# Guidelines for Smoking Cessation

# Literature Review and Background Information

# August 1999



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## 1. Introduction

- An estimated 4,700 New Zealanders die prematurely each year as a consequence of smoking.<sup>1,2</sup> Despite the **enormous impact** of smoking, many smokers enter and exit the health care system every day without receiving advice about this important health risk.
- Smoking has a particularly adverse impact on **Maori health**, with an estimated 31 percent of Maori deaths caused by smoking.<sup>3</sup> Without additional interventions, it is likely that the absolute number of deaths will increase markedly over the next 35 years. Evidence suggests that prevalence rates are decreasing among the general population, more so for non-Maori than Maori. As a result, the disparity between non-Maori and Maori may be increasing.
- There is now excellent evidence for the effectiveness of a number of smoking cessation **interventions** readily available to health care workers, particularly primary health care professionals. The New Zealand Guidelines outline what people working in the New Zealand health sector can do to help smokers quit.
- Advice to individuals about quitting smoking is only one strategy for reducing smoking. A comprehensive **tobacco control strategy** includes a broad range of measures such as taxation policy, health promotion initiatives, legislative measures banning tobacco advertising and sales to minors, and health warnings on cigarette packets.
- As in many other similar countries, New Zealanders in low socio-economic groups have the **highest smoking rates**. This is in contrast to the situation 25 years ago, when smoking rates were much more evenly distributed across socio-economic strata. The impressive overall reduction in smoking in New Zealand and other developed countries since the early 1970s has occurred mainly in socio-economically advantaged groups.
- **Socio-economic conditions** play an important role in determining whether individuals take up smoking and whether they can quit once addicted. Poor people can thus be doubly disadvantaged: not only are they more likely to smoke, they also find it more difficult to quit.
- Additional strategies are needed to help socio-economically disadvantaged smokers quit. As well as new smoking cessation strategies, of which the Quit campaign and other interventions outlined in these Guidelines are examples, broader socio-economic factors must also be addressed. Examples of effective strategies to achieve this have been documented by the National Health Committee in New Zealand,<sup>4</sup> and more recently by the Independent Inquiry into Inequalities in Health in the UK.<sup>5</sup>
- Most smokers are in contact with primary health care services so **primary health care professionals** are central to the effort to increase quit rates. Nearly 80 percent of current smokers visit their GP in any one year,<sup>6</sup> contact that provides a valuable opportunity to initiate smoking prevalence. There is good potential for this sector to improve the management of smoking cessation. Evidence elsewhere shows that only 30 to 50 percent of smokers who have seen their general practitioner in the previous year report being

asked about their smoking,<sup>7,8</sup> and only a minority report being asked to quit.<sup>9</sup> The situation may be similar in New Zealand.

- A systematic approach to ascertaining and **documenting tobacco use** is the first step in changing clinical culture and practice patterns to ensure every patient who smokes is offered treatment. When this information is available during consultations, it results in more opportunistic discussions about smoking.<sup>10</sup>
- Simple interventions, including brief advice to quit smoking can effectively boost longterm cessation.<sup>11</sup> One important finding from the US review of evidence is that virtually all types of **health professionals** — doctors, nurses, nurse practitioners, dentists, psychologists, pharmacists, physiotherapists and many others — can effectively deliver tobacco cessation interventions.<sup>12,13,14,15,16,17,18</sup> Pharmacists may reach smokers who do not access other primary care services.
- There is good evidence that the use of guidelines for smoking cessation can significantly increase quit rates.<sup>19,20</sup> The **New Zealand Guidelines** are consistent with US and British smoking cessation guidelines, and are designed to be practical, needing three minutes or less of direct health professional time.
- In summary, the evidence reviewed by the USDHHS:

suggests that tobacco use presents a rare confluence of circumstances: (1) a highly significant health threat; (2) a disinclination among clinicians to intervene consistently; and (3) the presence of effective, preventive interventions. The last point is buttressed by overwhelming evidence that smoking cessation interventions, if delivered in a timely and effective manner, greatly reduce a smoker's risk of suffering smoking-related disease.<sup>10</sup>

2.

# **The Guidelines Development Process**

#### 2.1 Scope

The New Zealand Guidelines for Smoking Cessation are intended principally for use by health professionals working in **primary care**, but are also relevant to people working in hospital settings and in other community settings. The impetus for the Guidelines comes from evidence that brief advice in a clinical setting can be effective in increasing smoking cessation.<sup>11</sup>

The Guidelines are intended to **support** health professionals to help smokers quit. It is recognised that, like all guidelines, they should be adapted to meet the needs of patients in different clinical and consultative contexts.

