

- For all patients who report to physical healthcare and addiction care services (and the mental health service), the use of tobacco is one of the issues raised. All regular smokers receive the advice to stop.
- For all of those who are not insensitive to this advice and for those in whom the health complaints are clearly associated with smoking, the offer is made to further support the smoking cessation in one or more follow-up consultations (less intensive intervention). This can be pharmaco-therapeutically supported.
- Relapsed smokers are offered a more intensive intervention that, if possible, is supported pharmaco-therapeutically.
- Persistent relapsed smokers and smokers under the addiction services receive a more intensive intervention which is provided in a specialist setting, and if possible is supported pharmaco-therapeutically.

Chapter 5

Pharmacological support

In applying the guidelines, clinicians should realise that any absolute cessation rates are based on research in selected populations and do not necessarily apply to the treatment of individual smokers. The research on which the rates in question are based was generally performed with selected groups of smokers who satisfied certain criteria, such as smoking at least 10 to 15 cigarettes per day or volunteers who had already tried to stop smoking on several occasions.

The smokers who participated had no choice in the resources used or the type of support they received. It is quite possible that if the clinician makes use of the characteristics of the individual smoker, the chance of success can accordingly be increased.

Finally it is important to acknowledge that industry sponsored research might be subject to 'publication bias' or 'sponsorship bias'.¹⁻⁴ In the case of publication bias some research is less likely to be published, due to negative outcomes or small research populations. Sponsorship bias refers to on average higher positive outcomes than other research; the quality of the research however is not questioned.²

5.1 Nicotine replacement therapies

This chapter is based on the most recent version of the Cochrane review of Silagy et al.¹ The review included 110 randomised clinical trials about the intended effects of nicotine replacement therapies. Cessation rates were measured after 6 or 12 months. The studies were carried out in a large number of countries and among smokers of both sexes, irrespective of the degree of addiction and the setting in which the study subjects were investigated.

5.1.1 Effectiveness

All nicotine replacement therapies were found to be an effective aid for smoking cessation.¹ If the separate data for the different nicotine replacement therapies are pooled then 17% of smokers were found to have stopped for a period of more than one year, as opposed to 10% in the control group. This is equivalent to an OR of 1.7 (95% CI 1.6-1.9). The Number Needed to Treat (NNT) of nicotine replacement therapies at 12 months (sometimes 6 months) follow-up is about 6 (the NNT of placebo is about 10). That means that for each quitter, 6 or 10 patients respectively need to be treated. The NNT of nicotine replacement therapies minus the placebo effect (the added value of nicotine replacement therapies) is about 14. A form of psychological support or behavioural therapy was given in virtually all of these studies in the Cochrane review. Therefore without this additional support the cessation rates could be lower.

Research into nicotine gum and transdermal patches reveals that the odds ratio is scarcely affected by the character of the control group: placebo or no therapy.¹

Differences

Very few comparative studies have been carried out to objectify the differences in effectiveness between the various nicotine replacement therapies. The effectiveness has only been established indirectly. In *table 8* the percentage of smokers who had still stopped after one year, is given per type of nicotine replacement therapy. The ORs per type of nicotine replacement therapy are also given.¹

Table 8 Overview cessation rates and NNT for the various nicotine replacement therapies

NRT	% stopping after 1 year (95% CI)	OR (95% CI)	NNT**
Gum	18 (17-19)	1.7 (1.5-1.8)	6
Transdermal patch	14 (13-15)	1.8 (1.6-1.9)	7
Nasal spray*	24 (20-28)	2.3 (1.6-3.2)	4
Inhaler	17 (14-21)	2.1 (1.4-3.0)	6
Sunbilingual tablet	20 (15-25)	1.7 (1.0-2.8)	5

* Not available in the Netherlands.

** Number of persons that need to be treated for one person to stop.

It cannot be concluded from *table 8* that one form of nicotine replacement therapy is more effective than another, even though the nasal spray and the inhaler seem to be more effective numerically speaking.¹

For people who are strongly nicotine dependent, a higher dose of nicotine gum (4 mg) is more effective than a lower dose (2 mg) (OR: 2.7; 95% CI: 1.7-4.2). If the results are not stratified for nicotine dependence, this difference in effect between the two doses is not observable.¹

Pooled data indicate that a patch with a higher dose is slightly more effective than one with a lower dose (OR: 1.2; 95% CI: 1.03-1.4).¹ There is no difference in effectiveness between a 16-hour and a 24-hour patch.¹

Combinations

There is insufficient evidence that combinations of different nicotine replacement therapies increase the cessation rates. The available studies are heterogeneous. Although some combinations of nicotine replacement therapies possibly increase the effect, other combinations do not.¹ However, it seems safe to combine different forms of nicotine replacement therapies.²

Support given by health professionals

There are very few studies that objectify the effect of the support provided by health professionals and in so doing differentiate this from the pharmacological support.

Combination with behavioural therapy

Compared to non-intensive supervision, intensive supervision does not ensure a significant increase in the effect of nicotine replacement therapies, although there is a trend in favour of intensive supervision.¹ The effect of nicotine replacement therapies is not enhanced by combining these with group therapy.¹ Here it is important to note that in the studies where the effect of nicotine replacement therapies was investigated, the nicotine replacement therapy was supplied by a health professional (and not as an over-the-counter drug). In practice, it is difficult to separate this type of supply from a brief supportive intervention. This makes it difficult to demonstrate the effect of extra support (group therapy).

Therefore, behavioural interventions should not be abandoned, because independent of nicotine replacement therapies, they are effective and a behavioural intervention without nicotine replacement therapies can also be chosen.

Patient categories

There is not enough evidence to demonstrate the effect of nicotine replacement therapies among people who smoke less than 10-15 cigarettes per day. For all categories of smokers who smoke more than 15 cigarettes a day, nicotine replacement therapies have proven their effectiveness. The effectiveness is lower among people who have been admitted to hospital, because their motivation is often insufficient.¹

Nicotine gum and nicotine patches are more effective among volunteers who respond to a selection advertisement than among smokers who are recruited by health professionals.

In so far as it has been investigated, there is no observable difference in effect between smokers from different socio-economic groups¹.

Furthermore, the scientific literature does not offer support for recommending specific nicotine replacement therapies to certain smokers.¹

Reducing the number of cigarettes

One study revealed that a nicotine inhaler reduced the consumption of cigarettes. The OR of the number of smokers that had reduced the number of cigarettes by 50% after two years was 3.6 (95% CI: 1.5-8.3).¹

Conclusions**Effectiveness**

Level I	Compared to placebo, nicotine replacement therapies increase the success rate of smoking cessation by 7% (from 10% to 17%).
A1	<i>Silagy 2002¹</i>

Differences

Level 1	<p>There is no convincing difference in effectiveness between the various administrative forms of nicotine replacement therapies.</p> <p><i>A1 Silagy 2002¹</i></p>
Level 1	<p>In the case of strong nicotine dependence, a high dose of nicotine (in the form of gum) is more effective than a low dose.</p> <p><i>A1 Silagy 2002¹</i></p>

Combinations

Level 1	<p>It is not clear whether combinations of different forms of nicotine replacement therapies increase the effectiveness.</p> <p><i>A1 Silagy 2002¹</i></p>
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Combination with behavioural therapy

Level 3	<p>Support or group therapy does not seem to substantially increase the effect of a health professional supplying nicotine replacement therapies, possibly because this involves the concomitant use of a brief supportive intervention by the health professional.</p> <p><i>B Silagy 2002¹</i></p>
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Patient categories

Level 3	<p>No studies have been found that related the effectiveness of nicotine replacement therapies to the intensity of smoking. Also the effectiveness of nicotine replacement therapies among people who smoke less than 10-15 cigarettes a day cannot be ascertained from the Cochrane review.</p> <p><i>B Silagy 2002¹</i></p>
Level 4	<p>Not enough research has been done to distinguish differences in the effect of resources in smoking cessation interventions between the specific groups, for example on the basis of socio-demographic groups.</p> <p><i>B Silagy 2002¹</i></p>

Reducing the number of cigarettes

Level 3

There are indications that nicotine replacement therapies can reduce the consumption of cigarettes.

B Silagy 2002¹

5.1.2 Safety and side effects

The working group considers nicotine replacement therapies to be safer than smoking. *Table 9* contains an overview of the most important inconvenient side effects of nicotine replacement therapies.¹

Table 9 Most important inconvenient side effects* of nicotine replacement therapies

Type of NRT	Side effects
Gum	Hiccupping, gastrointestinal complaints, jaw ache, oral-dental complaints
Transdermal patch	Irritated and hypersensitive skin, sleeping badly
Nasal spray	Irritation of the nose and runny nose
Nicotine inhaler	Irritation of the throat and mouth, coughing
Sublingual lozenge	Hiccupping, irritation of the throat and mouth, coughing and dry lips
Lozenge	Irritation of the throat and mouth, hiccupping, gastrointestinal complaints

* A detailed list of side effects is given in the *Farmacotherapeutisch Kompas³* and on www.cbg-meb.nl for the IB text).

Cardiovascular complaints

In one study among persons aged 45 years and older with at least one diagnosed cardiovascular complaint, no difference was observed in the occurrence of side effects and cardiovascular-related complaints due to the use of nicotine patches.¹ Nicotine replacement therapies appear to be safe if used by persons with a cardiovascular condition.²

Pregnant women

Without interventions, the chances of pregnant women who are persistent smokers successfully stopping are low. Therefore the working group is of the opinion that for women who are heavy smokers (more than 10 cigarettes per day) nicotine replacement therapies must be considered if other interventions fail. That certainly applies to women who have previously experienced a disrupted pregnancy and in which smoking played a role. Smoking appears to be more harmful than the use of nicotine replacement therapies (see also *section 7.3.3*).²

Young people

Little research has been carried out into the safety of nicotine replacement therapies among young people. There are no indications that these drugs are unsafe for this group.²

If smoking continues

At present there are no indications that the concomitant use of cigarettes and nicotine replacement therapies is harmful. The combination of smoking cigarettes and using nicotine replacement therapies might make an attempt to stop easier.²

Risk of addiction

There are no data which suggest that nicotine replacement therapies are addictive. A small proportion of the users of nicotine replacement therapies have been found to use them for a long time but it is not known if this can be characterised as an addiction.² These long-term users are heavy smokers.

Conclusions

Level 1	Nicotine replacement therapies have relatively mild side effects. <i>A1 Silagy 2002¹;</i> <i>D Farmacotherapeutisch Kompas 2003 [Dutch National Formulary]³</i>
Level 3	Giving nicotine replacement therapies to smokers with diagnosed cardiovascular diseases does not result in more cardiovascular-related complaints. <i>B Silagy 2002¹</i>
Level 3	Nicotine replacement therapies has demonstrated effectiveness in pregnant women and seem to be less harmful than smoking. Of course, consideration must be given to the risks. <i>C McNeil 2001²</i>
Level 3	From the limited literature available about the use of nicotine replacement therapies in young people aged 12-18 years, there are no indications for nicotine replacement therapies being unsafe <i>C McNeil 2001²</i>
Level 3	Combining smoking and nicotine replacement therapies does not seem to be harmful. <i>C McNeil 2001²</i>

Level 4

There are no data available to suggest that nicotine replacement therapies are addictive.

C McNeil 2001²

Recommendations

- For each form of support given to smokers who smoke 10 or more cigarettes per day, information about pharmacotherapy should be given. Nicotine replacement therapies are safe and effective resources for helping people to stop smoking, particularly for people who ask for such help themselves.
All available nicotine replacement therapies increase the chance of a successful attempt to stop smoking in the longer term by a factor of 1.5-2 (NNT of nicotine replacement therapies compared to placebo is about 14).
- The choice between the various nicotine replacement therapies can be based on the personal preference of the user, the side effects profile (see *appendix 7*, Dosages and contraindications for the pharmacological treatment of tobacco addiction) and the price. There is little difference in effectiveness.
- Nicotine replacement therapies can be used by 'risk groups' such as people with cardiovascular diseases but also by addicted young people aged 12 years or older. For pregnant or breastfeeding women nicotine replacement therapies can be considered when smoking cannot be stopped using any other approach and when the advantages of using nicotine replacement therapies weigh up against the risks of smoking (see also *section 7.3.3*).
- There is no evidence that the approach used for smokers from different socio-economic groups in the population or for different types of smokers (heavily as opposed to moderately addicted) should substantially differ.

5.2 Bupropion

Bupropion was registered as an antidepressant in the United States in 1985 under the trade name Wellbutrin. It has been available there since 1997 as an aid for smoking cessation. In December 1999 the Medicines Evaluation Board [College ter Beoordeling van Geneesmiddelen] registered bupropion for the indication of 'aid for smoking cessation' under the trade name Zyban. The Netherlands was the first country within the European Union to register bupropion for this purpose. Bupropion is only available on prescription. It is contraindicated for pregnant women and is not reimbursed by the health insurers.¹ The argumentation is based on a recent Cochrane review.² The majority of the studies have been sponsored by the pharmaceutical industry and most of the studies have been carried out among American smokers, who were mostly selected through advertisements (from the open population). Recruited smokers were mostly those without chronic or other diseases who smoked at least ten cigarettes per day and were motivated to stop smoking.

5.2.1 Effectiveness

The Cochrane review of Hughes et al. found that bupropion sustained release (SR) was an effective drug for helping motivated smokers during an attempt to stop.² Taken together, the results of 10 studies with 12 months of abstinence data and six studies with 6 months of abstinence data, resulted in an OR of 2.0 (95% CI: 1.7-2.3). After 12 months follow-up the NNT is 11 (95% CI: 9-14). In all of the studies included, the treatment with bupropion was combined with an intensive behavioural intervention.

COPD

Up until 2003, one controlled study had been carried out into the effect of bupropion SR as an aid for smoking cessation in patients with COPD.³ The results after 26 weeks suggest that bupropion SR is an effective product for smoking cessation in this group. The results after 12 months no longer revealed any significant difference between the experimental group and the control group (OR: 1.2; 95% CI: 0.6-2.4; NNT 15; 95% CI: 7.7-321).²⁻⁴

Cardiovascular complaints

Up until now one controlled study has been carried out into the effect of bupropion SR (300 mg over a period of 7 weeks) as an aid for smoking cessation in patients with a cardiovascular condition.⁵ After both 6 and 12 months, bupropion SR was found to be more effective than placebo (continuous abstinence at 6 months: OR 3.1; 95% CI: 2.0-5.0 versus 12 months: OR 2.8; 95% CI: 1.7-4.6; NNT at 52 weeks, 8; 95% CI: 5.5-14.5).

Schizophrenia

For schizophrenia two randomised, placebo-controlled studies have been carried out.^{6,7} One study was carried out with a prior and follow-up measurement, without a control group.⁸ In one study the participants in the experimental group received bupropion SR 300 mg over a period of 10 weeks combined with group therapy (weekly for 10 weeks, 60 minutes per session).⁶ The use of antipsychotics in addition to the study medication was continued during the study at the same dosage. The point prevalence of abstinence after 10 weeks was 50% in the bupropion group (8/16) and 13% in the placebo group (2/16); after 6 months this was 19% (3/16) and 6% (1/16) respectively.

In one study the participants in the experimental group received bupropion SR 150 mg over a period of 12 weeks and weekly cognitive behavioural therapy in groups for a period of 9 weeks (60 minutes per session).⁷ In this study the experimental medication was also added to the maintenance medication. After 6 months one participant from the experimental group (11%) was found to be abstinent and no participants from the control group (0%) were found to be abstinent.

Effectiveness of bupropion compared to nicotine replacement therapies

One study has been carried out into the effectiveness of bupropion (300 mg over a period of 9 weeks, starting 1 week prior to the planned stop day) compared to a nicotine replacement therapy product (in this case nicotine patches; 21 mg over a period of 6 weeks, after which

this was withdrawn over a period of 2 weeks). Furthermore, all of the participants underwent an intensive behavioural support programme. Bupropion SR was found to be more effective than nicotine patches (OR: 2.1; 95% CI 1.2-3.5; NNT 12 months 7 (95% CI: 4.7-15.3)).⁹

Combination with nicotine replacement therapies

Two studies have been carried out into the effectiveness of bupropion SR combined with nicotine replacement therapies.^{9,10} In the first study bupropion SR 300 mg (9 weeks) was combined with nicotine patches (21 mg over 6 weeks).⁹ This combination was found to be more effective than the use of nicotine patches only (OR: 27; 5% CI: 1.6-4.5). In the second study bupropion (300 mg, 7 weeks) was also combined with nicotine patches (2 months, dosage unknown).¹⁰ No difference in effectiveness was found in this study (OR: 0.8; 95% CI: 0.3-1.4). As these studies were heterogeneous (including, for example, the intervention) no pooled results have been calculated.

Combination with behavioural therapy

In one study the effectiveness of bupropion in combination with an intensive and less intensive behavioural treatment was investigated.¹¹ The most intensive treatment consisted of bupropion SR over a period of 12 weeks combined with four individual sessions varying from 5 to 20 minutes, five group sessions of 90 minutes and a self-help guide. The less intensive intervention consisted of bupropion SR over a period of 12 weeks combined with just the individual sessions (four of 5 to 20 minutes). The following point prevalence figures were found in weeks 24 and 52. The first intervention led to 27% (10/37) and 24% (9/37) stopped participants and the second to 22% (8/36) and 25% (9/36) respectively.

Conclusions

Level 1	Compared to a placebo treatment, bupropion SR is an effective aid for supporting smokers during an attempt to stop. <i>A1 Hughes 2003²</i>
Level 3	The use of bupropion SR for smoking cessation by patients with COPD does not seem to be more effective than placebo in the longer-term. <i>A2 Tashkin 2001³</i>
Level 1	Bupropion SR is an effective aid for supporting smokers with cardiovascular condition during an attempt to stop. <i>A2 Tonstad 2003⁵; A2 Jorenby 1999⁹</i>

Level 2	<p>It is not clear whether the combination of bupropion and nicotine patches leads to a greater percentage of quitters than the use of nicotine patches alone.</p> <p><i>A2 Jorenby 1999⁹; Simon 2002¹⁰</i></p>
Level 3	<p>The effectiveness of bupropion SR in combination with behavioural therapy is unclear. There does not seem to be any difference in effectiveness between a more intensive or a less intensive behavioural intervention for smoking cessation.</p> <p><i>A2 Hall 2002¹¹</i></p>

5.2.2 Safety

A number of review articles have been published in which the safety of bupropion compared to a placebo has been described. These reveal that generally speaking bupropion SR is a safe aid for smoking cessation, as long as the instructions on the package insert are followed and, in particular, special attention is paid to the possible presence of contraindications (for example, pregnancy).⁵ The safety has equally been demonstrated for smoking cessation by COPD patients. Due consideration must be given to the possible interaction with the current medication of this group of smokers and to their respiratory complaints.¹

A detailed list of side effects can be found in the *Farmacotherapeutisch Kompas 2003*¹² and on www.cbg-meb.nl (for the IB text).

Cardiovascular complaints

One controlled study has been carried out into the effect of bupropion SR (300 mg over a period of 7 weeks) as an aid for smoking cessation among patients with a cardiovascular complaint.⁵ The most frequently reported side effects were: insomnia (bupropion: 24%; placebo: 12%), dry mouth (bupropion: 18%; placebo: 10%) and nausea (bupropion: 13%; placebo: 6%). A total of 24 people from the bupropion group and 14 from the placebo group reported cardiovascular complaints (in particular, angina pectoris (bupropion: n = 7; placebo: n = 4), hypertension (bupropion: n = 2; placebo: n = 3) and palpitations (bupropion: n = 4; placebo: n = 1).