#### 2.2 Objective

The **aim** of the Guidelines is to increase the quit rate among smokers seen by health workers. They are designed to:

reinforce the importance of smoking as a preventable adverse health factor

**promote** the integration of smoking cessation interventions into routine clinical care throughout the health system

improve the information and support given people who want to stop smoking

**ensure** all health workers feel confident in the advice they give and the resources available to support smoking cessation

**promote** the use of nicotine replacement therapy.

Hopefully, the simple approach taken by the Guidelines for Smoking Cessation will give health workers in all parts of the sector renewed enthusiasm for **promoting smoking cessation**, confidence the problem can be regularly addressed within the constraints of normal consultations, and tools to effectively help smokers who want to quit.

#### 2.3 Process

The Guidelines were developed by a **working group** convened by the National Health Committee. The Guidelines were developed using the systematic approach advocated by the New Zealand Guidelines Group.

- 1. **Identification** of smoking as a significant health problem for which there are evidencebased interventions likely to improve health care outcomes.
- 2. **Selection** of a working group representing the various stakeholders primary care professionals, Maori health promotion agencies, funders, policy-makers and consumers including people with relevant skills.
- 3. **Identification** of the Guidelines' audience (all health workers in the community and primary care sector).
- 4. Agreement on the process for reviewing the evidence base.
- 5. **Development** of draft guidelines.

- 6. **Circulation** of draft Guidelines to approximately 90 individuals and groups considered to have an interest in this area for comment and peer review.
- 7. **International peer review** of the draft Guidelines by two individuals who have led the development of smoking cessation guidelines in Australia (Professor Brian Oldenburg, Queensland University) and Great Britain (Ann McNeill PhD, Health Education Authority).
- 8. **Focus group** discussion with current smokers to determine how they might react to the use of the Guidelines in practice (See Appendix 1).
- 9. **Analysis** of feedback and peer review on the draft Guidelines and annotation into the final Guidelines document.

The **finalised Guidelines** were approved for publication by the National Health Committee in July 1999.

The Guidelines will be **disseminated** to general practices and a range of health providers and health professionals.

The Health Funding Authority (HFA) has contracted with the National Heart Foundation to undertake an initial **implementation** programme. The National Health Committee will follow-up with the HFA regarding implementation of the Guidelines and funding for specific strategies e.g. nicotine replacement therapy. The involvement of the HFA in the Guidelines development process was designed to ensure a strong commitment to implementation.

The Guidelines will be **reviewed** in June 2001 by the New Zealand Guidelines Group.

#### 2.4 *Membership of the Guidelines team*

Associate Professor Boyd Swinburn (Chair), Medical Director, National Heart Foundation; Chairman Smokefree Coalition

Dr Philip Barham, General Practitioner; RNZCGP nominee

Dr Ashley Bloomfield, Public Health Physician, Guideline Programme Manager, National Health Committee

Dr Julia Carr, Public Health Medicine Registrar, National Health Committee; General Practitioner

Helen Glasgow, Health Promotion Manager, Cancer Society of New Zealand

Marewa Glover, PhD Scholar, School of Medicine, University of Auckland; Vice-chair Apaarangi Tautoko Auahi Kore

Donna MacLean, Practice Nurse, Pegasus Medical Group, Christchurch

Cynthia Maling, Senior Locality Manager, Public Health, Health Funding Authority, Wellington

Wilma Olsen, Quitline Advisor; consumer representative

Andrew Waa, Te Hotu Manawa Maori

Dr Nick Wilson, Public Health Physician representing the Health Funding Authority

#### 2.5 Funding

The Guidelines for Smoking Cessation development process was funded by the National Advisory Committee on Health and Disability (National Health Committee).

Publication and distribution of the Guidelines was funded by the Cancer Society, Health Funding Authority and National Health Committee.

#### 2.6 Endorsement

The following organisations have endorsed these guidelines:

Action on Smoking and Health (ASH) The Asthma and Respiratory Foundation of New Zealand (Inc.) Te Taumatua Huango, Mate Ha o Aotearoa Australian and New Zealand College of Anaesthetists Cancer Society of New Zealand Child Cancer Foundation Health Funding Authority Health New Zealand Ministry of Education Ministry of Health National Advisory Committee on Health and Disability (National Health Committee) National Heart Foundation of New Zealand New Zealand College of Clinical Psychologists New Zealand Dental Association New Zealand Occupational Health Nurses Association New Zealand Society of Physiotherapists Pharmaceutical Society of New Zealand Pharmacy Guild of New Zealand (Inc) **Rotorua General Practice Group** Royal Australasian College of Physicians Royal New Zealand College of General Practitioners **Smokefree Coalition** Social and Behavioural Research in Cancer Group, Dunedin School of Medicine The Stroke Foundation of New Zealand Inc. Te Ohu Rata o Aotearoa (Maori Medical Practitioner Association) Thoracic Society of Australia and New Zealand

#### 2.7 Copies

This background document can be viewed on and downloaded from the New Zealand Guidelines Group website (http://www.nzgg.org.nz). The Guidelines are also on the website or can be ordered by phoning 04 496 2277.

# 3. Smoking: Demographic Information and Trends

#### 3.1 Prevalence

Smoking prevalence declined markedly between 1984 and 1990<sup>21</sup> but has not changed greatly since, declining from 27 to 25 percent of the population between 1994 and 1998.<sup>1</sup>

Since the mid-1980s the **gender gap** in adult smoking prevalence has narrowed, with male smoking tending to decrease more rapidly.<sup>21</sup>

Approximately half of Maori, a third of Pacific Island people and a quarter of European New Zealanders are **cigarette smokers**.<sup>1</sup>

Among **Maori** youth, smoking rates are still high. Smoking prevalence among Maori men is decreasing.<sup>21, 22</sup> The 1996/7 New Zealand Health Survey reports that, among women, Maori had the highest smoking rates (48 percent) with particularly high rates for young Maori women. Nearly 60 percent of Maori women aged between 15 and 44 were smokers.<sup>6</sup>

Smoking prevalence among **Pacific Island** people has increased slightly over the 1990s.<sup>21</sup>

The 1996/7 New Zealand Health Survey confirmed that smoking rates for both men and women are strongly related to **socio-economic status**. More than double the proportion of people living in the most deprived areas of New Zealand, for example, reported they were current smokers, compared to those living in the least deprived areas, as measured by **the New Zealand Dep96 score.**<sup>6</sup>

Forty four percent of New Zealand smokers smoke 10 or less cigarettes per day, forty four percent smoke 11-20 a day, and thirteen percent smoke 21 or more per day.<sup>1</sup>

Adults (15 years and over) smoking any cigarette	(1998)	25 percent
Youth (15-24 years) smoking any cigarette	(1998) males	27 percent
	females	30 percent
Pregnant women smoking any type of cigarette	(1991)	33 percent
Maori women smoking during pregnancy	(1997)	44 percent
Maori adults smoking	(1998)	49 percent
Pacific peoples, adults smoking	(1998)	33 percent
		_

#### Table 1. Smoking Prevalence<sup>1,23</sup>

#### 3.2 Health impact of smoking

• Every year 4,700 people die from smoking, accounting for 17 percent of all deaths.<sup>1</sup> Eleven percent of all female deaths and twenty-two percent of all male deaths in 1990 were attributed to tobacco smoking.<sup>2</sup> Smoking causes one in four of all cancer deaths in

New Zealand.<sup>21</sup>

• The health effects of smoking are closely related to both the number of cigarettes smoked and the number of years one smokes them.<sup>6</sup>

#### 3.3 Quitting status of smokers

- The 1996/7 New Zealand Health Survey found more than one in five smokers (22 percent) were either thinking about **quitting**, or doing things to help them quit.<sup>6</sup> Younger smokers were more likely than older smokers to be thinking about stopping, or doing things to help them stop, smoking.
- There were differences across ethnic groups in reported readiness to quit: European 24 percent Maori 19 percent
   Pacific people 19 percent

#### 3.4 Health service utilisation

• The 1996/97 New Zealand Health Survey showed that current smokers and ex-smokers visit their GPs more often than non-smokers.<sup>6</sup> Around one in five of both smokers and ex-smokers reported they had visited their GPs at least six times in the last year.

4.

# **Evidence Review**

This section presents information on the effectiveness of smoking cessation interventions (summarised in Table 2) that can assist **decision-making** with individual patients. Factors other than evidence for effectiveness (such as cost, availability, acceptability and personal preferences) must also be taken into account when making decisions.