Conclusions

Level 1	<p>Bupropion SR is a safe aid for smoking cessation, as long as the instructions on the package insert are followed and particular attention is paid to contraindications that might be present (for example, pregnancy).</p> <p><i>A1 Tonstad 2003⁵</i></p>
Level 3	<p>Bupropion SR seems to be a safe aid for smoking cessation for COPD patients. For this group of smokers, due consideration must be given to the possible interaction with the existing medication for their respiratory complaints.</p> <p><i>A2 Wagena 2003⁴</i></p>
Level 3	<p>Bupropion SR seems to be a relatively safe aid for smoking cessation for people with cardiovascular conditions.</p> <p><i>A2 Tonstad 2003⁵</i></p>
Level 3	<p>The use of bupropion SR 300 mg compared to bupropion SR 150 mg is more effective in combination with an intensive behavioural treatment than the use of placebo in case of patients with schizophrenia.</p> <p><i>A2 George 2002⁶</i></p>

Recommendations

- In view of the side effects profile it is recommended that the treatment with bupropion should be accompanied by at least two appointments with a physician. The first appointment is to check for contraindications (for example, pregnancy) and to provide an explanation about the drug, and the second is for a follow-up consultation with the smoker and if need be to issue a further prescription. The pharmacist can also provide information in this phase.
- Although bupropion appears to be safe for schizophrenic smokers, it is recommended that it is not prescribed as the drug of first choice due to the relatively frequent occurrence of side effects, such as headache, insomnia and memory problems.

5.3 Nortriptyline

Nortriptyline is a tricyclic antidepressant. It has been internationally available since 1963 as a drug to treat depression. It is not registered as an aid for smoking cessation in the Netherlands and it is only available on prescription.

5.3.1 Effectiveness

The Cochrane review reveals that nortriptyline is an effective aid for helping smokers during an attempt to stop.¹ Combining the separate results from four studies with at least 6 months of abstinence data, results in an OR of 2.8 (95% CI 1.7-4.6) and an NNT of 10, (95% CI: 7-18).

Combination with nicotine replacement therapies

In one study the effectiveness of nortriptyline combined with nicotine patches was investigated. Nortriptyline 75 mg/day over a period of 12 weeks was combined with nicotine patches over a period of 8 weeks (dosage not known). This combination was found to be more effective than the use placebo-nortriptyline and nicotine patches (6 months abstinence: OR: 2.8; 95% CI: 1.2-6.9; NNT 7.2; 95% CI: 4-42).²

Support given by health professionals

Research has not revealed whether support by health professionals is necessary for nortriptyline to be effective. In view of the status of the drug (only available on prescription from a physician) it is in any case necessary that a smoker has at least one contact with a health professional. This contact is necessary to determine whether nortriptyline is indicated for the smoker in question and to give the smoker instructions about its use.

Combination with behavioural therapy

There are two studies in which the effectiveness of nortriptyline combined with intensive behavioural support has been compared with nortriptyline combined with less intensive support. In the first study the most intensive treatment consisted of nortriptyline (dose was titrated; length of treatment 12 weeks) combined with 10 sessions of 2 hours with 5-11 participants over a period of 8 weeks.³ The less intensive intervention consisted of nortriptyline (12 weeks) combined with five sessions of 90 minutes, also with 5-11 participants over a period of 8 weeks. The point prevalence figures in weeks 24 and 65 were 47% (24/51) versus 38% (18/48), and after 64 weeks 31% (16/51) versus 31% (15/48).

In the second study one group received nortriptyline combined with five individual sessions of 10-20 minutes conducted by a specialist (in weeks 1, 2, 5, 6 and 11).⁴ The second group received nortriptyline with 5 individual sessions and 5 sessions of 90 minutes conducted by a trained counsellor (in the same period). After 24 weeks the most intensive intervention seemed to be the most effective (26% (9/35) versus 18% (7/38)), after 52 weeks this difference had disappeared (17% (6/35) versus 18% (7/38)). However, the results should be interpreted with some caution, as these are not abstinence figures over a given period (for example, continuous abstinence or prolonged abstinence).

Effectiveness of nortriptyline versus bupropion

In one study nortriptyline as an aid for smoking cessation was compared with bupropion.⁴ This study revealed that after 24 and 52 weeks there was no significant difference between the two (point prevalence after 24 weeks 22% abstinence in the nortriptyline

group (16/73) and 25% (18/73) in the bupropion group; point prevalence after 52 weeks 18% abstinence in the nortriptyline group (13/73) and 25% abstinence in the bupropion group (18/73)). In a larger study group a different result could be obtained.

Conclusions

Level 1	<p>Nortriptyline is an effective aid for supporting smokers during an attempt to stop.</p> <p>A1 <i>Hughes 2003</i>¹</p>
Level 3	<p>Nortriptyline in combination with nicotine replacement therapies (patches) seems to be more effective than the use of just nicotine patches (in combination with placebo-nortriptyline) for supporting an attempt to stop.</p> <p>A2 <i>Prochazka 2001</i>²</p>
Level 1	<p>There are indications that there is no difference in effectiveness between a more and a less intensive behavioural intervention for smoking cessation in combination with nortriptyline.</p> <p>A2 <i>Hall 1998</i>³; <i>Hall 2002</i>⁴</p>
Level 3	<p>Up until now there seems to be no significant difference in effectiveness between nortriptyline and bupropion as products for smoking cessation.</p> <p>A2 <i>Hall 2002</i>⁴</p>

5.3.2 Safety

In the studies into the effectiveness of nortriptyline, the usual but inconvenient side effects occurred more frequently in the study group than in the placebo group (*table 10*).

Serious side effects have not yet been reported.

A detailed list of side effects can be found in the *Farmacotherapeutisch Kompas 2003*¹² and on www.cbg-meb.nl (for the IB text).

Table 10 Inconvenient side effects of nortriptyline use and the frequency of these (%). The frequency in placebo groups are given between brackets

	Hall 2004 ⁴	Hall 1998 ³	Da Costa 2002 ⁶	Prochaska 1998 ²
Dry mouth	72 (33)	78 (33)	44 (24)	59 (22)
Constipation	31 (14)	-	29 (16)	-
Dyspepsia	-	-	-	19 (8)
Head ache	-	-	9 (5)	10 (7)
Light head/dizzy	-	49 (22)	-	11 (7)
Visual disturbance	-	16 (6)	-	-
Gastro-intestinal problems	-	-	-	38 (23)
Sleepless	-	-	7 (12)	16 (25)
Being sleepy	-	-	-	22 (8)
Shaking hands	-	23 (11)	-	-

Conclusion

Level 4

Nortriptyline is a reasonably safe aid for smokers who are motivated to stop smoking.

D Farmacotherapeutisch Kompas 2003 [Dutch National Formulary]³

Recommendations

- The possibility of using nortriptyline can be discussed with all smokers who want to stop smoking.
- The presence of one or more contraindications should be checked before the advantages and disadvantages of using nortriptyline are discussed. Other drugs should be considered first in the case of pregnant women.
- The slight difference in effectiveness and the considerable difference in price between bupropion and nortriptyline makes nortriptyline an attractive drug. It is however not registered for smoking cessation.

5.4 Other pharmacotherapeutics: clonidine

Clonidine is not registered for the treatment of tobacco addiction.

In a Cochrane review of six placebo-controlled studies, both oral (3 studies) and transdermal administration (3 studies) of clonidine was more effective than placebo.¹

The pooled OR of the six studies together was 1.89 (95% CI: 1.30-2.74). However, none of the studies used the success criterion of 6 or 12 months continual abstinence.

Clonidine has many dose-dependent side effects, in particular a dry mouth, and has a sedative effect.¹

5.5 Alternative therapies

The Cochrane Collaboration examined four studies in which hypnosis was compared with a placebo intervention (just attention).¹ As the studies differed too much from each other in terms of design it was not possible to pool the results. Three studies showed no significant advantage of hypnosis compared to giving attention. None of the studies used 12 months continual abstinence as a success criterion.

Eighteen studies were identified for the Cochrane review about acupuncture.² In three placebo-controlled studies the data for 12 months of continual abstinence were presented. The pooled results revealed that the treatment was not better than placebo. The continual abstinence after 12 months was 8.6%. Herbal preparations and homeopathic remedies are also marketed. No placebo-controlled studies concerning these have been found.

Conclusion

Level 3

There are no indications that alternative therapies work better than placebo.

A2 *Abbot 2000*¹

5.6 The role of pharmacists

The pharmacist can fulfil a double role in influencing the smoking behaviour of his or her client. On the one hand the pharmacist has an educational role, certainly in regard to patients who are at greater risk than other smokers due to their use of drugs registered in the pharmacy. Asthma/COPD drugs, diabetes drugs and cardiovascular drugs are among the most important groups of drugs supplied in pharmacies. Smoking cessation is worthwhile in the case of all of these conditions.

On the other hand the pharmacist can play a role in providing advice about the choice, the use and contraindications of nicotine replacement therapy. The supervision of nicotine replacement therapy by a pharmacist has already been tried out in other countries in uncontrolled studies.¹ In view of the side effects profiles and the contraindications, the use of bupropion and nortriptyline should be supervised by a physician and a pharmacist. In addition to the medical supervision, the pharmacist can play a clear role in promoting compliance for bupropion. The importance of this is apparent from a study among Dutch bupropion users, in which it was found that half of these users did not complete the recommended course.²

5.7 Smokers' preferences

A client-perspective study among healthy smokers revealed that smokers are more interested in a group course than in bupropion due to the many negative stories and the fact that 'healthy' smokers would rather not take antidepressants. The preference is for nicotine replacement therapies which offer smokers something to do. In addition to this a replacement therapy must be part of the support and must not be prescribed without supervision.¹

5.8 Conclusion: choosing a pharmacological therapy

A Cochrane meta-analysis into the effectiveness of nicotine replacement therapies among people who smoked more than 15 cigarettes per day revealed that the chances of a successful attempt to stop was increased by a factor of 1.5 to 2 if a nicotine replacement therapy was given to this group of smokers during an attempt to stop. For people who smoke a lot, a higher dosage of nicotine replacement therapies is more effective than a lower dosage. There is limited evidence that for people who smoke more than 10 cigarettes but less than 15 cigarettes per day, nicotine replacement therapies can also increase the chances of success during an attempt to stop, even without intensive supervision. Up until now no research has been carried out into the effectiveness of bupropion without (intensive) supervision.

The side effects of nicotine replacement therapies are limited and nicotine replacement therapies can be used by people with cardiovascular diseases and COPD.

So far more than 12 studies have been carried out into the effectiveness of bupropion, among people who smoke more than 10 cigarettes per day. On the basis of these it can be concluded that bupropion in combination with an intensive supervision can increase the chances of a successful attempt to stop.

Up until now five randomised clinical trials into the effectiveness of nortriptyline have been carried out, four of which demonstrated a positive effect compared to placebo. The conclusion is that nortriptyline, in combination with intensive supervision, is more effective than placebo in supporting smokers during an attempt to stop. Up until now the effectiveness of nortriptyline and bupropion have been compared in one study, in which no difference in effectiveness was found between the two drugs. No research has been carried out into the effectiveness of nortriptyline without support. As nortriptyline has already been available for more than 30 years as an antidepressant, much is known about its side effects profile. However, the presence of contraindications should be established before this drug is prescribed.

Much of the research on the effectiveness of NRT and bupropion is sponsored by the pharmaceutical industry. The working group's opinion is that the exact size of the effect is therefore yet to be determined.

Other considerations

Nicotine replacement therapy has been extensively investigated over a long period of time, also in primary care and without intensive supervision. Nicotine replacement therapies are effective among all groups of smokers. The effectiveness seems to be limited but nicotine replacement therapies have a limited risk of side effects and are available over the counter.

Although less clinical studies have been carried out for nortriptyline with respect to the indication of 'treatment of tobacco addiction', there is as yet no evidence for a difference in effectiveness compared to bupropion. Nortriptyline is not registered for the indication of 'treatment of tobacco addiction'. Just like bupropion it is only available on prescription.

For this indication, a consultation with a physician is desirable as the effectiveness needs to be weighed up against the costs and possible side effects.

Bupropion has only been extensively investigated in selected populations with intensive support.

Recommendations

- For all smokers who smoke more than 10 cigarettes per day and who are considering an attempt to stop, the use of one of the nicotine replacement therapies during this attempt should be considered. These drugs can also be recommended in the case of a second attempt to stop.
- For all smokers who smoke more than 10 cigarettes per day and who want to stop, and for whom nicotine replacement therapies are not or are no longer an option, the use of bupropion or nortriptyline can be considered.

Chapter 6

Self-help materials

6.1 Paper, audio and visual

The Cochrane database discusses 11 studies in which the treatment consisted of posting a self-help guide to smokers (whether or not they were motivated to stop) sometimes accompanied by a letter from the physician. In these studies the control group did not receive any treatment. It was found that under these conditions the treatment led to a 24% higher success rate than no treatment after 12 months (OR: 1.24; 95% CI: 1.07-1.45), with 5.7% in the experimental group stopping versus 4.8% in the control group. After 12 months the continuous abstinence was 3.1%. However, this was only measured in 6 studies.

In practice, a self-help guide will often be supplied as part of a consultation. In a Cochrane review the effect of supplying a self-help guide by a physician or nurse (or other health professional), whether or not in combination with a formal advice to stop, was investigated. Under these conditions it was found that the advice did not add anything to the value of sending a self-help guide. Yet on the other hand it also did not demonstrate that the effect of an advice was increased if supplemented by written materials. Further it was found that adding self-help materials did not increase the effectiveness of nicotine replacement therapies; however, this was only investigated in two studies.

Conclusions

Level 1	The extra proportion of successful quitters after at least 12 months due to the use of written self-help materials is about 1%. It is not clear to what extent this percentage rises if this is combined with, for example, a brief supportive intervention. <i>A1 Lancaster 2003¹</i>
Level 1	Sending smokers a self-help guide through the post was found to increase the success rate for smoking cessation by 24% compared to no intervention. Supplying a self-help guide in combination with a brief stop advice by a health professional is not more effective. <i>A1 Lancaster 2002¹</i>

6.2 Internet courses

In the Cochrane database, 14 randomised studies into the effectiveness of a computerised tailored advice were identified. All of these cases concerned advisory texts compiled by the computer on the basis of a questionnaire. In three studies a control group that did not receive treatment was included. In the experimental group 6.5% stopped and in the control group 4.0% stopped (OR: 1.80; 95% CI: 1.46-2.23). In the remaining 10 studies the control group received a leaflet or self-help guide. In the experimental group 5.6% stopped and in the control group 4.4% stopped (OR: 1.36; 95% CI: 1.13-1.64).

In one study the effect of computerised advice in combination with advice from the physician was investigated. The pooled results of the 14 studies revealed that smokers with a tailored advice have more chance of stopping. The cessation rate in the experimental group was 6.1% compared to 4.3% in the control group (OR: 1.56; 95% CI: 1.36-1.80). Three studies reported figures over 12 months continuous abstinence. The pooled cessation rate was 6.6%.

Conclusion

Level 1

Tailored computerised advice is an effective resource for helping smokers with smoking cessation. After 12 months 6.6% of the smokers are able to stop smoking.

A1 Lancaster 2000¹

6.3 Effective components

From an analysis of 10 studies it could be demonstrated that tailoring educational materials improves the effectiveness of the smoking cessation intervention compared to a written intervention which is not tailored to the individual patient (OR: 1.36; 95% CI: 1.13-1.64). The studies provide too little insight into the differential quality and were used with a broad range of smokers varying from unmotivated to motivated. Most studies into the effectiveness of pharmacotherapeutic agents only include smokers who are motivated to stop. As a consequence of this, the cessation rates in the last mentioned studies are higher than in studies in which non-motivated smokers also participate.

Conclusion

Level 1

Tailoring educational materials to the individual results in more quitters (OR: 1.56; 95% CI: 1.36-1.80) and is more effective than self-help materials (OR: 1.36; 95% CI: 1.13-1.64).

A1 Lancaster 2002¹

6.4 Implementation of self-help materials

A characteristic of the level of proof in the Cochrane reviews is that the quality of the interventions varies, as a result of which a moderate effect occurs upon pooling. Another point is that – compared to, for example, clinical trials – it often concerns studies that were not carried out under optimal conditions (efficacy trials), but rather under real conditions (effectiveness trials). Effectiveness studies have lower effect scores.

The above mentioned studies show that an importance criticism of the traditional self-help materials – that they are not tailored to the characteristics of the person receiving them – is probably correct. Interventions tailored to the individual are more effective than self-help guides. This suggests that materials adjusted to the motivational stage could be more effective than materials that are not adjusted to this. Evidence for this was found in one study but only after 18 months.¹ Self-help materials might be more effective if there are several points of contact. However, a recent study found no support for this.² The Cochrane studies, however, failed to state that the effectiveness of tailored materials differs per motivational stage of the smoker. For example, in two Dutch studies the cessation rates of smokers who were motivated to stop smoking were 22% and 29.7% respectively, but only 1.2% and 3.4% respectively among smokers who did not want to stop. The studies included in the review do not clarify which components are effective for self-help materials. On the basis of research results it can be suggested that the content of the material must vary per motivational stage.³

Chapter 7

Practice settings and target groups

In *chapter 2* the damage which smoking can cause was detailed. In this chapter additional information for a number of specific groups will be given.

A number of smoking-related complaints fall under the health damage which can arise due to tobacco addiction. Well-known examples are cardiovascular diseases, chronic lung diseases, cancer and ear, nose and throat conditions.

First of all, further information for several practice settings is given. This does *not in anyway* mean that the recommendations made in this guideline do not apply to other health professionals. The provision of one-off advice and brief supportive interventions has been shown to be effective for all health professionals. The success rate can be increased if a health professional makes a direct link with a smoking-related complaint at the moment that a patient presents with this.

7.1 General practice

As 70% of the Dutch population visit the general practitioner each year, the general practice is the best place to reach a lot of smokers for a smoking cessation intervention. Even though many general practitioners have a high work pressure, they are nevertheless asked to play an active role in the smoking cessation policy. The proposed brief one-off advice scarcely costs any time and is a very effective and cost-effective intervention at a population level. This equally applies to the more extensive advice based on the minimum intervention strategy (MIS), which is included in many of the practice guidelines from the Dutch College of General Practitioners [Nederlands Huisartsen Genootschap].

This role can in part be fulfilled by the general practitioner and he/she can delegate part of it to the doctor's assistant, who is present in more than 30% of general practices. A proportion of the smokers can also be referred to more intensive forms of support. Doctor's assistants can train to become specialists in providing intensive or less intensive smoking cessation interventions.

7.1.1 Attitude of general practitioners

General practitioners find that they do not have enough time to provide all smoking patients with a brief supportive intervention for smoking cessation.^{1,2} General practitioners are more inclined to give an advice to stop smoking to smokers who have smoking-related complaints. General practitioners are often under the impression that giving unsolicited advice can damage the relationship with the patient. This impression

is not supported by research.^{3,4} There are, however, indications that people find an advice to stop smoking more acceptable if it is linked to the reason for the visit.⁵

There are no known data with respect to differences in the effectiveness of the advice. An unpublished study among a random sample of Dutch general practitioners in 2002 (n = 758) and another study (Smoking cessation in primary and specialised care, part 1: general practitioners [Stoppen met roken in de eerste en tweede lijns gezondheidszorg, deel 1: huisartsen]) reveal a number of typical responses of general practitioners. It should be noted that there is a possible bias among the respondents in the sense that they possibly respond in a more positive manner than non-respondents. The following was reported:

- General practitioners prescribe bupropion more frequently than nicotine replacement therapies, partly because nicotine replacement therapies are available over-the-counter.
- Nortriptyline is only prescribed on a very small scale.
- General practitioners who participated in the study frequently gave self-help materials to patients.
- No more than 30% of the general practitioners used the H-MIS.
- General practitioners mostly discuss smoking cessation with patients who have smoking-related complaints or with risk groups.
- For almost half of the general practitioners a motivated patient is a reason to decide to give an advice.
- A lack of time is the most important reason for not discussing smoking behaviour.
- A minority of general practitioners register the smoking behaviour of patients.
- General practitioners are of the opinion that the patient is responsible for smoking cessation.