The **evidence summary** reviews smoking cessation interventions, beginning with a review of behavioural interventions, followed by a discussion of pharmacological interventions and then a brief look at other treatment modalities. Relevant evidence for particular groups, such as pregnant women and adolescents, is reviewed.

Extensive work already undertaken in developing smoking cessation guidelines in the UK and USA has been used to develop the New Zealand Guidelines.<sup>10,24</sup> This evidence has been supplemented by a report prepared for the Health Funding Authority by Dr Nick Wilson,<sup>25</sup> which reviews articles on interventions aimed at preventing smoking, reducing tobacco consumption by smokers, reducing harm from tobacco products and promoting squitting. The Guidelines include evidence up to April 1999, and they will be reviewed in 2001.

**The British guidelines** were based on systematic reviews by the Cochrane Tobacco Addiction Review Group and the Agency for Health Care Policy and Research (AHCPR) in the USA.<sup>24</sup> The AHCPR guideline took several years to produce and involved around 125 people.<sup>10</sup> Computer searches identified 3,000 articles that were reduced to 300 after meeting criteria that the article:

- report the results of a randomised controlled **trial**
- provide at least five months **follow-up**
- be published in a peer-reviewed **journal** between 1975 and 1994
- be in **English**.

AHCPR reviewers created evidence tables from these articles that were subjected to **meta-analyses** (except for nicotine patch and gum for which they used meta-analyses already published).

## 4.1 Strength of evidence

For the New Zealand Guidelines for Smoking Cessation evidence quality was **graded** using The US Preventive Services Task Force grading system:<sup>26</sup>

I evidence obtained from at least one properly **randomised** controlled trial (RCT).

II-I evidence obtained from well-designed controlled trials without randomisation

II-II evidence obtained from well-designed cohort or case-control **analytic studies**, preferably from more than one centre or research group

II-III evidence obtained from **multiple time series** with or without the intervention

III **opinions** of respected authorities, based on clinical experience.

#### 4.2 Effective Interventions for Smoking Cessation

Intervention	OR (95 percent CI)	ARR	NNT	Reference
Brief	1.73 (1.47-2.02)	2.7%	37	Silagy <sup>11</sup>
counselling *				
Nicotine	1.77 (1.64-1.92) all NRT	7%	14	Silagy <sup>27</sup>
replacement	2.45 spray			
Therapy †	2.46 inhaler			
	1.98 patch			
	1.65 gum			
Combination	2.9 (0.93-4.72) 6 years	7.7%	13	Blondal <sup>51</sup>
NRT (Iceland	3.03(1.5-6.14) 1 year	16.2%	6	
only)				
Group	1.91 (1.2-3.04)	8%	13	Stead <sup>28</sup>
programme ‡				
Bupropion #	3.0 (1.4-3.9)	16%	6	Jorenby <sup>29</sup>
(2 studies of	2.1 (1.09-4.03)	11%	10	Hurt <sup>30</sup>
slow release)				
Bupropion and	3.0 (1.8-4.9)	20%	5	JorenbyErro
NRT patch				re. Il
-				segnalibro non
				è definito.

 Table 2 Summary of effectiveness of smoking cessation interventions

Notes:

OR Odds Ratio of being smokefree at 1 year (with 95 percent confidence intervals).

ARR Absolute risk reduction

NNT Number needed to treat to achieve 1 quitter at 12 months

\* Brief intervention involved advice by a health professional delivered in a consultation setting.

<sup>†</sup> The authors concluded there was no evidence for a significant difference in the effectiveness of the four different types of NRT, since the confidence intervals around estimates of effect overlapped.

‡ Group programmes involved behavioural intervention such as information, advice, encouragement, or cognitive behavioural therapy delivered in a group setting over at least two sessions.

<sup>#</sup> Bupropion is an atypical antidepressant that has both dopaminergic and andrenergic actions. The slow release preparation is currently being considered by Medsafe for use as a smoking cessation agent but it is not currently approved for use in NZ.

# 5. Behavioural interventions

#### 5.1 Smoking cessation advice by health workers

- At least 39 clinical trials have examined the effectiveness of **counselling** in non-pregnant adult smokers. A meta-analysis of these trials showed improved cessation rates associated with counselling.<sup>31</sup> A Cochrane review of 16 RCTs found simple advice from doctors had a small but significant effect on cessation rates (OR for quitting = 1.73, 95% CI = 1.47-2.02).<sup>11</sup>
- There was small advantage of **intensive advice** over minimal advice (OR = 1.5, 95% CI = 1.29-1.74).
- These results suggest that for every 37 smokers offered advice, one extra smoker quits at 12 months (compared with offering no advice).<sup>11</sup> For providing simple advice, the **cost** of preventing one premature death has been estimated at about US\$ 1500 (NZ\$2880).<sup>32</sup>
- A review by the British National Health Service considered brief advice from health professionals (taking around three minutes) decreased the proportion of people smoking by around two percent per year.<sup>33</sup> Increasing the **intensity of advice** (time spent giving advice and the duration of follow up) improves effectiveness, decreasing the proportion of smokers by around three to five percent.

**Summary**: personal advice and encouragement to quit by health professionals in a consultation setting has a small but **significant effect** on quit rates.

#### Quality of evidence: I

**Additional notes**: A review by Law and Tang (1995) found the efficacy of sudden cessation or gradual reduction in smoking was similar.<sup>32</sup> Follow-up should occur in one to three days after the quit date, as most smokers relapse in the first few days.<sup>34</sup> Nicotine replacement therapy (NRT) enhances the effectiveness of advice from health professionals.

#### 5.2 Self-help interventions for smoking cessation

- Self-help materials provide behavioral methods for smokers trying to quit without intensive contact with a therapist or counsellor. Most commonly, self-help materials are printed, but increasingly they are available for other media such as audio, video and computer.<sup>35</sup>
- A Cochrane review of 41 randomised controlled trials comparing self-help materials to no intervention, found a pooled benefit for increased quitting which just reached statistical significance (OR= 1.23, 95 percent CI=1.01-1.51).<sup>35</sup>

- There was evidence that materials tailored to the characteristics of individual smokers were more effective than standard materials (OR=1.51, 95% CI=1.13-2.02).
- Adding follow-up telephone calls from counselors also appeared to increase quitting (OR= 1.62, 95% CI=1.33-1.97).<sup>35</sup>

**Summary**: there is evidence that self-help materials alone are of some benefit. Tailoring materials to the characteristics of individual smokers and adding follow-up telephone calls improves effectiveness.

#### Quality of evidence: I

#### 5.3 Supportive group sessions for cessation

- A recent Cochrane Review of **group therapy** for smoking cessation looked at 10 studies comparing a group programme with a self-help programme presenting the same or similar information and behavioral techniques. Errore. Il segnalibro non è definito. There was an increase in cessation with the use of a group programme (OR= 2.10, 95% CI = 1.64-2.70).
- Group programmes were **more effective** than no intervention or minimal contact interventions (OR= 1.91, 95% CI = 1.20-3.04).
- **Comparison** of group therapy with advice from a physician or nurse found no evidence of an increased effect.
- The drawback to group programmes as a public health strategy is their **limited reach** to the smoking population. Participation rates in a number of the studies were low.<sup>28</sup> There have been few studies of the effectiveness of group programmes in particular sub-populations of smokers.

**Summary:** there is reasonable evidence that groups are better than self-help and other less intensive interventions, but they may be no better than advice from a health professional.<sup>28</sup>

#### Quality of evidence: I

#### 5.4 Counselling men at high risk of ischaemic heart disease

• A review of four RCTs found that counselling by health professionals was **highly effective** among men at high risk of ischaemic heart disease with a 21 percent quit rate at one year.<sup>32</sup> Only one trial examined counselling alone, while the other three included additional interventions. A combined odds ratio is unavailable.