In contrast to the perception of general practitioners, smokers scarcely have a problem with a general practitioner giving a smoking cessation advice, even if the patient has not asked for this.⁴

Conclusion

Level 3

A minority of general practitioners are of the opinion that whenever the opportunity arises they should give a brief supportive intervention to all smokers to help them stop smoking.

B McEwen 2001¹

7.1.2 Effectiveness of short supportive interventions in general practice according to the minimum intervention strategy (MIS)

The MIS has been specifically developed for Dutch general practice and is an effective method for carrying out brief supportive interventions for smoking cessation. In principle, the MIS can be carried out within the normal duration of a consultation. After

use of the MIS, the percentage of smokers who are still abstinent after 6 months is 8.2% as opposed to 3.1% in the control group.⁶

The MIS makes use of the stages of behavioural change which a smoker can be in. With two questions ('ask' and 'assess') smokers who are motivated to stop can be distinguished from those who are not. As a result of this the intervention can be targeted towards the smokers who are most likely to stop.

The MIS can be used for all smokers; there are no screening methods for identifying specific high-risk groups. However, in 20 of the 78 guidelines for general practitioners (see *appendix 6*) smoking cessation according to the MIS is advised as part of the non-pharmacological treatment.

In the CARPE project, a randomised study into the effect of a support programme aimed at the care of patients with cardiovascular risk factors, the number of general practices that used the MIS increased in the intervention group (n = 62) from 16% to 53%, whereas in the control group (n = 62) it decreased from 24% to 16%.⁷ In general practices which received support from a prevention consultant (with one practice visit about MIS), the registration of the risk factor smoking among 60-year-old, high-risk patients increased from 7% to 44% as opposed to an increase from 3% to 6% in the control group. The number of general practitioners that used the MIS increased in the intervention group (n = 300) from 28% to 37%, and in the control group (n = 300) from 23% to 28%.^{8,9}

Conclusion

Level 3

The MIS seems to be an effective and workable method in everyday general practice for supervising smokers during smoking cessation.

A2 Pieterse 2001⁶

Other considerations

General practitioners who received support in using the MIS, gave suggestions for its improvement: the inclusion of automated selection procedures in the general practitioners information system, support from a prevention consultant, incorporation of follow-up, fitting in a high-risk approach.² The introduction of practice assistants is a favourable possibility for furthering smoking cessation interventions in general practice. The MIS can be used by both general practitioners and practice assistants. The MIS has been available since 1994. The number of general practitioners that use MIS in everyday practice is about 30%.^{8,10} Factors which hinder the use of MIS are the workload of general practitioners, insufficient time for the practice assistant, difficulty in changing the manner of working, the lack of financial compensation, the doctor's assistant having insufficient knowledge and skills, and difficulty in motivating patients.⁶ Wherever possible, the MIS takes these obstacles into consideration. A large part of the MIS can be delegated to the doctor's assistant or a practice assistant.

7.1.3 Characteristics of smokers to whom general practitioners are more inclined to give a one-off advice or a brief supportive intervention

A study among 293 general practitioners reveals that they are better acquainted with the smoking behaviour of patients with smoking-related complaints and from risk groups (cardiovascular diseases and COPD), than with that of other patients. General practitioners are also more willing to give a smoking cessation advice to these smokers.^{2,11} They were found to give a smoking cessation advice more frequently to patients with an increased cardiovascular risk.⁷

There are no indications that an advice to a person from a risk group is more effective than to a smoker who does not belong to a risk group. However, general practitioners are under the impression that the risk reduction among people from these groups is greater when they stop smoking. Furthermore, for smokers – also without complaints – a smoking cessation intervention is extremely cost-effective. However, there are indications that an advice given to people with psychological complaints is less effective.

Conclusion

Level 3

The willingness among general practitioners to give smoking cessation advice (according to the MIS), is greatest for smokers who have smoking-related complaints and patients from high-risk groups.

C Drossaert 1999²; guideline UK 2000¹¹

Other considerations

The chances of the MIS being implemented in general practices is greatest if this fits in with how general practitioners work. The selection of eligible smokers from the general practice information system fits specific risk groups best. This concurs with the Dutch College of General Practitioners [Nederlands Huisartsen Genootschap]. Practice Guidelines for cholesterol, hypertension and diabetes, for example. Therefore for general practitioners who do not or who scarcely use the MIS, the advice to tackle this in a stepped care manner should be considered: Start with patients with a smoking-related complaint and with risk groups. Once the method is in use, it can later be extended to all smokers.

A finding from daily practice is that increasingly more smokers turn to the general practitioner for help and support.

7.1.4 Practice assistants or doctor's assistants

Indirect comparison reveals that support by a physician is not or scarcely more effective than that given by a health professional who is not a physician. Support given by two or more health professionals working together is possibly slightly more effective than that given by one health professional.¹² Advice given by nurses is more effective than no intervention or the usual care: OR: 1.50 (95% CI 1.29-1.73)¹³ The effect is also positive for the studies that focus on patients not admitted to a hospital: OR: 1.81 (95% CI: 1.39-2.36).

There was no direct comparative research into intensive intervention and a one-off advice or a brief supportive intervention by a nurse. Additional telephone advice and psychological feedback (spirometry, measuring the CO value) had no clear added value. There is no evidence that advice from a nurse during a health check-up is effective. Individual counselling by a specialist not involved in the normal provision of care is more effective than this normal care or an advice shorter than 10 minutes (OR: 1.62; 95% CI: 1.35-1.94).¹⁴ Behavioural support provided by a specialist (several contacts over a period of at least four weeks) to moderate to heavy smokers who seek help to stop smoking, results in an increase in the cessation rate of 7% (95% CI: 3%-10%).¹⁴ For definitions and an overview of the studies used see *tables 15-18, appendix 5*.

Conclusions

Level I	<p>Intervention provided by a doctor's assistant or practice assistant has a limited effect, as a result of which the intensity of the intervention (up to a maximum of 10 minutes) has little effect.</p> <p><i>A1 Rice 2002</i>¹³</p>
Level I	<p>The effectiveness of an intervention is scarcely dependent on the type of health professional (general practitioner, practice assistant and doctor's assistant are overall just as effective as each other). The effectiveness possibly increases with the number of different types of health professionals involved in the intervention.</p> <p><i>A1 Fiore 2000</i>¹²</p>
Level I	<p>Behavioural support (counselling) given by practice assistants who have undergone special training is effective, as a result of which the intensity of the intervention possibly has no effect (up to a maximum of 10 minutes). Counselling by a practice assistant is probably more effective than a brief supportive intervention by a practice assistant or a doctor's assistant.</p> <p><i>A2 Rice 2002</i>¹³; <i>A1 Lancaster 2002</i>¹⁴; <i>A1 Fiore 2000</i>¹²</p>

Other considerations

In December 2001 and January 2002 the Dutch Association of Doctors' Assistants [*Nederlandse Vereniging van Doktersassistenten*] carried out a national smoking cessation project. This project linked in with the smoking cessation campaign from the Dutch government and STIVORO for a smokefree future. In this project, the NVDA assumed that a policy supported by the entire general practice (general practitioner, practice assistant and doctors assistant) would increase the effectiveness of a campaign.

There is considerable variation in practice organisation. For example, there are general practices in which practice assistants work, but also practices in which doctor's assistants perform duties that are carried out by practice assistants in other practices (for example, monitoring patients with diabetes, asthma/COPD or hypertension). There are also practices where medical and other tasks are scarcely delegated to assistants.

The majority of doctor's assistants carry out medical and other duties, largely on the orders of the general practitioner, and these nearly always concern patient-specific tasks. These tasks would appear to make doctors' assistants particularly suitable for offering personal supervision. Doctors' assistants can be used in a smoking cessation policy that is both supported and implemented by all practice staff. For example, assistants can be involved in carrying out the MIS. Assistants can also be deployed for telephone counselling, as long as they have been trained for this purpose.

The following recommendations are made for general practice in addition to those already made in the general chapter:

Recommendations

- When the general practice has to set priorities with respect to the investment of time, the practice staff can best focus on smokers with a high motivation. Such smokers particularly deserve attention if they have (or have a high risk of) smoking-related complaints.
- General practitioners should actively give a smoking cessation advice to smokers with smoking-related complaints and from risk groups (cardiovascular diseases, COPD and pregnant women).
- In order to promote the implementation and satisfactory use of one-off and brief smoking cessation advice in the general practice (in general practice often according to the H-MIS, see *appendix 8*), general practitioners, doctor's assistants and practice assistants should receive sufficient practical support and training.
- General practitioners (or the practice assistant or doctor's assistant) should assess the smoking behaviour and motivational level of smokers, and then use a brief supportive intervention for motivated smokers, for example according to the H-MIS method.
- A smoker should preferably be given a smoking cessation advice once a year during a visit to the general practice, irrespective of whether he/she requests an intervention.
- In the case of smokers who are not motivated to stop, a one-off advice is sufficient; for smokers who are motivated to stop, the motivation and the factors which are obstacles and stimulants are discussed, a stop date and follow-up consultation are agreed upon and a leaflet is given to the patient (preferably Dutch College of General Practitioners – Dutch acronym: NHG [Nederlands Huisartsen Genootschap] Patient letter). If necessary this can take place with pharmacological support (see also H-MIS, *appendix 8*).

- The general practitioner can partly or completely delegate the intervention to a trained doctor's assistant or practice assistant. The cooperation of health professionals is recommended. The use of a longer investment of time (up to 90 minutes) and as many contacts as possible per smoker seem to be worthwhile and cost-effective.
- The ideal is a practice assistant who, after special training, provides intensive individual counselling during special hours outside of the normal provision of care.

Table 11 The MIS step plan published in Dutch College of General Practitioners CME booklet Smoking cessation, June 2000

1	Record smoking profile	Nicotine dependence if: first cigarette within 30 minutes of getting up and/or 20 or more cigarettes per day
2	Motivation	Disadvantages of smoking, advantages of stopping, countering excuses
3	Barriers	List and discuss barriers: why haven't you succeeded yet, which difficulties are expected? Also discuss barriers (previous unsuccessful attempts, stress, weight increase, addiction, social pressure, concentration).
4	Stop date	Record stop date
5	Resources	Smoking cessation booklet, nicotine replacement therapies
6	Aftercare	Make an appointment for follow-up consultation/telephone contact after stop day and enquire about smoking behaviour during follow-up consultations

The As in the MIS carried out by doctor's assistants

Using the five As in the MIS clarifies where specific, patient-focused tasks of assistants can best be used:

- 'Ask' In the initial consultation with a new patient the assistant can record whether he/she smokes in the general practice information system (Dutch acronym: HIS). This can also be done for patients who are already registered with, for example, smoking-related complaints.
- 'Assess' On behalf of the general practitioner the assistant can establish the extent to which the willingness to stop smoking is present.
- 'Advise' It is expected that the initial advice can best be given by the general practitioner, because he/she can more specifically link this to the risk profile.
- 'Assist' An assistant can draw up a stop plan with the patient and offer practical support. Pharmaco-therapeutic agents can be prescribed by the general practitioner.
- 'Arrange' Within the framework of relapse prevention the assistant can take care of follow-up contacts. Telephone counselling seems to be an excellent way of doing this.

7.2 Dental practice

The dentist is probably the only health professional who can easily broach the subject of smoking cessation: 'I see that you smoke. Have you ever thought about stopping?' (The word dentist also includes dental surgeon, orthodontist, dental hygienist and dentistry student.) In addition to this, dentists are frequently visited by children and young adolescents, as a result of which their practice seems to be the ideal location for expressing preventive messages. The international dentist organisation FDI urges all members of the dental team to support patients with smoking cessation.¹ Dentistry courses should also be involved in this.²

This section will first consider the relationship between tobacco use and oral hygiene, so as to make clear which aspects the dentist should pay particular attention to and where there are opportunities to bring up the subject of smoking cessation. Then consideration will be given to the smoking behaviour of dentists, their attention for the topic of smoking cessation and how dentists can support their patients during smoking cessation.

7.2.1 Tobacco use and oral hygiene

Tooth decay

In four studies a relationship was established between tobacco use and tooth decay. In one study it was concluded that smoking is a significant indicator for the loss of teeth and tooth decay.³ In a recent study a direct relationship has been established between passive smoking and dental decay in both deciduous teeth and changing teeth.⁴ A study among teenagers established a direct relationship between smoking behaviour and the prevalence of dental caries.⁵ A study among the elderly revealed that smoking is a significant risk factor for tooth loss, tooth neck decay and tooth root decay.⁶

A direct aetiological link with smoking – with the exception of the faster growth of *Streptococcus mutans* – has never been demonstrated. Smokers having a different lifestyle possibly plays a role.

Abnormalities of the mucous membrane

There is a clear relationship between tobacco use and the occurrence of malignant and premalignant abnormalities in the oral cavity.⁷ Smokers are two to four times more likely to develop oral cancer than non-smokers. Cigarette smokers run a higher risk than cigar or pipe smokers. Smoking has a direct carcinogenic effect on the epithelial cells of the mucous membranes of the mouth. Smoking cessation reduces the enhanced risk of oral cancer within 5 to 10 years. If smokers regularly drink a lot of alcohol as well, the chances of a malignant condition in the mouth can be 6 to 15 times as high.^{8,9}

Leukoplakia is six times as prevalent among smokers than among non-smokers. Upon smoking cessation the abnormality can regress or disappear.¹⁰

Of the other smoking-related complaints in the oral cavity, smoker's melanosis is found in about one-third of heavy smokers. This visible melanin pigmentation occurs mainly in the attached gingiva and sometimes on the lips and cheeks. After smoking cessation

the abnormality disappears after about two years. Stomatitis nicotina manifests as red spots on the white mucus membrane of the palate. This benign abnormality is also reversible.

Gum diseases

There is a clear link between smoking and the prevalence and seriousness of periodontal complaints.¹¹⁻¹⁵ Smokers suffer from more marginal bone loss, deeper pockets, more loss of attachments and more furcation problems.^{16,17}

Periodontal treatments are much less effective among smokers than among non-smokers.^{18,19} This applies to both surgical and non-surgical treatments. Also the success rates of periodontal regenerative surgery are noticeably lower.

Implants

Extensive research has been carried out into the effect of smoking on the success rate of implants. From a 15-year-long prospective study it has been established that smoking has a more negative effect on the success rate of implants than a poor oral hygiene.²⁰

Failure rates of more than 4% among non-smokers as opposed to more than 11% among smokers have been described. If only implants in the upper jaw are considered then this failure rate increases to almost 18% among smokers. The shorter the period for which implants are used the greater the negative effect of smoking.²¹ A significantly higher bleeding index, a greater cavity depth, more local inflammations and more bone loss were demonstrated in the smokers' group.²² It was also found that if the patient stopped smoking between one week before and seven weeks after the placing of implants, a significant reduction in the failure rate occurred compared to the group of patients who continued to smoke.²³

Disrupted wound healing

Tobacco use has a negative effect on wound healing. This is because smoking leads to increased plasma concentrations of adrenaline and noradrenaline, which gives rise to peripheral vasoconstriction. For example, tobacco use negatively affects wound healing after periodontal surgery and extractions and dry sockets and more painful extraction wounds are reported significantly more frequently for smokers.²⁴

Discoloration of the teeth

Smoking causes a discoloration of the dental elements with a resulting aesthetic loss. This influence of smoking is more important than the drinking of tea and coffee.²⁵ Further, discolorations of dental restorations and prostheses are seen more frequently and to a greater extent among smokers.

7.2.2 Smoking behaviour of dentists

A survey among Dutch dentists revealed that 12% smoke daily, 15% smoke occasionally, 30% have stopped smoking and 43% have never smoked. From an international perspective,

Dutch dentists seem to have a mid-table position in terms of smoking behaviour.²⁶ Six percent of American dentists smoke as opposed to 33% of Italian dentists.^{27,28} Dutch research from 1995 reveals that at the time 25% of medical specialists smoked; 36% had stopped smoking and 40% had never smoked. In that same year, 44% of nurses smoked, 26% had stopped and 30% had never smoked.²⁹ Thirty-five percent of the entire Dutch population aged 15 years and older smoked.³⁰ Smoking is completely prohibited in 86% of Dutch dental practices and partially prohibited in 11% of practices.²⁶

7.2.3 Dentists' smoking policy

Although it is easy for dentists to establish whether their patients smoke, they give an advice to stop smoking less frequently than other health professionals.³¹⁻³³ Nevertheless the majority think that it is important to be involved in smoking cessation campaigns.³⁴⁻³⁸ This discrepancy between the attitude of dentists and their actual behaviour is striking.³⁹ A small proportion (18%) of Dutch dentists regularly inform smoking patients about the harmful consequences of tobacco use. In the case of smoking-related oral complaints that proportion increases to 59%.²⁶

Short opportunistic advice or a brief supportive intervention

Research reveals that 2.5% of the people who received a stop advice lasting several minutes accompanied by an information leaflet, no longer smoked after one year.⁴⁰ If that advice is given over several sessions during periodontal treatment, 13% of the patients stop smoking.⁴¹

In a study carried out in 75 dental practices (35,000 patients) 4761 tobacco users were divided into three groups: no intervention, minimal intervention (ask, give leaflet) and extensive intervention (stop date, video, telephone) (Severson 1998).⁴⁰ After 12 months no difference between the interventions was seen (OR: 0.9), but a difference was seen between 'no intervention' and 'minimum or more extensive intervention' (OR: 1.11; cessation rate after three months 4.7 versus 5.3; after 12 months 2.4 versus 2.6). In the 'more extensive intervention' group significantly more attempts to stop were made than in the group with 'minimal intervention'.⁴²

In a study among 154 dental patients in London who received a brief supportive intervention and nicotine patches, the cessation rate after 9 months was 11% (with continuous control).⁴³ For patients who were heavy smokers, a cessation rate after one year of 16.9% was reported.⁴⁴ These patients received a repeated brief supportive intervention and nicotine gum. In the control group who only received a brief supportive intervention, 7.7% stopped. Training of the dental staff led to an increase in both the quality and the quantity of the time spent on stop advice, as well as the numbers of stop advice issued. The more frequently dentists are reminded about their supportive task, the more frequently they give stop advice (29% versus 18%).⁴⁵ The interior design of the practice can also help in this respect: no smoking allowed, posters, photos.^{46,47}

Implementation of smoking cessation interventions

Of all of the Dutch dentists surveyed, 38% are of the opinion that informing/advising patients to stop smoking is one of the dentist's duties.⁴⁸ More than half (57%) do not consider it to be the dentist's responsibility to convince people to stop smoking. Nevertheless, 38% think that the patient will value the information that the dentist provides about smoking cessation. About two-thirds of Dutch dentists (64%) think that the majority of people will not stop smoking if dentists advise them to do that.