**Summary**: evidence from one systematic review suggests specific counselling is effective for this group of patients.

#### Quality of evidence: I

#### 5.5 Toll-free telephone help-lines

- There has been favorable experience with toll-free help-lines but their effectiveness seems to be dependent on **effective promotion** of the service (by a concurrent mass media campaign, for example).
- None of the studies compare the **help-line** with a control group, although one compared a self-help manual alone with a manual and telephone hotline. The results are expressed as percentages of callers remaining abstinent.<sup>37</sup>
- The **Scottish Smokeline** service (supported by mass-media advertising) had significant reach (six percent of Scottish smokers) and was associated with a high quit rate of 24 percent at one year.<sup>36</sup>
- A 10-county **USA study** found a smoker's hotline enhanced quit rates, relative to use of a manual only.<sup>37</sup> At 12 months, 10 percent using the hotline and a self-help manual had quit for at least three months, compared with 7.1 percent using the manual only (biochemically validated results). The hotline achieved a 2.9 percent increase in quit rate at 12 months, compared to a self-help manual only.<sup>37</sup>
- An Australian National Quitline Service was associated with the National Tobacco Campaign. Twelve months after first calling the Quitline, the self-reported quit rate of callers was 29 percent. The proportion who had quit for the entire 12 months was six percent.<sup>38</sup>
- A similar study of callers to the Quitline in a pilot campaign in the Waikato-Bay of Plenty regions in **New Zealand** showed a quit rate at five months of 15 percent. Six percent of callers had quit for the entire five months.<sup>39</sup>

**Summary**: this evidence suggests toll-free quitlines are valuable in supporting quit attempts. Effective promotion — through a mass media campaign, for instance — is a major factor in their success.

Quality of evidence: II - II (at best)

#### 5.6 Specialist smoking cessation clinics

- Specialist clinics are usually located in hospital settings and offer a **variety of interventions**, including one-to-one counselling by health care professionals, use of NRT and other pharmacological adjuncts, and group counselling sessions.<sup>40</sup>
- Such clinics report relatively **high success rates** e.g. self-reported total abstinence of 27 percent at six months follow-up, among 12 hospital-based smoking cessation clinics in Paris;<sup>41</sup> 22 percent at six months at the Mayo Clinic;<sup>42</sup> and 32 percent abstinence rate at 12 months in one New Zealand clinic.<sup>43</sup>

• Populations attending such clinics are generally **highly selected**. Information is needed on the cost-effectiveness of interventions delivered by specialist staff in a hospital setting, compared with general practice and community-based interventions.

**Summary**: there is good evidence for some interventions provided in specialist clinics. Few studies examine the effect of the hospital setting as an independent factor.

**Quality of evidence**: Good evidence for particular interventions Insufficient evidence for effectiveness of hospital setting compared to community setting.

## 5.7 Aversion therapy (including 'rapid smoking')

- Aversion therapy pairs the pleasurable stimulus of smoking a cigarette with an unpleasant stimulus, with the aim of extinguishing the urge to smoke. 'Rapid smoking' usually consists of asking subjects to take a puff every six to ten seconds for three minutes, or until they consume three cigarettes or feel unable to continue. This is repeated two or three times, and subjects are asked to concentrate on the unpleasant sensations it causes. Rapid smoking is typically accompanied by explanation and supportive counselling.<sup>44</sup>
- A Cochrane Collaboration meta-analysis of 24 randomised controlled trials for various aversion treatments conducted for the Cochrane Collaboration, found no evidence of benefit from aversion methods other than rapid smoking (OR= 1.19, 95% CI = 0.77-1.83).<sup>44</sup>
- The odds ratio for abstinence following 'rapid smoking' compared to control was 2.08 (95% CI = 1.39-3.12). The reviewers suggest this finding should be treated with caution due to serious methodological problems in most trials. They comment that the only trial using biochemical validation of cessation gave a non-significant result.<sup>44</sup>

**Summary**: there is no evidence of benefit from aversion methods in general. There is some evidence for 'rapid smoking' but this is based on trials with significant methodological problems.

**Quality of evidence**: I (no effect for aversion methods generally) Insufficient for 'rapid smoking'.

## 5.8 Behaviour modification therapy

• A systematic review of 30 randomised controlled trials covering behavioral interventions (other than aversion therapy) found a combined estimate of efficacy of two percent (an overall increase in quit rate compared to control group of two percent).<sup>32</sup> Trials with at least six months follow-up were included in this meta-analysis. However, there was significant heterogeneity among the 30 trials. Interventions included relaxation as an alternative to smoking, rewards and punishments, visualising unpleasant consequences of smoking, individual sessions with a psychologist, group sessions and use of a self-help manual.

Summary: behaviour modification therapy takes many forms and there is evidence of a small benefit when compared to no intervention. However, this effect appears to be no greater than simple advice from a health professional, while the cost is generally several times higher.<sup>25</sup>

#### Quality of evidence: I

#### 5.9 Hypnotherapy

- In a meta-analysis of 10 RCTs of hypnotherapy and smoking cessation, the combined estimate of efficacy was 23 percent.<sup>32</sup> Since no trial measured biochemical markers of tobacco smoke intake to confirm verbal claims, the authors of this review considered this intervention unproven.
- The most recent systematic review considered nine RCTs comparing hypnotherapy with 14 different control interventions. The studies varied in the type of hypnotic induction used. The reviewers concluded that there was insufficient evidence to determine whether hypnotherapy was better than either no treatment or any of the alternative interventions<sup>45</sup> and other issues such as cost had to be considered.

**Summary:** there is no conclusive evidence that hypnotherapy has more effect than no treatment.

#### Quality of evidence: I

Intervention	OR (95% CI)	ARR	NNT	Reference
Brief advice	1.73	2.7%	37	Silagy <sup>11</sup>
	(1.47-2.02)			
Self-help	1.23	n/a		Lancaster <sup>35</sup>
materials	(1.01-1.51)			
Group sessions	1.91	8%	13	Stead <sup>28</sup>
	(1.2-3.04)			
Toll-free	Unable	6% quit at 12		Wakefield <sup>38</sup>
phonelines	to calculate	months		
'Rapid smoking'	2.08*		n/a	Croghan <sup>42</sup>
	(1.39-3.12)			
Other aversive	1.19	No significant		Croghan <sup>42</sup>
therapy	(0.77-1.83)	effect		
Hypnotherapy	Insufficient			Abbot <sup>45</sup>
	evidence			

#### Table 3. Effectiveness of behavioural interventions

Notes: OR

NNT number needed to treat to achieve one quitter at one year

odds ratio confidence interval CI

ARR absolute risk reduction

\* Results should be treated with caution due to serious methodological problems in most trials

6.

# Pharmacological aids to smoking cessation

#### 6.1 Nicotine replacement therapy

Nicotine replacement therapy (NRT) is considered a cornerstone of smoking cessation in the US, <sup>10, 67</sup> and the UK.<sup>24</sup> NRT makes it easier to avoid smoking by replacing some, but not all, of the nicotine obtained from smoking.<sup>46</sup>

Inhalation of nicotine through cigarettes is the most addictive method of nicotine delivery.<sup>47</sup> Because nicotine from cigarettes is absorbed through the lungs, it takes only 10-19 seconds for the drug to reach the brain, faster than an intravenous injection of nicotine.<sup>47</sup> Nicotine levels in the blood reach a peak within seconds then decline rapidly and this pattern is repeated and reinforced with every inhalation.<sup>48</sup> Currently available nicotine replacement products do not produce the high nicotine levels in the blood obtained from smoking.<sup>46</sup> Thus, NRT reduces withdrawal symptoms from smoking by supplying nicotine in a safe manner, without the harmful constituents contained in tobacco smoke.<sup>49</sup>

- In New Zealand, nicotine replacement therapy (NRT) is available from pharmacies in the following forms:
  - over-the-counter as transdermal nicotine (nicotine **patches**)
  - over-the counter as nicotine **gum**
  - by pharmacist consultation (and record of sale) as nicotine inhaler
  - by doctor's prescription as nicotine **nasal spray**
- **Strong evidence** exists that all forms of NRT commercially available in New Zealand (nicotine gum, transdermal patch, nicotine nasal spray and nicotine inhaler) increase quit rates at 12 months approximately 1.5 to 2 fold compared with placebo, regardless of the setting.<sup>27</sup>
- A recent Cochrane review of 74 RCTs confirmed that nicotine gum, patches, nasal spray and inhaled nicotine were all highly effective components of smoking cessation in heavier smokers.<sup>27</sup> The odds ratio for abstinence with NRT compared to control was highly significant (OR = 1.77, 95% CI = 1.64-1.92)
- Long-term cessation rates with NRT are improved when NRT is used as part of a structured behavioural intervention. All the trials in the Cochrane review included some form of **support** in addition to the use of NRT.
- The USPSTF (1996) also considers the evidence from RCTs of NRT to be 'good'. Data from US **community surveys** suggest nicotine patch use was associated with a 2.74 times greater likelihood of quitting (95 percent CI = 2.25-3.35).<sup>50</sup>
- There is evidence that **combined use** of nicotine patches and nicotine nasal spray is more effective than use of the patch alone.<sup>51</sup>