Conditions

Lack of time is a barrier for advising patients about smoking cessation: 27% of dentists, 33% of medical specialists and 24% of nurses stated this.⁴⁹ Swedish dentists more frequently see the lack of time as a barrier than their Dutch colleagues: 61%, while this applies for just 20% of Danish dentists.^{50,26,3} The most frequently cited barrier among Dutch dentists is the lack of information about smoking cessation (47%). A lack of information about the harmful consequences of smoking (37%) and a lack of skills for holding a conversation about smoking cessation (29%), were frequently mentioned. Fifty-two percent of dentists considered written information to be indispensable for advising patients. Information leaflets for the dental team and for patients have now been published in the Netherlands.^{51,52}

Interventions by practice assistants

Canadian research has revealed that the results of the smoking cessation policy are more effective if all members of the dental team participate. This is partly explained by the enthusiasm that arises due to everybody sharing in the success.^{53,54}

Conclusions

Level 3	<p>There are strong indications that dentists giving advice about smoking cessation is effective. At least 2%-13% of all smokers stop smoking for at least 12 months, dependent on the duration and frequency of the advice.</p> <p>C <i>McGregor 1996</i>⁴¹; <i>Severson 1998</i>⁴⁰</p>
Level 3	<p>In general, Dutch dentists are well-informed about the harmful effects of tobacco use and in their patient care, they are prepared (68%) to devote attention to the harmful effects of smoking for the health in general and for the mouth and teeth in particular. In addition to this, 41% want to focus on all smoking patients and 27% just on patients with smoking-related oral complaints.</p> <p>C <i>Allard 2000</i>⁴⁸; <i>Allard 2000</i>⁵⁵</p>

Level 3	<p>Dentists want to be well-informed about smoking and oral health and the manner in which they should approach patients. Educational material for patients is an indispensable part of this. Dentists are of the opinion that their efforts must be financially compensated.</p> <p>C Allard 2000⁴⁸; Allard 2003⁵⁰; Allard 2000⁵⁵; Albert 2002⁵⁶; Campbell 1999⁵³; Jennet 1998⁵⁴; Fried 1992⁵⁷; Gerbert 1989⁵⁸</p>
Level 4	<p>The results are more favourable if the entire dental team participates in the effort.</p> <p>D Campbell 1999⁵³; Jennet 1998⁵⁴</p>

Recommendations

- In view of the added value of their stop advice, dentists should be involved in smoking cessation campaigns.
- It must be established whether the existing educational material for dentists and patients is sufficient. Courses for the training of dentists should be developed and offered.
- A charge should be introduced for a smoking cessation consultation in order to encourage the implementation of smoking cessation advice by dentists.
- It is recommended that courses are not only organised for dentists, but also for other practice staff.

7.3 Midwifery practice (all disciplines)

Pregnant women form a special group because not only is smoking associated with risks for the unborn child and the outcome of the pregnancy, but also for the child after its birth. Furthermore, the period in which the smoking cessation interventions must occur is relatively short. On the other hand pregnancy provides an opportunity to realise a longer-term change in a woman's smoking behaviour. In particular providing parents with information that the unborn child or child can also experience negative effects from the mother's (and the father's) smoking, can result in smoking cessation interventions being more effective. This is an important responsibility for all health professionals involved in care relating to pregnancy and birth. It is preferable to initiate smoking cessation interventions prior to conception.¹ This allows more time to be devoted to the interventions and possibly increases the chances of success.

In the Netherlands, 35%-50% of women smoke during pregnancy.^{2,3} Smoking during pregnancy is associated with maternal, foetal and childhood morbidity and mortality. There is an increased chance of spontaneous abortion, extra-uterine pregnancy, intra-uterine growth retardation, smaller skull circumference, placenta praevia, placental

abruption, premature rupture of the amniotic membranes, premature birth and perinatal mortality.⁴⁻⁸ Smoking during pregnancy is possibly responsible for 15% of all premature births.⁹ The ‘population attributable risks’ (PARs) of maternal smoking on perinatal death are 6.3%, a birth weight < 2500 g 11.1% and < 1500 g 5.7%.¹⁰ If smoking no longer occurred among pregnant women then the incidences of perinatal death and low birth weight would decrease by 10%.

If the woman smokes then after the birth more childhood health disorders occur such as cot death (doubling of the risk) and hospital admissions, including more lower respiratory infections and asthma. There is also probably a higher chance of developmental and behavioural disorders occurring.

7.3.1 Effectiveness of brief smoking cessation interventions for pregnant women

In the most recent review, 34 randomised clinical trials were evaluated with respect to smoking cessation interventions in primary and specialised healthcare (by general practitioners, midwives and gynaecologists).¹¹ In the review the OR for smoking cessation interventions during the third trimester of pregnancy versus no interventions is 0.53 with a 95% CI of 0.47-0.60; an absolute difference in the number of women that stops smoking of 6.4%. Smoking cessation interventions also reduce the risks of a low birth weight (< 2500 g; OR: 0.80; 95% CI: 0.67-0.95) and prematurity (OR: 0.83; 95% CI: 0.69-0.99) and resulted in an increase in the birth weight (average 28 g; 95% CI: 9-49 g). No clear effects were demonstrated for perinatal mortality or the incidence of low birth weight (< 1500 g).

In a meta-analysis of the Agency for Healthcare Policy and Research (AHCPR) an intervention (one contact of 10 or more minutes with additional self-help materials and/or a referral for intensive supervision) resulted in a doubling of the number of quitters during pregnancy from 8% to 15%.¹²

Another meta-analysis of 10 randomised studies demonstrated an increase of 50% in smoking cessation between the sixth and ninth month of the pregnancy as a result of an organised prenatal smoking cessation intervention.¹³ The MIS, a 5-15 minute intervention consisting of the steps ‘ask’, ‘assess’, ‘advise’, ‘assist’ and ‘arrange’, is effective for pregnant women who smoke less than 20 cigarettes per day.^{14,6} Although it is most advantageous to stop in the early stages of pregnancy, stopping at any point during the pregnancy is to be recommended.

Conclusions

Level I	<p>Smoking during the pregnancy is associated with considerable risks for the child. Interventions of 5-15 minutes consisting of the steps 'ask', 'assess', 'advise', 'assist' and 'arrange' are effective for pregnant women who smoke less than 20 cigarettes per day.</p> <p><i>A1 Melvin 2000¹⁴; ACOG 1997⁶</i></p>
Level I	<p>Smoking cessation interventions reduce the risk of a low birth weight (< 2500 g; OR: 0.80; 95% CI: 0.67-0.95) and prematurity (OR: 0.83; 95% CI: 0.69-0.99) and result in an increase in the birth weight (average 28 g; 95% CI: 9-49 g). Although smoking cessation at the start of the pregnancy offers the most advantages, stopping at any point during the pregnancy is favourable.</p> <p><i>A1 Lumley 2003¹¹</i></p>

Other considerations

Focus group interviews with smoking pregnant women and smoking women who wish to have children reveal a number of issues which could be important in offering smoking cessation interventions to these target groups:

1. Relapse mainly occurs in the period after childbirth and after the women have stopped breastfeeding. Despite the lack of scientific support, the working group is of the opinion that it is important to devote attention to relapse prevention. Research into relapse prevention after childbirth would be worthwhile.
2. The expected stress is stated as being an important *barrier* to smoking cessation. They emphasised that it is more difficult to break the psychological dependence than the physical dependence. Further, smoking pregnant women and female smokers who want to have children indicated that they are afraid of gaining weight and they want to receive more information about the harmful effects of smoking on the unborn child. The pharmacist can play a role in providing information about the use of nicotine replacement therapies. The client's own motivation should take centre stage in the intervention, as this is considered to be the most important success factor for a successful attempt to stop smoking.
3. A proactive role is expected from the midwife. Women experience the advice given by midwives as encouraging. Furthermore it is expected, valued and accepted. Complete smoking cessation should be the basic principle, but health professionals recognise that it is better to reduce the amount smoked than to continually walk around with a feeling of stress.
4. A smoking health professional is less credible.

5. Smoking pregnant women and female smokers who want children feel that pharmacological support does not work. At the same time a number of those questioned indicated that nicotine replacement therapies and bupropion should be promoted more. There is a preference for bupropion as opposed to nicotine replacement therapies because as it is an antidepressant, bupropion is thought to have a better effect on the emotional state. The working group advises against the use of bupropion during pregnancy (contraindication).
6. There is a considerable interest in alternative methods, and the opinions about telephone counselling are diverse, ranging from useful and encouraging to too personal and therefore not a subject that you talk about with a stranger.

TNO Prevention and Health, STIVORO for a smokefree future) and the Free University Amsterdam (Department of Social Medicine, EMGO Institute) have developed an educational programme to reduce passive smoking by children. For this, four basic issues were answered by means of a wide-ranging questionnaire given to 413 employees of infant welfare centres (issue 2), 1702 parents, (issues 1 and 3) and 2534 mothers (issue 4):

1. What is the prevalence of passive smoking by children?
2. What are infant welfare centres doing about providing information about passive smoking?
3. Which factors determine whether or not smoking is permitted in the vicinity of the child?
4. What is the effect of the educational material about passive smoking provided at the infant welfare centre?

The study revealed that (in 1996) 42% of the children aged 0-12 months were exposed to cigarette smoke in the living room and that the majority of infant welfare centres did little to prevent passive smoking. The most important obstacles for this were the lack of time and materials. A lack of parental prevention was mostly associated with a negative attitude, a negative social influence from the partner, a low self-efficacy and a higher age of the child. On the basis of these findings an educational programme was developed, consisting of a leaflet for parents and a guide for health professionals with a five-step plan to discuss passive smoking. In 1999, two years after the dissemination of the programme within infant welfare centres, passive smoking by children aged 0-10 months had decreased from 41% to 18%.

The bodies responsible for the study concluded that the educational programme 'Smoking? Not when the little one is around' [Roken? Niet waar de kleine bij is] was effective in reducing passive smoking by children. The effect probably decreases if the advice is not repeated as the child becomes older. Therefore the development of educational material for older children is desirable.

Recommendations

- Due to the considerable risks of smoking during pregnancy for both the mother and child, all smoking pregnant women must receive the urgent and clear advice to stop smoking. Smoking cessation interventions should preferably go further than a brief supportive advice.
- Although smoking cessation at the start of the pregnancy provides the most benefits, stopping at any moment during pregnancy is favourable. Smoking cessation interventions should therefore be offered at least once each during pregnancy, preferably during the initial consultation.
- Midwives, gynaecologists and general practitioners should note the smoking behaviour and motivation level of pregnant women and then give a brief advice to motivated smokers. The V-MIS is an effective method for this purpose, at least in the short-term. The smoking cessation advice to pregnant smokers could adopt the following form (Melvin 2000).¹⁵
- ASK-1 minute:
Ask the patient to indicate which of the following statements best describes her:
 - A I have NEVER smoked or have smoked less than 100 cigarettes in my entire life.
 - B I stopped smoking BEFORE I discovered I was pregnant and I do not smoke now.
 - C I stopped smoking AFTER I discovered I was pregnant and I do not smoke now.
 - D I still smoke occasionally but I reduced the number of cigarettes when I discovered that I was pregnant.
 - E I smoke regularly, about the same as BEFORE I knew that I was pregnant.

In the case of B or C, congratulate the woman with her decision to stop and encourage her to keep this up both during and after the pregnancy.

In the case of D or E, record her smoking status in the records and apply a one-off or brief supportive intervention according to the 5 As model ('assess', 'advise', 'assist' and 'arrange', see *appendix 1*.) The five As are intended for every smoker who wants to stop.
- For motivated smokers it is worthwhile devoting attention and support to smoking cessation throughout the course of the pregnancy (therefore during several consultations).
- As good experiences have been gained with the educational programme 'Smoking? Not when the little one is around' [Roken? Niet waar de kleine bij is], this can be used as a good example for reducing passive smoking by children.

7.3.2 Factors which facilitate stopping

The following factors are associated with smoking cessation during pregnancy: starting to smoke at an older age, no previous children, smoking little, a higher level of education, supported by partner, non-smoking parents.¹⁶

Women who continue to smoke during pregnancy, are younger, more likely to be unmarried, poor, and emotionally stressed, have a lower educational level, have previously been pregnant and are heavy smokers.¹⁷ Special support by 'peers', in addition to the MIS ('ask', 'assess', 'advise', 'assist' and 'arrange'), results in a decrease in the number of cigarettes smoked per day and an increase in the birth weight (not in the number of women who stopped).¹⁸

Other considerations

It is important to devote extra attention to the heaviest smokers who want to have children or who are pregnant, particularly those with a disrupted obstetric history.

7.3.3 Pharmacological support

Nicotine replacement therapies must be considered if other interventions fail, and certainly in the case of women who smoke heavily (more than 10 cigarettes a day) and who have had a previously complicated pregnancy in which smoking played a role. The possible risks of nicotine replacement therapies will need to be weighed up against the advantages of smoking cessation or smoking less. However, a randomised clinical trial revealed that nicotine patches had no effect on smoking cessation but did affect the birth weight (average difference of nicotine patches versus placebo 186 g; 95% CI: 35-336 g).¹⁹ Nicotine replacement therapies are safer than cigarettes.²⁰ The Royal College of Physicians recommends the use of nicotine replacement therapies by pregnant women after other interventions have failed.²¹

The teratogenic risks and contraindications of nicotine replacement therapies, bupropion and nortriptyline are detailed in the Farmacotherapeutisch Kompas²² and the IBI text can be found at www.cbg-meb.nl.

Recommendation

For pregnant women or breastfeeding women, nicotine replacement therapies can be considered when smoking cannot be stopped using any other approach and when the advantages of stopping weigh up against the risks of nicotine replacement therapies (see also *section 7.3.3*). It is recommended that further clinical research be carried out into the effectiveness and safety of nicotine replacement therapies for pregnant smokers. The use of bupropion is contraindicated. The risks of using nicotine replacement therapies at the same time as smoking must be emphasised (risk of lower birth weight).

7.3.4 Relapse prevention among pregnant women

Two-thirds of the women who stopped smoking during pregnancy, start smoking once again within three months of the birth.²³ Therefore, continuing support after the birth is essential (if needs be with nicotine replacement therapies). However, five randomised clinical trials (RCTs) demonstrated that interventions during pregnancy had no effect on the level of relapse after giving birth.¹¹ One RCT (randomised clinical trial) describes no significant effect six months postpartum. This could also be explained by the fact that the obstetric health professionals devote little attention to relapse prevention and that pregnant women mainly stop for the sake of their unborn child. Very few pregnant women have received the relapse booklet. A systematic review of intervention studies targeted towards smoking cessation by pregnant women revealed that 5 of the 44 studies included contained a component geared towards relapse prevention, for women who had stopped smoking at the first antenatal visit to the health professional. These RCTs show no effect. The pooled OR for smoking during late pregnancy is 0.75 (95% CI: 1.1-1.6), equivalent to an absolute difference of 4.9%.

Recommendation

Women who have stopped smoking during pregnancy must also be offered support after childbirth. The care provided by midwives ends one week after childbirth, and is then followed by a one-off check up at six weeks after childbirth. The effect of an intervention aimed at relapse prevention can possibly be increased by clearly transferring this task from the midwife or gynaecologist to the infant welfare centre, the general practitioner or possibly the paediatrician.

7.3.5 Attitudes and experiences of gynaecologists and midwives

There are indications that midwives are more reticent in issuing the advice to stop smoking than in issuing the advice to smoke less. However, reducing the amount smoked has a very limited value and therefore smoking cessation must be the object of the advice.²⁴ Midwives are possibly afraid of enhancing the feelings of guilt with respect to an unfavourable pregnancy outcome.

Midwives with a positive view of their task with respect to smoking cessation supervision are in general more convinced about the advantages of providing information about smoking cessation for the health of mother and child, and expect more support from their colleagues with respect to this task. They are convinced that they carry out their task as a midwife better if they advise and supervise their clients during smoking cessation. The perception of self-efficacy with respect to giving smoking cessation information was low, both among midwives with a positive view of their tasks and midwives with a less positive view of their tasks.²⁵

The study of Bakker describes a number of characteristics and opinions of midwives which were investigated by means of a written questionnaire among 237 midwives. Midwives indicated that they spent an average of 3.5 minutes on the conversation about

smoking during the initial consultation. Midwives are prepared to spend an average of 17.5 minutes on smoking cessation supervision spread over the consultations.

7.3.6 Short opportunistic advice and brief supportive intervention by midwives.

One study describes the effect of minimal intervention by midwives and self-help material especially aimed at pregnant women (randomised clinical trial (RCT) about intervention by midwives in primary care); six weeks postpartum. In total, 38.2% of the experimental group had stopped compared to 23.4% of the control group. Women in the experimental group were more inclined to attempt stopping (OR: 3.2; $p < 0.01$; 95% CI: 1.47-6.18). The effect of brief supportive interventions (such as the V-MIS) in the longer term has not been demonstrated.

Other considerations

We emphasise that midwives should offer support for smoking cessation. Whether a client actually stops smoking or attempts to stop smoking is the responsibility of the client and her partner.

7.3.7 Implementation of brief smoking cessation interventions by midwives and gynaecologists

The V-MIS has been developed for giving pregnant women the advice to stop smoking and for supervising this. It is a plan consisting of several steps: establishing the motivation level and nicotine dependence (1), increasing the motivation level (2), discussing barriers (3), agreeing a stop date (4) and offering the self-help guide and/or video (5). In addition to this there is a postpartum intervention targeted at relapse prevention (6). The V-MIS is based on the female smoker's stage of behavioural change.

The intervention is effective and costs relatively little time.

Conclusion

Level 4

The V-MIS is an effective method for supervising smoking women during smoking cessation.

D Bakker 2001²⁵

7.4 Parents of newborns and young children

Paediatricians, infant welfare centre doctors, school doctors and other health professionals involved in the care of children can be confronted with smoking-related health problems at four levels:

- the consequences of pregnant women smoking for the foetus (this has been discussed in the previous section);

- the consequences of passive smoking by children in general (babies, toddlers, preschool children and schoolchildren);
- the consequences of passive smoking by children with respiratory diseases;
- teenagers who start smoking.

7.4.1 Consequences

Passive smoking is one of the risk factors for respiratory complaints in children.¹ A series of meta-analyses reveals a clear relationship between passive smoking and acute lower respiratory tract infections, passive smoking and ‘asthma and wheezing’, and passive smoking and the prevalence of respiratory symptoms and asthma.²⁻⁴ Furthermore, in a meta-analysis Anderson and Cook describe the relationship between passive smoking and cot death.⁵ It is difficult to relate passive smoking to the severity of the respiratory complaints in children with respiratory diseases. On the basis of clinical observations, theoretical considerations and the literature about the relationship between smoking and the severity of asthma in adults, it can be stated that respiratory conditions, and in particular asthma, more frequently occur after exposure to tobacco smoke. If children have respiratory problems, the motivation of parents to avoid passive smoking is greater. Paediatricians, general practitioners, infant welfare centre doctors, school doctors and other health professionals involved in the care of children are therefore in a suitable position to facilitate smoking cessation among parents/guardians.^{6,7} There is also a notable ‘carry-over effect’ which lasts for several years after an intervention.⁸

Parents do not necessarily have to stop smoking. Parents who smoke outside or who only smoke at work do not damage the health of their child. Paediatricians and other health professionals must try to convince parents and other people who look after children not to smoke in the house, which is a less difficult task than convincing them to stop smoking. Even if people smoke by an open window or under a ventilation cap many smoke particles still enter the house.

7.4.2 Effectiveness

There are several studies that describe interventions aimed at reducing passive smoking by young children. The studies differ in the outcome measures they use. It is still not clear whether a one-off advice (two As) is effective.⁹ The studies measure the decrease in the reported number of cigarettes smoked or the decrease in smoke particles in the home environment of young children. The decrease in the concentration of nicotine in the urine is only marginally present in one study.⁷ Furthermore, the effect of the interventions often diminishes over time and therefore attention needs to be devoted to follow-up/relapse prevention.

In the Netherlands, STIVORO for a smokefree future has developed an intervention programme for infant welfare centre doctors and nurses, under the title ‘Smoking? Not when the little one is around’ [Roken? Niet waar de kleine bij is] (see *section 7.3.1*). Dutch

market research institute [NIPO] continually investigates smoking habits; 2000-IV. This reveals encouraging results with respect to passive smoking. Between 1997 and 2000 the percentage of children up to the age of 4 years who passively smoked decreased from 48% to 35%.¹⁰ The programme can also be used by municipal health centres [GGDs] with parents of children aged five to eight years.

Conclusions

Level I	<p>Passive smoking is a health risk for children. Passive smoking by children with respiratory conditions exacerbates the complaints and is therefore an extra health risk.</p> <p><i>A1 Strachan 1997²; A1 Strachan 1998³; A1 Cook 1997⁴; A1 Anderson 1997⁵; B Hofhuis 2002¹⁰; B Martinez 1995¹</i></p>
Level I	<p>Brief supportive and intensive interventions have been shown to be effective and the effect lasts longer in the case of repeated interventions and/or longer interventions.</p> <p><i>A2 Emmons 2001¹¹; A2 Hovell 1994⁶; A2 Wahlgren 1997⁸; A2 Hovell 2002⁷</i></p>

Other considerations

The Dutch population knows far less about the harmful effects of passive smoking than it does about the harmful effects of smoking.

Recommendations

- Paediatricians, general practitioners, infant welfare centre doctors, school doctors and other health professionals should include a one-off advice and a brief supportive intervention about smoking cessation in their policy for each new patient/parent contact, for example according to the MIS approach.
- Children with respiratory complaints suffer more from passive smoking. For this group of children in particular, paediatricians, general practitioners, infant welfare centre doctors, school doctors and other health professionals involved in the care of children should be particularly vigilant in offering systematically given one-off advice and brief supportive interventions, for example according to the MIS approach.

7.5 Teenagers

Smoking is of course extremely harmful for the health of teenagers, especially if they also suffer from a respiratory disorder.

Teenagers who have started to smoke form a special group. On the one hand they are mostly not or not yet addicted to nicotine, which is an advantage. On the other hand, a successful attempt to stop by a young person results in a lot of extra benefit, the degree of addiction among young people is often underestimated and young people's view on things often differs from that of adults, whose views they often want to rebel against. This is a disadvantage in approaching this group. It is therefore important to relate as much as possible to young people's outlook; however there is no reason to treat these young people in a fundamentally different manner than adults. Health professionals should familiarise themselves with the techniques of behavioural interventions, such as the MIS and the basics of motivational interviewing (MI). Motivational interviewing is a supportive communication technique in which the patient (in this case a smoking teenager with a respiratory disorder) is encouraged to take his or her own decisions. There is a lot of literature about how the smoking habits of teenagers in the general population are influenced. These studies largely originate from the United States. The results are variable and often disappointing. However, no literature was found about how the smoking behaviour of teenagers with a respiratory condition is influenced.

Conclusion

Level 2

No consistent effects can be reported about the effectiveness of the interventions among teenagers. However, there are indications that intensive interventions can be effective.

A2 *Nutbeam 1993*¹; A2 *Aveyard 1999*²; A2 *Adelman 2001*³

Recommendation

In view of the considerable health risks of smoking for teenagers, paediatricians, general practitioners, infant welfare centre doctors, school doctors and other health professionals should encourage teenagers to stop smoking. It is not clear which intervention or combination of interventions is particularly effective for this target group. There is no reason to treat this group in a fundamentally different manner, but it is important to relate as much as possible to the outlook of young people.

7.6 Patients with smoking-related complaints

7.6.1 Cardiovascular diseases

The MIS, which has been found to be effective in Dutch general practice (see *section 7.1.2*) and midwifery practice (see *section 7.3.1*), has also been investigated for its effectiveness in the outpatients' setting (so-called P-MIS) and the clinical setting (so-called C-MIS) for patients with a cardiovascular disorder. The C-MIS protocol was found to be effective in

the short-term (after 3 months) but long-term effects (after 12 months) were not found.¹ On the one hand this was due to methodological limitations in the research, including a high drop-out and an incomplete implementation. On the other hand it was established that the intervention, and in particular the follow-up care after discharge from hospital (relapse prevention), needed to be extended. A study into the effects of the P-MIS after one year found that this method was not effective.² Van Berkel recommends a more intensive intervention than the minimum intervention strategy in order to produce effects among patients with coronary disease who visit the outpatients' clinic.

Reviews on which the American and British guidelines for the treatment of tobacco addiction are based, did not specifically look at heart patients when assessing the effectiveness of interventions but rather at the general population admitted to hospital.^{3,5} The previously mentioned five As ('ask', 'assess', 'advise', 'assist', 'arrange') are necessary in an effective intervention. It should be noted that the C-MIS is also based on these components. In their Cochrane review of interventions by nurses in the area of smoking cessation, Rice & Stead indicate that intensive telephone support after discharge from hospital is an essential component of an effective intervention for heart patients.^{4,6} Telephone support is also included in the C-MIS. The review also states that the study of Ockene, in contrast to the study of Bolman, found some effects of a smoking cessation intervention among patients with a severe myocardial infarct.^{1,7}

A brief advice given by nurses to patients with a coronary bypass is effective. Patients with a myocardial infarct are twice as likely to successfully stop than patients after a bypass operation.⁸

Also a more intensive programme carried out by nurses for patients who were admitted to a Norwegian hospital due to coronary heart failure, was found to be very effective. Patients who during their stay in hospital had a twice-weekly group session and in addition to this received telephone follow-up on several occasions until six months after discharge, had (after 12 months) a biochemically confirmed chance of stopping of 57% compared to 37% in the group of patients who only received an advice to stop (NNT = 5 (95% CI: 3-6)).⁹ Medicinal support for patients increases the chance of successfully stopping and is safe.^{10,11} More intensive behavioural counselling increases the chances of successfully stopping by a factor of two to three.^{3,4,11}

Conclusions

Level 1

The five As ('ask', 'assess', 'advise', 'assist', 'arrange') form a necessary part of an effective method to supervise people with a coronary heart disease during smoking cessation.

A2 Bolman 2001¹; A1 Fiore 2000³; A1 Rice 1999⁴; A1 Raw 1998⁵

Level 3	<p>The C-MIS is an effective method in the short term (3 months after the method is used for heart patients admitted to hospital) for supervising smoking cessation.</p> <p>A3 <i>Bolman 2001</i>¹</p>
Level 3	<p>Medicinal support combined with nicotine replacement therapies increases the chances of cardiovascular patients successfully stopping.</p> <p>A2 <i>Tonstad 2003</i>¹⁰</p>
Level 3	<p>More intensive supervisory programmes are effective.</p> <p>A2 <i>Miller 1997</i>⁶</p>

Other considerations

In the case of patients who are not motivated to stop smoking, an intervention should take place which focuses on increasing the motivation to stop smoking. Motivational interviewing is one of the techniques that can be used for this (see also *section 7.5* and *appendix 2* for the five Rs intended for smokers who are not currently willing to undertake a quit attempt).

Recommendation

Cardiologists and the nurses involved should record the smoking behaviour and motivational level of their patients with a smoking-related disorder and then support motivated smokers in their attempt to stop. This should also include attention and support for the period following discharge from the hospital. Patients who are not motivated to stop smoking should first of all be motivated. The C-MIS is a method that can be used for this. For longer-lasting and greater effects a more intensive intervention is recommended, with follow-up care following discharge from hospital and attention for relapse prevention.

7.6.2 Chronic lung diseases

Considering the strong relationship between smoking and COPD it is surprising how few smoking cessation interventions have been developed and investigated for this specific target group. A Cochrane review published in 2003 identified five controlled smoking cessation studies for COPD.¹² No studies were found which compared behavioural interventions with no intervention. The most up to date description of recommendations

associated with the literature in the area of COPD can be found in the Dutch Institute for Healthcare CBO [CBO] guideline on COPD.

Some reviews collected the evidence for the effectiveness of pharmacotherapeutic smoking cessation interventions among patients with COPD. The results revealed that nicotine replacement therapies (gum and spray) and bupropion increased the cessation figures. Nortriptyline also increased the cessation figures.^{13,14} However, the study from Tashkin et al. included in the Cochrane review and described above, no longer reveals any difference between the intervention and control groups after 12 months: 21 smokers (10%) in the intervention group were continuously abstinent compared to 16 (8%) in the control group (OR 1.32, 95% CI 0.67-2.61).¹⁵

The pharmacological interventions were not offered without psychosocial interventions so that the single effect of the pharmacological interventions cannot be precisely determined. There are indications that there is no difference in effectiveness between a more and a less intensive behavioural intervention for smoking cessation in combination with nortriptyline. Up until now there seems to be no significant difference in effectiveness between nortriptyline and bupropion as agents for smoking cessation.¹⁶

In a Dutch project, carried out by the University of Twente, the use of the L-MIS was compared with an intensive 'Smoke Stop Therapy' (SST) in smoking cessation interventions at three outpatients' clinics. The SST is a combination of psychosocial counselling in small groups and individually plus pharmacotherapy (nicotine replacement therapies or bupropion). The results of this study are not published at this time.

The results of a controlled study into the effects of antidepressants on smoking cessation in patients with COPD, carried out by the Universiteit van Maastricht are also not yet published.

The following data are known with respect to the attitude of the pulmonologist and the nurses involved:¹⁷

1. The pulmonologist always asks about the smoking status during the initial visit.
2. During a follow-up consultation about half of the pulmonologists once again enquire about the smoking status.
3. The pulmonologist nearly always register the smoking status of a patient.
4. During the initial consultation, almost three-quarters of the pulmonologists advise smoking patients to stop smoking.
5. If a patient cannot/does not want to stop then in one in five cases the pulmonologist advises the patient to reduce the amount smoked.
6. More than two-thirds of the pulmonologists refer a patient to the pulmonary nurse, and some general practitioners refer to the pulmonologist.
7. Twenty-seven percent of pulmonologists use the MIS (it is still in the implementation phase).
8. Almost half of the pulmonologists provide the patient with self-help material.

9. Pulmonologists are of the opinion that the smoking status should be enquired about during every consultation.
10. Pulmonologists are of the opinion that all smokers must receive the advice to stop smoking.
11. Pulmonary nurses are given an important role by pulmonologists.

Conclusion

Level I

The number of methodologically sound studies into the effects of smoking cessation interventions among COPD patients is limited. Less intensive interventions are effective for COPD patients. This is particularly the case for a combination of psychological and pharmacological interventions.

A1 Van der Meer 2003¹²

Recommendation

Pulmonologists and the nurses involved should record the smoking behaviour and motivational level of the patients with a smoking-related disorder and then support motivated smokers in their attempt to stop, and in so doing, attention and support should also be devoted to the period following discharge from the hospital. Patients who are not motivated to stop smoking should first of all be motivated. The L-MIS is a method that can be used for this. For longer-lasting and greater effects a more intensive intervention is recommended, with follow-up care following discharge from hospital and attention for relapse prevention.

7.7 Patients undergoing a surgical intervention

About one-third of all patients who undergo an operation smoke, but this figure varies according to the role that smoking plays in the problem which leads to the operation. Various publications have revealed that smoking is a real risk factor for the development of intraoperative and postoperative complications.¹ In this phase of treatment, smokers more frequently develop pulmonary and circulation problems compared to non-smokers. In addition to this, infections and slower wound healing more frequently occur and these patients more often have an indication for intensive care. Mechanisms that probably underlie the complications that occur in smokers, are pulmonary changes which lead to poor oxygenation and reduced functioning of the cardiovascular and immune system. A reduced collagen production with altered structure is mentioned as well. Physiological investigations have demonstrated that the changes induced by smoking are reversible to a certain extent and the period needed for substantial improvement varies from 6 to 8 weeks. A Cochrane review found insufficient evidence for the positive effect of preoperative smoking cessation interventions in reducing the preoperative and postoperative complications.¹ However, clinical observations suggest a favourable effect of smoking cessation prior

to the operation. After coronary bypass surgery, smokers run a significant risk of a repeat operation, myocardial infarct and death.²⁻⁴

In a more recent randomised controlled study, favourable effects were found for a smoking cessation programme, that was started 6 to 8 weeks before the operation.⁵ Furthermore, a retrospective study of osseo-integrated dental implants, arthrodesis operations, inguinal hernia surgery, coronary bypass surgery and patients with a carcinoid in the head-neck region, revealed that there is a correlation between perioperative complications and smoking.⁶⁻¹³

Conclusion

Level 3

Smoking cessation prior to an operative intervention appears to reduce the chances of complications. The preoperative reduction in smoking or smoking cessation appears to be most effective if it takes place 6 to 8 weeks prior to the operation.

A2 Møller 2002⁵

7.8 Psychiatric smoking patients and multiple addiction smokers

Patients with psychiatric clinical pictures smoke more than the average member of the population.¹⁻³ This probably applies to patients with psychotic disorders, mood disorders, alcohol and drug addiction and to adolescents with ADHD or behavioural disorders. There are several theories to explain this, in which – as is the case for all addictions – the factors that bring about the use can be different from those that maintain the use. One of the explanations for the relationship with the other addictions is a possible genetic disposition for addiction. Further, due to their similar effect of the substances on the neuroreceptors these addictions enhance and maintain each other. The dopamine receptor is the key receptor in all addictions.

Social factors might play a role at the start of a smoking habit, such as relating to a peer group in which many disorders also occur, for example a group of young people with behavioural disorders. However, neurobiological factors might play a role as well. Nicotine has an effect on several neurotransmitter systems in the brain and the symptoms of some clinical pictures might decrease if nicotine is used. This has mainly been put forward for the negative symptoms of schizophrenia such as the loss of initiative and the dulling of the emotions.¹ The correlation between psychiatric complaints and smoking is, however, far from clear. In a prospective study among young people it was found that the presence of complaints is not always a predictor of more smoking behaviour.³ Once the use of nicotine has become established and addiction occurs, other factors play a role among smoking psychiatric patients. Nicotine probably reduces the effectiveness of some medicines.¹ Smoking could therefore be a way of experiencing less side effects from these medicines. Further more general factors also play a role: it could be the case that for a patient with a severe psychiatric clinical picture, the harmful effects of smoking are not a major concern and therefore he/she is less likely to think about stopping. It might also

be the case that the options for achieving pleasurable experiences in a normal manner drastically decrease and so both the patient and those treating the patient continue to 'allow' the patient his cigarette.

The effect of long-term, continuous nicotine use can also lead to complaints.³ In a prospective study among young people, there were indications that if smoking increased then, in particular, symptoms of stress and depression worsened. It is also known that smoking has negative effect on sleep.

7.8.1 Addiction

Smoking cessation by normal people causes complaints of disquiet, irritability and anxiety but this is only during the first few weeks or months. After this the well-being once again increases and is often better than before stopping. There is no reason to assume that this will be any different for psychiatric patients. However, it appears that the detoxification symptoms in psychiatric patients can be substantial and the psychiatric symptoms, in particular depressive complaints, can strongly increase shortly after smoking cessation.⁴

This can mean that not only the patient is afraid to continue an attempt to stop, but that those treating the patient and those near to the patient are also afraid (more or less under the motto 'rather smoking than suicidal').

People with alcohol dependence

Alcohol-dependent people smoke more than average. At least 80% of this group smokes. Conversely, 33% of heavy smokers have or have had an alcohol problem.⁵ The term 'alcoholics' is taken to include alcohol-dependent people, those with an alcohol addiction and 'alcoholics'. It therefore concerns people who are placed in ICD-10 under alcohol dependence (F12): 'a cluster of symptoms of a physical, behavioural and cognitive nature that develops after the repeated use of substances and typically includes a strong desire to use the substance, difficulty in controlling the use of this, persistent use of this despite the harmful consequences, and giving other activities and duties less priority than the use of the substance, increased tolerance and sometimes a physical withdrawal state'.

Past or present alcohol problems make it more difficult to stop smoking.⁶⁻⁸ The use of both substances is strongly conditioned. Drinking alcohol leads to a desire for a cigarette and vice versa. Nicotine and alcohol both affect the dopamine receptor and in addition to this they both affect the various other neuroreceptors such as the noradrenaline, serotonin, GABA, glutamate and endorphine receptors.

Heroin and methadone

Heroin and methadone cause an increase in the need for nicotine and vice versa. Ninety-eight percent of drug addicts and methadone users smoke. Half of this population started smoking before the age of 15 years.⁹

Cocaine

Just like nicotine, cocaine is a highly addictive substance. Nicotine can lead to an increased use of cocaine. As the development of a dependency is also determined by factors such as price, availability and social circumstances, cocaine addiction occurs much less frequently.¹⁰

7.8.2 Motivation

The severity of the psychiatric clinical picture can be important in efforts to encourage smoking cessation. For example it is possible that a chronically psychotic person views his/her body and what happens in it in such a way that talking about smoking cessation is pointless, whereas a patient suffering from depression or an alcohol problem would benefit from this. All existing interventions also require that an awareness of the problem is present and that the smoker possesses a certain degree of self-control. In the case of clinical pictures which affect these functions, such as organic injuries to the brain or chronic psychotic disorders, it cannot be expected that existing interventions will work.

Nevertheless few efforts are made to motivate psychiatric patients to stop smoking and psychiatric patients also run all of the risks that other smokers do. The subject ought to be brought up more frequently in psychiatric treatment settings.

Knowledge about the correlation between nicotine addiction and psychiatric complaints and clinical pictures is far from complete and mainly consists of hypotheses. Far more research, and in particular prospective research, is necessary to determine the relationship. However, it needs to be borne in mind that this involves a population that is not easily available for research in both practical and ethical terms.

7.8.3 Treatment

Positive results have been reported for the treatment of this category of nicotine addicts for both behavioural and pharmacological interventions.⁴ There are no indications that treatment with nicotine replacement therapies would be disadvantageous for psychiatric patients. The use of bupropion for this category of patients is less favourable, in view of the possible side effects profile (agitation, anxiety, depression and loss of concentration in 1%-10% of the users).¹¹ Further, bupropion in combination with other medicines that are used by psychiatric patients can give rise to dangerous reactions (in particular seizures): antidepressants, antipsychotics, antiepileptics and antihistamines. For all psychiatric patients, the treating psychiatrist must be informed of the patient's attempt to stop and will need to see the patient more frequently for a given period of time (several months). As well as withdrawal symptoms or alterations in the known complaints, the effect of medicines can also increase with resultant toxic symptoms.

A different problem occurs in patients who have been dependent on public facilities such as residential wards within psychiatric institutes or sheltered forms of accommodation for a longer period of time or even their entire lives.¹² The new tobacco law requires that

smoking is no longer permitted in many of the facilities used by these patients. As these patients have no alternatives where they can spend their time this can lead to a considerable worsening in the quality of life. There is also a chance of increasing inconvenience caused by smoking patients loitering in various places because they have lost their old trusted spot for smoking and of dangerous smoking behaviour in places where smoking is prohibited.

Recommendations

- Patients with psychiatric clinical pictures can benefit just as much from the positive effects of smoking cessation as other smokers.
- The person treating a psychiatric patient will need to be aware that smoking cessation can have consequences for both the pattern of the symptoms as well as the effect and side effects of medication. It might be necessary to change medication dosages after the patient has stopped smoking.
- In view of the side effects profile and the possible interactions with other medicines, prescribing bupropion to patients with psychiatric disorders is less preferable than treatment with nicotine replacement therapies. As nicotine can have a positive effect in the case of some psychiatric clinical pictures, nicotine replacement therapies would also seem to be the most suitable option.
- For serious, chronic psychiatric patients there might be reasons why treatment of the nicotine addiction is not possible, for example because their ability to realise a problem and exercise self-control has been damaged. If these patients are dependent on residential care institutes for a longer period of time, the quality of life should take centre stage, with due consideration to the handicaps present.

Chapter 8

Starting points for implementation

8.1 Introduction

Although many health professionals agree that recommending smoking cessation is part of their duties, the treatment of tobacco addiction is scarcely integrated into daily practice.¹⁻⁵ The reasons given for this are lack of time, lack of knowledge and training, frustration about the low success rates, low motivation of the patient, costs and the lack of specialist support.

Unpublished research among general practitioners indicates that about one-third use the H-MIS, although it is not known how this is used. Three-quarters of the general practitioners say that they give advice to stop to patients with smoking-related diseases, and two-thirds advise motivated patients to stop. Almost no general practitioner gives advice to stop to all smoking patients.

Unpublished research among pulmonologists reveals that two-fifths of the pulmonologists provide a treatment for tobacco addiction or use the L-MIS. Almost all pulmonologists indicate that they enquire about the smoking status and register this and three-quarters indicate that they give the advice to stop to all smoking patients.

8.2 Method

A systematic review was carried out into the effectiveness of various forms of educational or practice-oriented programmes to investigate the involvement of health professionals in the treatment of tobacco addiction.⁶ This review is based on the methodology of the Effective Practice and Organisation of Care Group (EPOC) of the Cochrane Collaboration.⁷ Studies were identified using Medline (1966-2001), Embase (1980-2001), Cinahl (1982-2001) and Cochrane Library, supplemented with manual searching in the journals Tobacco Control and Addiction.

The search terms that were used are defined by the Cochrane Collaboration. This concerns words related to: (1) interventions⁷ such as 'intervention studies', 'evaluation trials', 'continuing education', 'reminder systems', 'guidelines', 'screening programmes'; (2) primary healthcare (Cochrane Collaboration 2002) such as 'physicians family', 'primary healthcare', 'family practice', 'nurse clinicians'; and (3) tobacco⁸ such as smoking cessation, tobacco use disorder, 'nicotine', 'smoking'.

8.3 Results

Twenty-four programmes were identified within the criteria of EPOC,⁶ including randomised clinical trials (RCTs), controlled clinical trials (CCTs), cost-benefit analyses (CBAs), and interrupted time series designs (ITSSs) with at least three measuring points before and after the intervention. These also concerned objective measurements of the occurrence, change in behaviour of the practitioner or health, or patient outcomes.

The programmes lead to a 15% increase in the numbers screened by the practitioner over and above the average numbers screened of 48%, to a 13% increase in the giving of a stop advice over and above the average stop advice of 51%, and up to a 4.7% increase in biochemically-validated cessation figures over and above an average of 16.9%.

Programmes with more than one component were found to be more effective than programmes with just one component in the improvement of screening implementation or giving an advice to stop. Programmes in which educational and practice methods were combined, were found to be more effective with respect to an increase in screening than programmes that only contained one of these components.

Programmes outside the practice were found to be more effective than programmes in the practice with respect to increasing the use of biochemically-validated cessation figures. Programmes with one component were found to be more effective than the programmes with more components. Programmes for trainee health professionals were found to be more effective than programmes for qualified health professionals. Programmes for trainee health professionals were found to be more effective with respect to an increase in the giving of an advice to stop and cessation figures, but not in terms of screening figures. Educational interventions which took place within the practice, consisted mostly of single interventions and were focused on tobacco, were found to be effective. For qualified health professionals, programmes were found to be effective with respect to changes in the screening and advice to stop, but not in terms of the number of smokers stopping. Programmes which took place outside of the practice, contained more than one intervention and combined education with practice, were found to be the most effective.

Conclusions

Level I	<p>Training during the medical education led to an increase in the use of protocols, the giving of the advice to stop and biochemically-validated cessation figures.</p> <p><i>A1 Bero 2002⁷</i></p>
Level I	<p>The introduction of practice-oriented systems, such as screening resources and computerised support, leads to an increase in screening and the advice to stop.</p> <p><i>A1 Bero 2002⁷</i></p>

8.4 Smoking cessation treatment centres and specialised help

Specialised help via smoking cessation treatment centres is necessary due to: the provision of support for non-specialists working in primary or specialised care, support for smokers who are difficult to treat and a basis of knowledge and expertise.

An important barrier for generalists in primary or specialised care is that they experience too little support from the referral possibilities available. By creating a specialised form of treatment for support and referral, there is more likely to be an increase in health professionals in primary and specialised care giving a brief advice to stop, because there is a possibility to refer patients to smoking cessation treatment centres. Smokers need a broad range of options, but also need to be able to refer themselves to a treatment centre. These treatment centres can carry out research and disseminate knowledge for improving the effectiveness of support methods.

One aspect of the English tobacco control policy, 'Smoking Kills', was the creation of smoking cessation clinics. With the €34 million made available for a population of 50 million (including the costs of treatment), 125,000 smokers stopped smoking within four weeks. The clinics apparently drew more smokers from disadvantaged groups than from less-disadvantaged groups. These clinics were found not only to be effective, but also cost-effective, with the cost per extra year of life gained varying from €5,475 to €9,603, excluding the savings in healthcare. The greater the number of patients treated, the lower costs per extra year of life gained. The system led to an estimated saving in care costs of about €23 per patient.

Smoking cessation treatment centres can be developed at a provincial or regional level, with at least one clinic per 500,000 inhabitants. The centres must guarantee a good throughput of smokers in order to provide adequate specialised expertise and skills. For example, they can be set up in centres for addiction care or existing primary or specialised care centres. The provinces or regions can choose the best structure for their populations. The treatment centres could be selected on the basis of both the expertise of the practitioners and the services provided. The practitioners should be trained and accredited, with regular post-qualification training. The treatments provided by the centres, should be more intensive than the interventions which are normally provided in primary or specialised care.

Effective referral possibilities and follow-up ought to be introduced so that primary care practitioners are informed about their patients.

8.5 Expertise centres

The treatment centres ought to be related to expertise centres which can be housed in a number of existing research organisations/treatment centres. The tasks of the expertise centres are to translate existing and developed evidence into policies and implications for policymakers and health professionals. The expertise centres can learn from the knowledge already acquired by existing provisions in primary and specialised care, and from smoking cessation treatment centres. They are responsible for developing new lines of research to establish the effect and effectiveness of treatments and are responsible for ensuring that the services provided improve.

Recommendations

- In line with the Health Facilities Board [College van Zorgvoorzieningen], the working group recommends that smoking cessation interventions that have been demonstrated to be effective are reimbursed.⁸
- It is recommended that general practices can call upon a sufficient level of practice support for the use of the H-MIS.⁸
- Accredited training must be further developed and should be offered to trainee health professionals.
- Practice-oriented screening, intervention protocols and resources must be further developed and disseminated among all primary care and hospital health professionals, including pharmacists and dentists, with instructions for usage.
- All cost-effective, evidence based, behavioural and pharmacological forms of support must be reimbursed for all smokers who make use of these and all health professionals who offer these.
- Smoking cessation treatment centres must be developed and implemented with one such centre per 500,000 head of population. Expertise centres with a link to treatment centres must be commissioned to provide the treatment centres with scientific support.

Chapter 9

Cost-effectiveness

This chapter is a summary based on the report of Feenstra et al., entitled: *Cost-effectiveness analysis of smoking interventions by professionals: a dynamic modelling study*.¹

The costs of smoking cessation interventions are low in comparison with the yields in terms of prevention, mortality, morbidity and treatment costs for smoking-related diseases. International reviews suggests that the costs per year of life gained vary between €215 and €6,200 (converted to Dutch euros, value of 2000). The majority of the studies give cost-effectiveness ratios of less than €2,500 per year of life gained. That is often an overestimate, as these studies mostly do not include the savings due to smoking-related diseases not manifesting, as a result of which the benefits will be higher. These data should be interpreted with caution, as it is difficult to translate data from studies performed outside of the Netherlands to the Dutch situation. There is no generally accepted threshold value for cost-effectiveness in the Netherlands. For preventive interventions such as smoking cessation it is often stated that a cost effectiveness ratio below €20,000 per year of life gained is cost-effective. This amount was first used in the cholesterol consensus of 1998. Compared with this amount, interventions aimed at smoking cessation are extremely cost-effective.

In the Netherlands, the cost-effectiveness of five smoking cessation interventions compared to the current practice was calculated, assuming that these five interventions would be implemented over a period of one year and that 25% of the smokers would be reached. These calculations were made using a simulation model in which a time horizon of 75 years was adopted, with 2000 as the baseline year, and a discounting of 4% per year of both costs and effects. The interventions considered were:

1. H-MIS given by the general practitioner of practice assistant in one or two consultations with a total duration of 12 minutes.
2. H-MIS, as described above, including nicotine replacement therapies for a period of 8 weeks.
3. Intensive counselling (IC) by a trained counsellor (for example a pulmonary nurse) given over a period of 12 weeks, with a total duration of 90 minutes, including a brief advice to stop from the pulmonologist (given via the outpatients' department or otherwise) and including nicotine replacement therapies.
4. IC, as described above, including bupropion for a period of 9 weeks.

5. Telephone counselling (TC) according to need by STIVORO for a smokefree future], consisting of one initial consultation of 30 minutes and six subsequent appointments of 15 minutes, each based on the content of an electronic questionnaire completed by the quitter. For the different methods, the figures after 12 months of continuous abstinence with a 95 percent confidence interval were used as given in *table 12*.

Table 12 Abstinence after 12 months for various methods

Intervention	Abstinence (in %: 95% CI)
Usual practice	3.4
H-MIS	7.9 (4.7-11.1)
H-MIS + NRT	12.7 (11.9-13.5)
IC + NRT	15.1 (14.1-16.1)
IC + Bupropion	17.2 (14.0-20.4)
TC	7.6 (6.9-8.3)

Calculations were made on the basis of the assumption that in the year 2000, 25% of all smokers would have made use of one of the interventions. This percentage is not much higher than the current percentage of 21% of smokers who indicate that they want to stop smoking within one year. The estimates contain cost-savings for the non-treatment of the following 11 smoking-related diseases: acute myocardial infarct, coronary heart disease, stroke, COPD, lung cancer, throat cancer, oral cancer, oesophagus cancer, pancreatic cancer, bladder cancer and kidney cancer. In 1999 the costs for these diseases were estimated to be 9% of the total healthcare costs in the Netherlands.² The intervention costs per smoker are estimated to be €21 for minimal counselling by the general practitioner (H-MIS), €163 for minimal counselling by the general practitioner with nicotine replacement therapy, €349 for intensive counselling with nicotine replacement therapy, €334 for intensive counselling with bupropion and €70 for telephone counselling according to need. The extra costs per additional quitter vary from €440 for minimal counselling by the general practitioner to €2,800 for intensive counselling with nicotine replacement therapy. Minimal counselling in general practice, over a period of one year, in which 25% of smokers were reached, was found to lead to cost-savings. In other words the estimated cost-savings for not having to treat the 11 smoking-related diseases (€57 million) were greater than the costs of intervention (€23 million). For every €10 spent on minimal counselling in general practice, €25 is saved in healthcare costs (*table 13*).

Table 13 Basic estimates of the number of years of life gained (LYs), for quality corrected years of life (QALYs), total extra intervention costs, total care savings and cost-effectiveness: Costs per extra year of life gained and costs per extra gained, 4% discount in both costs and effects (based on the Dutch euro in 2000)

Intervention	Gain LYs* x 10,000	Gain QALY** x 10,000	Intervention costs* x 1,000,000	Cost savings for treating diseases x 1,000,000	Costs per LY gained	Costs per QALY gained
H-MIS	1.4	1.7	23	57	†	†
H-MIS + NRT	2.8	3.6	180	120	2300	1700
IC + NRT	3.5	4.5	190	150	6800	5200
IC + Bupropion	4.1	5.3	170	170	4700	3600
TC	1.2	1.6	77	53	2000	1500

† Minimal counselling by the general practitioner was not only more effective than the current practice, but also cheaper.

The costs per QALY for the other interventions are €1,700 for H-MIS + nicotine replacement therapy, €5,200 for IC + nicotine replacement therapy, €3,600 for IC + bupropion, and €1,500 for TC. The costs per QALY were lower, the higher the age of the participants in the interventions.

In reality the interventions are possibly even more cost-effective, as the effects of smoking cessation on the progression of diseases, the effects of passive smoking, and the effects of smoking during pregnancy on babies are not included. Furthermore, only the medical costs have been included, and not the productivity costs. Yet on the other hand the effectiveness of the three interventions is based on trial data and is possibly on the high side. In conclusion, all five interventions were found to be highly cost-effective, with ratios of much less than €20,000 per year of life gained. The H-MIS is a net cost-saving intervention. The more expensive interventions are also cost-effective.

The possible impact of smoking cessation interventions has not been taken into consideration. Apart from the possible capacity problems, every smoker should simply be able to make use of the available telephone support. The reach of minimal counselling is probably somewhat lower, because smokers must first of all visit their general practitioner. The impact of intensive counselling is even less still, as it is assumed that this will be given by pulmonologists.

Appendices

Appendix I

The five As: intended for every smoker who wants to stop

'Ask': systematically ask (preferably every year) whether he/she is a smoker

<i>Action</i>	<i>Implementation strategy</i>
Design a department-wide/organisation-wide manner in which, for every patient, it is established (preferably yearly) whether he/she smokes and record this. Exception: adults who have not smoked for a considerable period of time, and for whom the status is clearly established.	Implement prompts for health professionals to systematically enquire about smoking behaviour, for example, stickers on the smoking status or by placing a reminder in the patient's electronic record. Smoking status: smoker, has stopped, never smoked

'Advise': emphatically advise him or her to stop smoking

<i>Action</i>	<i>Implementation strategy</i>
Advise the smoker to stop smoking, in a clear, strong and person-specific manner.	Clear: I think that it is important that you stop and I think that I can help you. Emphatic: you should know that giving up smoking is the best way of keeping your health in the future. Specific to the person: Look at personal motives for the smoker: relationship with disease, cost-savings, in the children's interest, etc

'Assess': establish the willingness to stop smoking

<i>Action</i>	<i>Implementation strategy</i>
Establish whether the smoker is willing to undertake an attempt to stop at this moment (e.g. within the next 30 days).	<ul style="list-style-type: none"> • Prepared to stop now; proceed to assistance • Needs intensive support; offer this or refer • Not prepared to stop now; intervene at the motivation level • Special circumstances (child, pregnant, etc.) consider giving additional information

'Assist': help him/her in undertaking the attempt to stop

<i>Action</i>	<i>Implementation strategy</i>
Make a 'stop plan' together with the smoker	Agree on a stop date Arrange social support from others (tell everybody) Anticipate difficult moments (withdrawal symptoms) Remove tobacco products from places (home and work) where the smoker comes
Give practical support	Stop completely; do not even smoke half a cigarette Evaluate previous failed attempts Establish how the person can recognise a difficult moment Suggest avoiding difficult moments (e.g. whilst having an alcoholic drink) Try to get partners, relatives and friends to stop at the same time
Offer support	Where can the smoker always go to in the event of questions and problems?
Try to arrange support from others	Ask partners, parents and colleagues to support the smoker in the attempt to stop
Advise pharmacotherapy, except in special situations	Consider advising pharmacotherapy if a smoker smokes more than 10 cigarettes per day Explain why this increases the chances of stopping See <i>chapter 4</i> for effectiveness and special groups
Obtain additional information	See addresses at the end of this guideline

'Arrange': care for follow-up as a form of preventing relapse

<i>Action</i>	<i>Implementation strategy</i>
Determine dates for follow-up contact, in person or over the telephone.	Timing: follow-up contact must take place soon after the planned stop date, preferably within one week, and a second within one month. Actions in follow-up: celebrate the success; if the person has still smoked, evaluate why and try to once more obtain a commitment for a complete stop; remind the smoker that failure can be seen as a learning step; discuss difficult moments and anticipate future ones; evaluate pharmacotherapy and consider more intensive treatment

Appendix 2

The five Rs: intended for smokers who are not prepared to undertake an attempt to stop at present

'Relevance':

Tell the smoker why stopping is worthwhile, make this as personal as possible, for example by making a link with the disease, the risk of diseases, children, etc. In so doing bear in mind possible personal barriers for the person.

'Risks':

Ask the smoker about the risks of smoking. Emphasise the risks if these specifically apply to the person in question. Emphasise that the smoking of so-called light cigarettes does not take away the risks. The risks can be divided into the following categories:

- acute risks: impotency, asthma, harm during pregnancy
- long-term risks: cardiovascular diseases, COPD, cancer etc.
- risks for the environment: harm to others.

'Rewards':

Ask the smoker about the benefits of smoking cessation. Emphasise the benefits if they are specifically relevant to the person in question. Examples are:

- improved health
- money
- foods taste better
- you smell nicer
- you feel physically fitter
- good example for your children
- skin improves

'Roadblocks':

Ask the smoker about obstacles/barriers which could arise if an attempt to stop smoking is made. If possible refer to the treatment possibilities to overcome specific barriers (pharmacotherapy, problem-solving training, etc):

- withdrawal symptoms
- worry about failing, decreasing motivation
- weight increase
- lack of support and social support in particular
- pleasure of tobacco

'Repetition':

Repeat this strategy for so long as the smoker is not motivated, also tell the smoker that the majority of people only manage to stop smoking after several attempts.

Appendix 3

Relapse prevention

Problem: lack of support

Solution:

- make agreements for follow-up (if needs be by telephone)
- try to find sources of support in the neighbourhood of the stopped smoker
- refer to a relevant organisation which can provide support

Problem: negative mood/depression

Solution:

- provide support, see if medication can help and refer to a relevant health professional

Problem: strong withdrawal symptoms

Solution:

- see if medication or an adjustment to the medication is needed

Problem: weight increase

Solution:

- emphasise the importance of a good diet, discourage strict dieting and try to encourage extra physical activity. State that an increase in weight is normal, but that after a while the weight no longer increases
- consider continuing to use medication which postpones the weight increase, for example bupropion
- refer to a relevant organisation which can provide support

Problem: decreased motivation and slackness

Solution:

- emphasise that this is a normal reaction
- recommend rewarding activities
- discourage temporary tobacco use and emphasise that smoking (even one cigarette) only makes it more difficult to stop.

Appendix 4

Overview tables with supporting research results

In a systematic literature review, data were collected about standard forms of smoking cessation support in the Netherlands. Various proven effective cessation methods were found to be available. Long-term success rates varied between 7% and 24% (*see table*).

Effectiveness and stop percentages of smoking cessation methods available in the Netherlands based on data in Cochrane reviews¹⁹⁻²⁶

intervention	relative effectiveness		abstinence after at least 6 months follow-up (point prevalence)		continual abstinence during 12 months	
	no. studies	pooled odds ratio (95% CI)	no. studies	no. patients (%)	no. studies	no. patients (%)
self-help guide, without contact	9	1.23 (1.02-1.49)*	12	447/8165 (5.5)	6	114/3651 (3.1)
self-help guide with personal	8	0.91 (0.70-1.17) [†]	8	123/1734 (9.7)	2	41/631 (6.5)
specific advice	8	1.41 (1.14-1.75) [‡]	8	223/3987 (5.6)	3	75/1128 (6.6)
individual counselling	10	1.55 (1.27-1.90) [§]	10	263/1831 (14.4)	4	137/851 (16.1)
telephone counselling	13	1.56 (1.38-1.77)	13	734/7845 (9.4)	9	434/5757 (7.5)
group course	5	1.91 (1.20-3.04) [¶]	5	68/424 (16.0)	0	–
nicotine chewing gum	51	1.66 (1.52-1.81)**	51	1508/7674 (19.6)	26	812/4860 (16.7)
with intensive supervision			29	922/3541 (26.0)	15	434/2302 (18.9)
with minimal supervision			21	526/3747 (14.0)	11	292/2664 (11.0)
nicotine patches	33	1.76 (1.59-1.95)**	34	1419/9895 (14.3)	17	801/6142 (13.0)
with intensive supervision			22	764/4909 (15.6)	11	313/2640 (11.7)
with minimal supervision			12	655/4986 (13.1)	6	488/3502 (13.9)
nicotine inhaler	4	2.08 (1.43-3.04)**	4	84/490 (17.1)	4	84/490 (17.1)
nicotine tablet	2	1.73 (1.07-2.80)**	2	49/243 (20.2)	2	49/243 (20.2)
bupropion	7	2.54 (1.90-3.41)**	7	152/958 (15.9)	4	89/518 (17.2)
nortriptyline	2	2.77 (1.73-4.44)**	3	58/286 (20.3)	1	24/99 (24.2)
hypnotherapy	4	pooling impossible	0	–	0	–
acupuncture	3	1.02 (0.72-1.43)**	10	160/1015 (15.8)	3	55/636 (8.6)

* Control: no treatment.

[†] Control only advice to stop.

[‡] Control: self-help or self-help guide.

[§] Control: usual care or minimal intervention.

^{||} Control: no treatment or self-help (guide).

[¶] Control: waiting list or a leaflet.

** Control: placebo.

Source: Willemsen MC, Wagena EJ, Schayck CP van. De effectiviteit van stoppen-met-rokenmethoden die in Nederland beschikbaar zijn: een systematische review op basis van Cochrane-gegevens [The effectiveness of smoking cessation methods available in the Netherlands: a systematic review on the basis of Cochrane data]. *Ned Tijdschr Geneesk* 2003;147:922-7.

Appendix 5

Tables with supporting research results

*Effectiveness of one-off brief supportive interventions (MIS)***Table 1 Effectiveness of one-off, brief supportive interventions¹ (= 5 months follow-up; preferably 1-week point prevalence)**

Advice	No. arms in study (7 studies)	Estimate OR (95% CI)	Estimate abstinence ratio (95% CI)
No advice to stop (reference group)	9	1.0	7.9
Advice from physician to stop	10	1.3 (1.1-1.6)	10.2 (8.5-12.0)

Table 2 Effectiveness of one-off, brief supportive interventions

Author	Level of evidence	Year	Therapy	No. patients	Duration therapy and follow-up	OR (95% CI)	Measure of effectiveness
Ashenden 1997 ²	A1	1972-1995	Advice*	14,047 in 16 RCTs	One-off contact, ≥ 6 months	1.27 (1.11-1.45)	Strictest criterion***
Ashenden 1997 ²	A1	1984-1994	Advice*	17,233 in 6 RCTs	More than 1 contact, ≥ 9 months	1.46 (1.18-1.80)	Strictest criterion***
Silagy 2002 ³	A1	1972-1997	Advice*	13,575 in 16 RCTs	Maximum 2 contacts with first contact < 20 min and no educational methods other than a leaflet, ≥ 6 months	1.69 (1.45-1.98)	Strictest criterion***
Silagy 2002 ³	A2 (heterogeneous)	1984-1995	Advice*	5,325 in 5 RCTs	First contact > 20 min, > 2 contacts, or educational methods other than leaflet, ≥ 12 months	2.11 (1.74-2.54)	Strictest criterion***
Pieterse 2001 ⁴	A2	2001	MIS**	530 and 22 GPs	1-2 contacts, 12 months	3.04 (1.7-5.6)	Continuous abstinence, self-reporting

* Versus no intervention or usual care.

** Versus usual care.

*** For each RCT the strictest outcome measure used in the study concerned was adopted; this was at the very least the point prevalence of self-reported abstinence after 6 months.

Table 3 Effect of the type of intervention¹ (= 5 months follow-up; preferably 1-week point prevalence)

We hebben ook geprobeerd dit te vertalen, maar dit is niet goed mogelijk, er bestaan geen duidelijk Nederlandse termen voor dus eigenlijk wilden we gewoon in deze hele tabel het Engels handhaven

Type counseling en gedragstherapie	Aantal armen (62 onderzoeken)	Schatting OR (95%-BI)	Schatting abstinenteratio (95%-BI)
Geen counseling/gedragstherapie	35	1,0	11,2
Ontspanning/ademhaling	31	1,0 (0,7-1,3)	10,8 (7,9-13,8)
'Contingency contracting'	22	1,0 (0,7-1,4)	11,2 (7,8-14,6)
Gewicht/dieet	19	1,0 (0,8-1,3)	11,2 (8,5-14,0)
'Cigarette fading'	25	1,1 (0,8-1,5)	11,8 (8,4-15,3)
Negatief affect	8	1,2 (0,8-1,9)	13,6 (8,7-18,5)
Sociale steun binnen de behandeling*	50	1,3 (1,1-1,6)	14,4 (12,3-16,5)
Sociale steun buiten de behandeling**	19	1,5 (1,1-2,1)	16,2 (11,8-20,6)
Probleemoplossing algemeen	104	1,5 (1,3-1,8)	16,2 (14,0-18,5)
Overig aversief roken	19	1,7 (1,04-2,8)	17,7 (11,2-24,9)
Snelroken	19	2,0 (1,1-3,5)	19,9 (11,2-29,0)

* Interventiecomponent die gericht is op het geven van aanmoediging, een gevoel van bezorgdheid en geïnteresseerd empathisch luisteren door leden van het behandelteam.

** Interventiecomponent die gericht is op het geven van 'tools' aan patiënten of hulp bij het verkrijgen van sociale steun buiten de behandeling.

Table 4 Effect of the type of intervention

Author	Level of evidence	Year	Therapy	No. patients	Duration therapy and follow-up	OR (95% CI)	Measure of effectiveness
Silagy 2002 ³	B (1 study)	1999	Consultation focussed on motivation versus brief advice	536	One or more contacts, \geq 6 months	2.00 (0.59-6.72)	Point-prevalence abstinence, self-reporting
Park 2002 ⁵	A1	1981-1992	Intervention plus partner-support versus intervention	1757 in 9 RCTs	Variable, \geq 6 months	1.08 (0.81-1.44)	Point prevalence abstinence, self-reporting
Riemsma 2003 ⁶	A1 (review)	1991-2002	Stage-based versus non-stage based or none	23 RCTs	-	-	-

Table 5 Intensity of the intervention¹ (= 5 months follow-up; preferably 1-week point)

Level of (intensity of) contact	No. arms in study (43 studies)	Estimate OR (95% CI)	Estimate abstinence ratio (95% CI)
No contact	30	1.0	10.9
Minimal counselling (< 3 minutes)	19	1.3 (1.01-1.6)	13.4 (10.9-16.1)
Low intensity of counselling (3-10 minutes)	16	1.6 (1.2-2.0)	16.0 (12.8-19.2)
Higher intensity of counselling (> 10 minutes)	55	2.3 (2.0-2.7)	22.1 (19.4-24.7)

Table 6 Duration of the intervention¹

Level of (intensity of) contact	No. arms in study (35 studies)	Estimate OR (95% CI)	Estimate abstinence ratio (95% CI)
Less than one minute	16	1.0	11.0
1-3 minutes	12	1.4 (1.1-1.8)	14.4 (11.3-17.5)
4-30 minutes	20	1.9 (1.5-2.3)	18.8 (15.6-22.0)
31-90 minutes	16	3.0 (2.3-3.8)	26.5 (21.5-31.4)
91-300 minutes	16	3.2 (2.3-4.6)	28.4 (21.3-35.5)

Table 7 Number of sessions of the intervention¹

Number of sessions	No. arms in study	Estimate OR (95% CI) (45 studies)	Estimate abstinence ratio (95% CI)
0-1 sessions	43	1.0	12.4
2-3 sessions	17	1.4 (1.1-1.7)	16.3 (13.7-19.0)
4-8 sessions	23	1.9 (1.6-2.2)	20.9 (18.1-23.6)
> 8 sessions	51	2.3 (2.1-3.0)	24.7 (21.0-28.4)

Table 8 Duration and intensity of the intervention

Author	Level of evidence	Year	Therapy	No. patients	Duration therapy and follow-up	OR (95% CI)	Measure of effectiveness
Ashenden 1997 ²	A1	1982-1993	Brief versus one-off advice contact	6,275 in 7 RCTs	More than 1 contact versus one-off contact \geq 9 months	1.07 (0.88-1.29)	Strictest criterion*
Silagy 2002 ³	A2 (heterogeneous)	1982-2000	Intensive versus brief advice	9,775 in 14 RCTs	For brief advice max. 2 contacts with initial contact < 20 min and no educational methods other than a leaflet, \geq 6 months	1.44 (1.23-1.68)	Strictest criterion*
Silagy 2002 ³	A1	1982-1991	Advice and follow-up-visit versus one-off advice	1,254 in 5 RCTs	Several contacts versus 1 contact, \geq 6 months	1.60 (1.10-2.33)	Strictest criterion*
Stead 2002 ⁷	A1	1991-1999	Advice and telephone follow-up versus advice	2,078 in 4 RCTs	Varied per RCT, \geq 6 months	1.08 (0.87-1.34)	Strictest criterion*

* For each RCT the strictest outcome measure used in the study concerned was adopted; this was at the very least the point prevalence of self-reported abstinence after 6 months.

Table 9 Effectiveness of adding self-help materials¹ (= 5 months follow-up; preferably 1-week point prevalence)

Form	No. arms in study (58 studies)	Estimate OR (95% CI)	Estimate abstinence ratio (95% CI)
No form	20	1.0	10.8
Self-help	93	1.2 (1.02-1.3)*	12.3 (10.9-13.6)

* Similar outcome for studies in which self-help methods (considerable range of methods) formed the only difference between the arms. Addition of a self-help guide to individual counselling was not effective (Fiore 2000, p. 51).¹

Table 10 Effectiveness of adding self-help materials

Author	Level of evidence	Year	Therapy	No. patients	Duration therapy and follow-up	OR (95% CI)	Measure of effectiveness
Silagy 2002 ³	A2 (heterogeneous)	1978-1997	Advice without resource*	14,053 in 16 RCTs	1 to more contacts, ≥ 6 months	1.95 (1.54-2.45)	Strictest criterion**
Silagy 2002 ³	A2 (heterogeneous)	1986-1995	Advice with resource*	4,290 in 5 RCTs	1 to more contacts, ≥ 6 months	1.88 (1.63-2.18)	Strictest criterion**
Silagy 2002 ³	B (1 study)	1999	Advice and spirometry and CO level versus advice	536	1 or more contacts, ≥ 6 months	0.61 (0.26-1.14)	Point-prevalence, self-reporting
Lancaster 2002 ⁸	A1	1983-1998	Advice and self-help material versus advice	5,309 in 11 RCTs	Mostly one-off contact, ≥ 6 months	0.97 (0.78-1.21)	Strictest criterion**

* Versus no intervention or usual care.

** For each RCT the strictest outcome measure used in the study concerned was adopted; this was at the very least the point prevalence of self-reported abstinence after 6 months.

Table 11 Characteristics of the smoker which are related to the effectiveness of the intervention¹

Pregnant smokers	No. arms in study	Estimate OR (95% CI)	Estimate abstinence ratio (95% CI)
Usual care (advice to stop often given in combination with self-help materials or referral)	7	1.0	6.6
Intervention with more than the usual components	8	2.8 (2.2-3.7)	16.8 (13.1-20.5)

Table 12 Intensity of the intervention

Author	Level of evidence	Year	Therapy	No. patients	Duration therapy and follow-up	OR (95% CI)	Measure of effectiveness
Silagy 2002 ³	A1	1982-1992	Intensive versus one-off or brief advice	6,002 un-selected smokers in 10 RCTs	1 or more contacts, ≥ 6 months	1.23 (1.02-1.49)	Strictest criterion*
Silagy 2002 ³	A1	1974-1990	Intensive versus one-off or brief advice	3,773 high-risk-smokers in 5 RCTs	1 of more contacts, ≥ 6 months	1.82 (1.44-2.29)	Strictest criterion*
Senore 1998 ⁹	C (regression analysis)	1998	Various types of interventions	861 in intervention group	Several contacts, 12 months	0.19 (0.07-0.52) for previous advice versus no previous advice	Continuous abstinence, biochemically validated
Pieterse 2001 ⁴	C (regression analysis)	2001	MIS	530 and 22 GPs	1-2 contacts, 12 months	1.39 (1.2-1.7) for high versus low nicotine-dependence	Continuous abstinence, self-reported
Lumley 2003 ¹⁰	A2 (heterogeneous)	1976-1998	Various types of interventions versus usual care and sometimes biochemically validated care	9,945 in 34 RCTs	1 or more contacts, until third trimester	0.53 (0.47-0.60)	Continue smoking; self-reported
Lumley 2003 ¹⁰	A2 (heterogeneous)	1984-1998	Very intensive interventions versus usual care and sometimes biochemically validated cares	4,028 in 13 RCTs	Several contacts, until third trimester	0.54 (0.46-0.63)	Continue smoking; self-reported

* For each RCT the strictest outcome measure used in the study concerned was adopted; this was at the very least the point prevalence of self-reported abstinence after 6 months.

Reactive telephone counselling

Table 13 Effectiveness of reactive telephone quit lines

Author	Level of evidence	Intervention	Type of respondents	No. participants	Measure of effectiveness
Platt 1997 ¹¹	C	Reactive 'quit line'	Callers to the 'smokeline service'	848	Point prevalence after 12 months
Wakefield 1999 (not published)	C	Reactive 'quit line'	Callers to the 'Quit Line Victoria'		Point prevalence after 12 months
Owen 2000 ¹²	C	Reactive 'quit line'	Callers to the national helpline	905	Point prevalence after 12 months

*Proactive telephone counselling***Table 14 Effectiveness of proactive telephone counselling**

Author	Level of evidence	Year	Therapy	No. participants / studies or comparisons	Duration intervention	Duration follow-up	Measure of effectiveness
Fiore 2000 ¹	A1	1975-1999	Proactive/ telephone counselling compared to no intervention	?/26 comparisons	Various	> 5 months	Point prevalence closest to 6 months
Stead 2003 ¹³	A1	to Sept. 2002	Proactive telephone counselling compared to interventions without personal contact	16,462 participants/ 13 studies compared to	Various	> 6 months	Strictest possible criterion
Stead 2003 ¹³	A1	to Sept. 2002	Proactive telephone counselling added to a personal intervention	2,078 participants/ 4 studies	Various	> 6 months	Strictest possible criterion
Stead 2003 ¹³	A1	to Sept. 2002	Proactive telephone counselling added to a nicotine replacement therapy	1,499 participants/ 4 studies	Various	> 6 months	Strictest possible criterion

*Practice support staff or assistants***Table 15 Influence of type of health professionals on effectiveness of the intervention¹ (= 5 months follow-up; preferably 1-week point prevalence)**

Type health professional	No. arms in study (29 studies)	Estimate OR (95% CI)	Estimate abstinence ratio (95% CI)
No clinician	16	1.0 10.2	
Clinician, not physician	39	1.7 (1.3-2.1)	15.8 (12.8-18.8)
Clinician, physician	11	2.2 (1.5-3.2)	19.9 (13.7-26.2)

Table 16 Influence of number of health professionals on the effectiveness of the intervention¹

Type health professional	No. arms in study (37 studies)	Estimate OR (95% CI)	Estimate abstinence ratio (95% CI)
No clinician	30	1.0	10.8
1 type of clinician	50	1.8 (1.5-2.2)	18.3 (15.4-21.1)
2 types of clinician	16	2.5 (1.9-3.4)	23.6 (18.4-28.7)
3 or more types of clinician	7 2.	4 (2.1-2.9)	23.0 (20.0-25.9)

Table 17 Effectiveness of very intensive interventions¹

Form	No. arms in study (58 studies)	Estimate OR (95% CI)	Estimate abstinence ratio (95% CI)
No contact	30	1.0	10.9
High intensity of counselling (> 10 minutes)	55	2.3 (2.0-2.7)	22.1 (19.4-24.7)

Table 18 Effectiveness of interventions by nurses and 'Smoking cessation counsellors'

Author	Level of evidence	Year	Therapy	No. patients	Duration therapy and follow-up	OR (95% CI)	Measure of effectiveness
Rice 2002 ¹⁴	A2 (heterogeneous)	1987-2000	Advice from nurse*	8,192 in 16 RCTs	1 or more contacts, ≥ 6 months	1.50 (1.29-1.73)	Strictest criterion***
Rice 2002 ¹⁴	A1	1987-2000	Advice from nurse*	5,275 non-admitted patients without cardiovascular disease in 8 RCTs	1 or more contacts, ≥ 6 months	1.81 (1.39-2.36)	Strictest criterion***
Rice 2002 ¹⁴	A1	1987-1996	Advice from nurse*	1,791 in 5 RCTs	Initial contact < 10 minutes, no self-help materials or methods other than a leaflet, and max. 1 follow-up visit, ≥ 6 months	1.47 (1.26-1.72)	Strictest criterion***
Rice 2002 ¹⁴	A2 (heterogeneous)	1990-2000	Advice from nurse*	6,401 in 11 RCTs	Initial contact > 10 minutes, self-help materials or methods other than a leaflet, or more than 1 follow-up visit, ≥ 6 months	1.67 (1.14-2.45)	Strictest criterion***
Lancaster 2002 ⁸	A1	1988-2001	Individual counselling**	5,182 in 14 RCTs	> 10 minutes, ≥ 6 months	1.62 (1.35-1.94)	Strictest criterion***
Lancaster 2002 ⁸	A1	1991-2001	Intensive versus brief counselling	602 in 3 RCTs	> 10 minutes, ≥ 6 months	0.98 (0.61-1.56)	Strictest criterion***

* Versus usual care

** Versus usual care or an advice shorter than 10 minutes.

*** For each RCT the strictest outcome measure used in the study concerned was adopted; this was at the very least the point prevalence of self-reported abstinence after 6 months

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Appendix 6

Dutch College of General Practitioners' Practice Guidelines in which attention is devoted to smoking cessation

M01	Type 2 Diabetes mellitus
M02	Hormonal contraception
M10	Problematic alcohol use
M11	Acute sore throat
M13	Peripheral arterial disease
M16	Venous leg ulcer
M17	Hypertension
M20	Cholesterol
M24	Asthma in children
M26	COPD and adult asthma: diagnosis
M27a	COPD: treatment
M27b	Asthma in adults: treatment
M32	Pregnancy and childbirth
M36	Stomach complaints
M43	Angina pectoris
M45	TIA
M48	Allergic and hyperreactive rhinitis
M51	Heart failure
M69	Osteoporosis
M78	Acute coughing

Appendix 7

Dosages and contraindications for the pharmacological treatment of tobacco addiction

1. Nicotine replacement therapies

Dosage: Prior to the therapy, smoking should be given up completely. The initial dose should be determined on the basis of the individual's nicotine dependency.

Inhalation: According to need at least 6 units and no more than 12 units per day. After the first period of 3 months (according to dosage recommendations) withdraw over a period of 3 months with a 25% reduction per month. The total treatment duration is a maximum of 6 months.

Chewing gum: The tablet should be used if the patient feels the need to smoke a cigarette. *Adults:* Initially 4 mg per occasion, with a maximum of 28 mg per day, for a period of 4-6 weeks. Then dependent on the response switch to 2 mg per occasion for a maximum period of 1 year.

Patch: Nicorette: Apply 1 patch in the morning on waking up and remove this again in the evening before going to sleep; initially 1 patch with 15 mg nicotine (30 cm²) per 16 hours, after 4-6 weeks of not smoking and in the event of sufficient effect switch to 1 patch with 10 mg nicotine (20 cm²) per 16 hours; after 2-4 weeks switch to 1 patch 5 mg of nicotine (10 cm²) per 16 hours for a period of 2-4 weeks. Nicotinell: 1 patch with regulated release per 24 hours; initial dosage per day 1 patch with 35 mg nicotine (20 cm²) if the patient smoked no more than 20 cigarettes per day or with 52.5 mg (30 cm²) if the patient smoked more than 20 cigarettes per day. In the event of sufficient effect the dosage can gradually be reduced, making use of treatment periods of 3-4 weeks. Maximum dosage 1 patch of 30 cm² per day. Maximum treatment duration with the patch is 3 months. Apply the patch to an undamaged part of the skin on the torso, upper arm or hip. Apply a new patch to another part of the skin and only use the old position again after 3-5 days.

Sublingual tablet: The tablet should be used if the patient feels the need to smoke a cigarette. Guideline: one tablet every 1-2 hours, heavy smokers 2 tablets, place under the tongue; normal dosage 8-12 tablets per day, heavy smokers 16-24 tablets per day; maximum 30 tablets per day. Gradually reduce the dosage after 2-3 months.

Lozenge: The tablet should be used if the patient feels the need to smoke a cigarette. Guideline: initially suck one tablet every 1-2 hours; normal dosage 8-12 tablets per day; maximum 25 per day. Gradually reduce the dosage after about 3 months.

Contraindications: Recent myocardial infarct. Unstable or deteriorating angina pectoris, Prinzmetal angina.

Serious cardiac arrhythmias. Recent cerebrovascular accident. An oral or pharyngeal inflammation or active oesophagitis (chewing gum, sublingual tablet and lozenge). Skin disorders which complicate transdermal therapy. Hypersensitivity for menthol (inhalation fluid).

Pregnancy/lactation: Nicotine influences the circulation and the respiration of the foetus. The danger of a strongly nicotine-dependent pregnant woman continuing to smoke can, however, form a greater risk for the foetus than the use of nicotine replacement therapies in a supervised smoking cessation programme. A pregnant woman should only start using nicotine replacement therapies on a doctor's advice. Nicotine is secreted in breastmilk. Do not breastfeed if smoking or using a nicotine replacement therapy.

Side effects: The side effects are dose-dependent and mostly occur during the first few weeks of treatment. Some of the side effects can be attributed to withdrawal symptoms (dizziness, headache, insomnia) and some to the method of administration (topical side effects). Systemic effects of nicotine can be: increase in pulse rate and blood pressure. Often (1-10%): gastrointestinal disorders, nausea, painful mouth or throat, dry mouth, burning sensation in the mouth, blocked nose, coughing, pruritis, tachycardia. Occasionally (0.1-1%): nervousness, irritability, tremor, dysphoria, aggressiveness, anxiety, fatigue, lively dreams, elevated perspiration and salivation, mouth ulcers, erythema. Rare (0.01-0.1%): reversible atrial fibrillations, dyspnoea, muscle cramps in the legs whilst using the patch, urticaria, angio-oedema, infiltration and skin reactions at locations other than where the patch is placed. Contact allergies have been described. If the chewing gum, sublingual tablet or lozenge is used then initially hiccups can occur and also a mild form of dyspepsia or heartburn.

Interactions: Dependent on the amount smoked, nicotine and/or other substances in the tobacco can cause a change in the biological availability, distribution or elimination of a number of drugs. Smoking increases the metabolic activity of CYP1A2. Giving up smoking, whether or not this is followed by nicotine replacement therapy, can therefore give rise to a change in the individual response to concomitantly administered drugs such as theophylline, tacrine, clozapine and ropinirole, which might make an adjustment to the dosage necessary. Particular care should be taken in the event of an altered insulin response. Due to a decrease in the rate of metabolism in the liver, an adjustment to the dosage of theophylline and pentazocine might even be necessary several months after smoking cessation. Both smoking and nicotine replacement therapy can cause an increase in circulating serum cortisol and catecholamine concentrations, as a result of which it might be necessary to adjust the dosages of adrenergic agonists or blockers.

Warnings and precautions: Caution should be exercised in the event of serious hypertension, pheochromocytoma, stable angina pectoris, cerebrovascular insufficiency, occlusive

peripheral arterial conditions, cardiac insufficiency, hyperthyroidism, diabetes mellitus, liver or adrenocortical insufficiency, peptic ulcers, chronic throat conditions and asthma. In the case of serious or persistent skin reactions the treatment should be suspended. If contact allergies have occurred during the use of transdermal nicotine, a serious reaction can occur upon exposure to nicotine-containing products or smoking. These products should not be used on patients under 18 years of age, as there is no experience with this age group. The experience with patches among the 65+ age group is limited. Psychosocial guidance is necessary for an optimal treatment. This guidance should preferably be continued for some time after the therapy has been completed. Suspend the therapy if the patient has not stopped smoking after one month. If the user of the patch still continues to smoke, the side effects can occur more frequently and explicitly. Then there is also a chance of a myocardial infarct.

Overdose: Dosages which are tolerated by adult smokers, can cause serious toxic effects and be fatal in young children. *Symptoms in children:* excitement, gastrointestinal complaints, paleness, weakness, absent reflexes, muscular convulsions in the extremities. *Symptoms in non-smoking adults:* paleness, perspiration, excessive saliva, gastrointestinal complaints, headache, dizziness, tremor, confusion, muscular weakness, convulsions, exhaustion, absent reflexes and respiratory insufficiency. Lethal doses cause convulsions and mortality occurs as a consequence of cardiac insufficiency or (more frequently) as a consequence of peripheral or central respiratory paralysis. For non-smoking adults the acute lethal oral dose is 40-60 mg. Chronic smokers can tolerate very high doses due to habituation.

2. Bupropion/Zyban

Dosage: The treatment with bupropion should be started whilst the patient is still smoking and a target date to stop smoking should be set, preferably during the second week of treatment. The treatment can be combined with nicotine patches. Initial dosage 150 mg once per day for 6 days; increasing to 150 mg twice per day. Allow an interval of at least 8 hours between 2 consecutive doses. The maximum dose is 150 mg per occasion and 300 mg per day. In the case of a reduced liver or renal function and *for elderly patients* the recommended dosage is 150 mg once per day. The treatment duration is 7-9 weeks, but can be longer in individual cases. If no effect has been observed after 7 weeks, stop the treatment. If the treatment is stopped the dosage should be reduced gradually. The tablet should be taken whole (without chewing) with a glass of water.

Contraindications: Serious liver cirrhosis. Manifest epilepsy or a medical history of convulsions or bipolar disorder. Tumour of the central nervous system. Anorexia nervosa or bulimia in the case history. Abrupt abstinence from alcohol or benzodiazepines.

Pregnancy/lactation: Insufficient data are available about the use of this drug to assess the possible harm of this during human pregnancy. Up until now there have been no

indications for harm in animal experiments. Do not use bupropion during pregnancy. Bupropion and the active metabolites are secreted in breastmilk. Breastfeeding is advised against.

Side effects: Very frequent (> 10%): insomnia. Often (1-10%): dry mouth, headache, dizziness, tremor, excitement, anxiety disorders, depression, concentration disorders, gastrointestinal disorders (such as nausea, vomiting, abdominal pain and constipation), taste disorders, fever, transpiration, acute exanthema, pruritis, urticaria. Occasionally (0.1-1%): tachycardia, increased blood pressure (sometimes serious), blushing, chest pain, neurasthenia, anorexia, confusion, tinnitus, visual disorders. Rare (0.01-0.1%): vasodilatation, orthostatic hypotension, syncope. Serious hypersensitivity reactions such as angio-oedema, dyspnoea/bronchospasms and anaphylactic shock, arthralgia, myalgia and fever associated with acute exanthema; (these symptoms can be similar to those of serum disease), erythema multiforme and Stevens-Johnson syndrome, exacerbation of psoriasis. Blood glucose disorders, elevated liver enzymes, jaundice, hepatitis, convulsions (dose-dependent), irritability, hostility, hallucinations, depersonalisation, dystonia, ataxia, parkinsonism, muscular convulsions. The side effect of insomnia occurs less frequently if a dose of bupropion is not administered prior to sleeping.

Interactions: Smoking cessation is associated with a decrease in the CYP1A2 activity. This can cause a reduced elimination with clinically relevant consequences for theophylline, tacrine and clozapine in particular. Bupropion should not be combined with MAO inhibitors due to the significant increase in the toxicity of bupropion. There should be a period of at least 14 days between stopping with irreversible MAO inhibitors and starting treatment with bupropion. For reversible MAO inhibitors a period of 24 hours is sufficient. Further, considerable caution should be exercised in the combination with drugs which reduce the threshold for convulsions, such as antidepressants, antipsychotics, sedative antihistamines, antimalarial drugs, tramadol, quinolones, theophylline and systemic corticosteroids. For patients who are prescribed such drugs, a maximum dosage of 150 mg per day during the treatment should be considered. Bupropion inhibits the CYP2D6 enzyme system. The concomitant use of bupropion with drugs that are metabolised by these enzymes in a clinically relevant amount, can theoretically result in a reduced elimination of drugs such as some antidepressants (desipramine, imipramine, paroxetine), some antipsychotics (risperidone, thioridazine), beta-blockers (metoprolol) and class 1C antiarrhythmics (flecainide, propafenone). Caution should be exercised in combining bupropion with drugs that exert a significant effect on CYP2B6, the enzyme system that partially converts bupropion into hydroxybupropion (such as orphenadrine, cyclophosphamide). Caution should also be exercised in combining bupropion with carbamazepine, phenytoin, phenobarbital, valproate and cimetidine due to the influence of these on the kinetics of bupropion. At present, it is not possible to predict the final effect of these interactions in advance. Bupropion can enhance the effect of levodopa and amantadine and the consequence of this is a higher incidence of side effects.

Warnings and precautions: Considerable caution should be exercised in the case of conditions which predispose for a lowered convulsion threshold, head injuries in the case history, tumour of the central nervous system, alcohol abuse, sudden abstinence from alcohol or benzodiazepines, treated diabetes mellitus, the use of stimulants. Neuropsychiatric side effects and a decreased alcohol tolerance are rarely reported for the concomitant use of alcohol. Administration in the case of bipolar depression can induce a manic phase during the depressive phase of the disease. Psychotic episodes can be induced in sensitive patients. Depressive moods (also with suicidal thoughts) can be a symptom of nicotine withdrawal. This can also occur during a treatment with bupropion.

Animal experiments suggest a potential for abuse. Studies about sensitivity in humans and an extensive clinical experience reveal that bupropion has a low potential for abuse. Stop administering bupropion if hypersensitivity reactions occur during the use. The patient's baseline blood pressure should be measured before treatment is started and the blood pressure should be monitored during the treatment. Hypertension (also serious) can occur during the use of just bupropion but more frequently in combination with transdermal nicotine systems. In the event of a clinically significant increase of the blood pressure, withdrawal of the bupropion therapy should be considered. Usage can lead to a reduced ability to respond and concentrate. Many daily activities (for example driving) can become more difficult as a result of this. There is no experience concerning the use of bupropion in patients less than 18 years of age and in the case of renal function disorders.

3. Nortriptyline (not registered for smoking cessation)

Dosage: The dosage should be determined on an individual basis. It is recommended that the patient is started on as low a dose as possible in order to minimise the severity of the side effects. The dosage can gradually be increased every 2-3 days. *For elderly patients* the guideline for the initial dose is: 1/3-1/2 of the dosage for adults. Initial dosage 10-25 mg two to three times per day or 50 mg once per day; then gradually increase to 75-150 mg per day. *Elderly patients and adolescents:* initial dose 10 mg per day and gradually increase to 100 mg per day; thereafter gradually reduce to a maintenance dose of 20-50 mg per day.

Due to possible sleep disorders the last dose should be taken no later than in the afternoon. The working group proposes a slightly different dosing scheme for the indication of tobacco addiction: 25 mg once daily for the first 3 days; 25 mg twice daily for the next 4 days and from the 7th day onwards 25 mg three times daily. Duration of treatment 7-12 weeks.

Contraindications: Recovery phase of a myocardial infarct. Restraint should be exercised in the case of epilepsy, organic brain damage, urine retention, prostate hyperplasia, pylorus stenosis, cardiovascular diseases, hyperthyroidism, liver and kidney function disorders.

Pregnancy/lactation: Insufficient data are available about the use of this drug to assess the possible harm of this during human pregnancy. Up until now there have been no indications for harm in animal experiments.

Nortriptyline is secreted in breastmilk.

Side effects: Anticholinergic effects such as a dry mouth, reduced gastrointestinal motility, mydriasis, accommodation disorders, urine retention and tachycardia; orthostatic hypotension; weight increase, elevation of liver enzymes. Occasionally: tremors, convulsions; libido and potency disorders; drowsiness; cardiovascular abnormalities such as sinus tachycardia and other arrhythmias; perspiration, allergic skin reactions; confusion, delirium, insomnia; dizziness and hypertension. Rare: thrombocytopenia, agranulocytosis, cholestatic icterus and dysarthria.

Interactions: the effects of alcohol and other substances that suppress the central nervous system can be enhanced as equally the effects of kinidin and other membrane stabilising antiarrhythmics, parasympatholytics and sympathicomimetics such as epinephrine and norepinephrine. The antihypertensive effect of centrally-working antihypertensives such as clonidine can decrease. Enzyme inducing substances such as barbiturates and carbamazepine can reduce the plasma levels of tricyclic antidepressants. Cimetidine, antipsychotics and fluoxetine can cause an increase in the plasma concentration of tricyclic antidepressants. The resorption of various drugs is reduced due to the delayed emptying of the stomach and increased breakdown. In combination with MAO inhibitors, serious intoxications (hyperpyretic and hypertensive crises, serious convulsions and cases of mortality) have occurred. This reaction can occur up until 14 days after the last dose of an MAO inhibitor was administered. Thyroid hormones enhance the effect.

Warnings and precautions: Usage can lead to a reduced ability to respond and concentrate. Many daily activities (for example driving) can become more difficult as a result of this. Use by children under the age of 12 years is advised against. Caution should be exercised in the case of elderly patients due to the heightened sensitivity for the anticholinergic and cardiovascular side effects. Due to an increased risk of dental caries, a dental check-up is indicated. An underlying psychosis or mania can become manifest or exacerbate. It is recommended that the blood picture is monitored during treatment, particularly if a sore throat and fever occur. Regular monitoring of the blood pressure is necessary. Careful observation is necessary to prevent suicide attempts, particularly during the first week of treatment, and patients should not be able to access large quantities of antidepressants. A treatment cannot suddenly be stopped; the dosage must be reduced gradually. This drug can increase the ocular pressure due to pupil dilation and cause an attack of acute glaucoma.

Overdose: Symptoms: Anticholinergic symptoms, fever, depressed breathing, serious arrhythmias, cardiac shock and coma.

Appendix 8

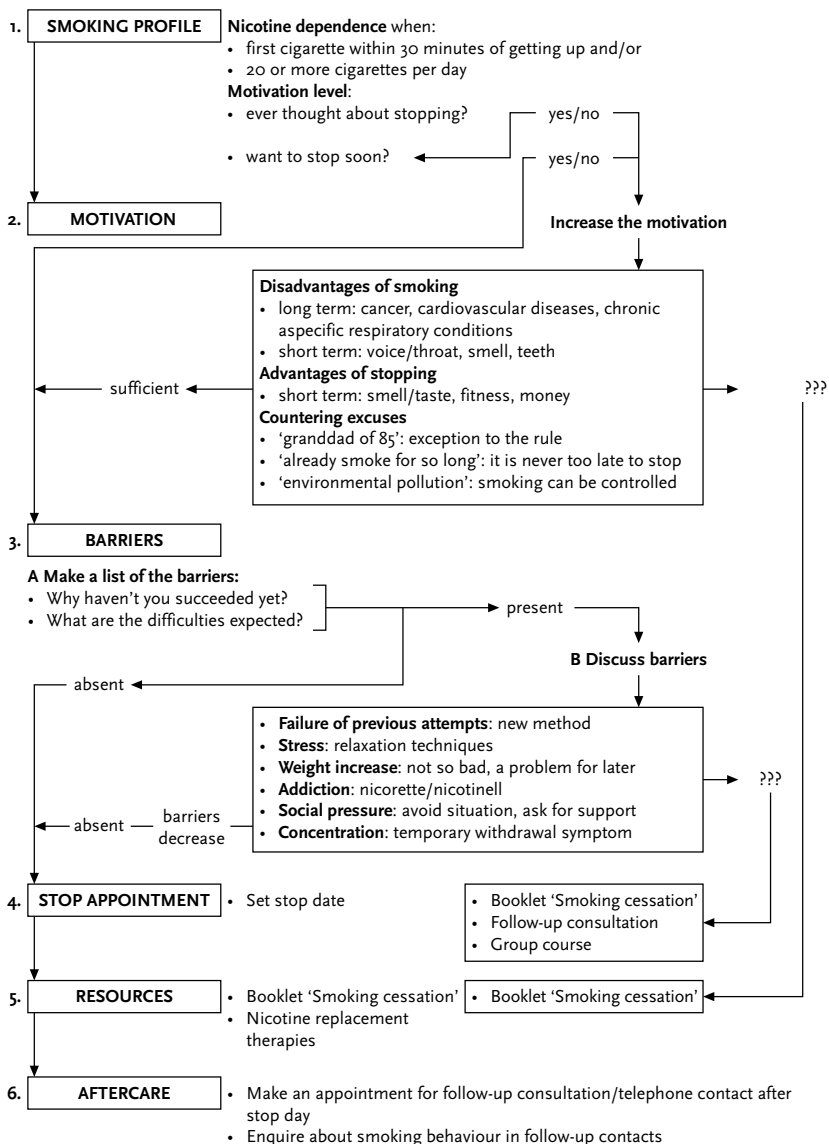
Various MISs (H-MIS, L-MIS, V-MIS, C-MIS)



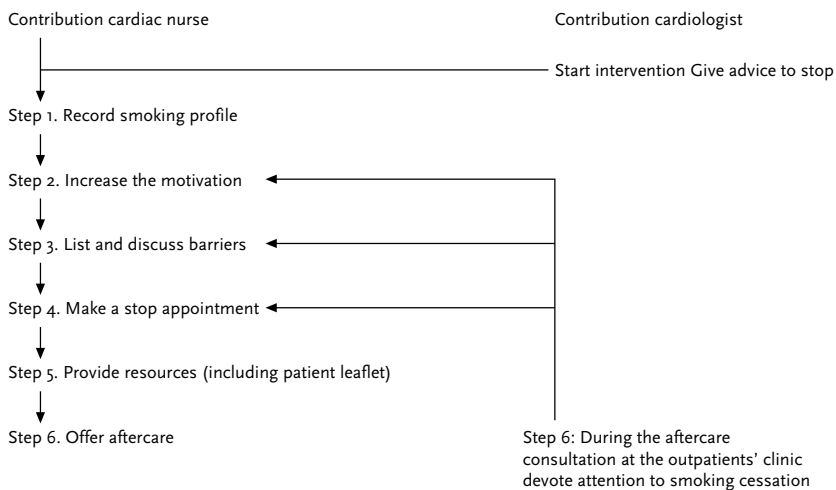
MIS FLOW CHART



MINIMUM INTERVENTION STRATEGY FOR SMOKING CESSATION



C-MIS



L-MIS

Consultation	Step	Contribution nurse	Physician's contribution
Consultation physician	Step 1		Give advice to stop
Initial consultation nurse	Step 2	Record smoking profile	
Initial and second consultation nurse	Step 3	Increase the motivation	
Initial and second consultation nurse	Step 4	List and discuss the barriers	
Second consultation nurse	Step 5	Make a stop appointment	
Second consultation nurse	Step 6	Discuss resources	If necessary issue prescription for bupropion
Third consultation nurse + two aftercare consultations + two extra telephone consultations	Step 7	Offer aftercare	During the consultations at the outpatients' clinic devote attention to smoking cessation

V-MIS

The approach consists of seven simple steps:

1. SMOKING PROFILE

Establish the motivation to stop and the degree of addiction.

2. MOTIVATION

If necessary increase the motivation to stop.

3. BARRIERS AND SUPPORT

Discuss and remove obstacles for smoking cessation and mobilise support in the immediate environment.

4. STOP APPOINTMENT

With the pregnant woman (and her partner) choose a date for the stop day.

5. ISSUE MATERIALS

Issue magazine and videotape to pregnant woman and partner with instructions. (This always takes place, even if steps 2,3 and 4 have not lead to the desired result.)

6. HELP AFTER THE STOP DATE

Arrange and provide a follow-up.

7. RELAPSE

Prevent relapse after childbirth.

Appendix 9

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