- Fiore et al (1994) found treatment with nicotine patches beyond **eight weeks** did not increase efficacy, and there was no extra benefit from 'weaning' patients off the patches.<sup>52</sup> Wearing the patch only during waking hours (16 hours/day) is as effective as wearing it for 24 hours/day.<sup>27</sup>
- There is little evidence about the role of NRT in individuals smoking less than 10-15 cigarettes per day.<sup>27</sup>
- Empirical studies have shown the nicotine patch is **safe** in patients with stable cardiac disease.<sup>53,54,55,56</sup>
- Table 4 compares the **cost** of different forms of nicotine and nicotine replacement therapy available in New Zealand

Туре	Manufacturer	Brand name	Nicotine dose	Level of addiction for which product is recommended (usual no of cigarettes per day	Approximate retail price per day of use
Cigarettes	Rothmans BAT	Winfield Holiday B&H	1.2 to 2.4 mg per cigarette	_	\$3.15-\$7.90 (10-20 cigarettes/day)
Gum	Pharmacia & Upjohn	Nicorette	2mg 4 mg*	10-20 >20	\$4.80 \$6.45
Inhaler	Pharmacia & Upjohn	Nicorette	10mg (max. ~4 mg is absorbed)	10-20	Starter kit \$15.40 \$8.00 per day (6 cartridges)
Patch	Pharmacia & Upjohn	Nicorette (16 hours)	5 mg 10 mg 15 mg	- 10-20 >20	\$4.20 \$4.45 \$5.05
Patch	Novartis	Nicotinell (24 hours)	10 sq cm 20 sq cm 30 sq cm	- 10-20 >20	\$4.50 \$4.80 \$5.50
Patch	SmithKline Beecham	Nicabate (24 hours)	7 mg 14 mg 21 mg	- 10-20 >20	\$4.55 \$4.95 \$5.00
Nasal Spray	Pharmacia & Upjohn	Nicorette (1 dose = 1 spray each nostril)	100 doses of 1 mg (2 sprays) in each bottle	>20	\$3.20 - \$4.55 + doctor consultation fee (prescription medicine)

#### Table 4 Nicotine products and their approximate cost per day

\*These products are generally the most suitable for smokers with a high level of addiction

Note: A version of this table first appeared in: Laugeson M. Cigarettes in the Auckland region. Cause of disease or item of trade? *Auckland Healthcare Public Health Quarterly Report* 1999 5:2. Used with permission. Information on the nicotine inhaler added and prices updated. Prices are based on average use and on recommended or actual retail prices in April 1999.

\* The actual dose of nicotine absorbed varies between different products and delivery systems. All NRT delivery systems deliver less nicotine than cigarettes.

**Summary**: there is good evidence of benefit for all forms of nicotine replacement therapy for those smoking more than 15 cigarettes per day in the context of additional support for quitting.

#### Quality of evidence: I

#### 6.2 Other pharmacological aids

• The most detailed smoking cessation guideline yet produced (the AHCPR guideline<sup>10</sup>) did not favour any **pharmacotherapy** other than nicotine replacement. However, evidence for commonly available alternatives is briefly summarised here.

#### 6.2.1 Anti-depressants

- Nicotine replacement therapy has been the mainstay of pharmacotherapy for tobacco addiction, but other medications, such as anti-depressant drugs bupropion, fluoxetine and nortriptyline, have also been shown to be **effective**.<sup>57</sup>
- Bupropion's efficacy in smoking cessation does not appear to be due to its antidepressant effects.<sup>58</sup> The exact mechanism by which bupropion works is unknown but it is presumed to alleviate cravings associated with nicotine withdrawal by affecting noradrenaline and dopamine, two chemicals in the brain that may be key components of the nicotine addiction pathway.<sup>58</sup>
- The conclusion of a 1997 Cochrane systematic review of randomised controlled trials of antidepressants for smoking cessation was that fluoxetine and bupropion have a small effect on cessation, and that other antidepressants might also be effective.<sup>59</sup>
- Two recent RCTs of bupropion versus placebo, and bupropion compared with nicotine patch, placebo or both bupropion and patch, showed a positive effect on cessation for bupropion, either alone (OR = 2.3, 95 percent CI =1.4-3.9) or in combination with nicotine patch (OR =3.0, 95 percent CI =1.8-4.9). Errore. Il segnalibro non è definito.
- The suggested dose is 300 mg/day (although it has been shown to be effective at a dose of 150 mg/day<sup>Errore. II segnalibro non è definito.</sup>) and the duration of treatment is 7 to 12 weeks.<sup>60</sup>

Summary: there is evidence for the effectiveness of some antidepressants either alone or in combination with NRT. Bupropion is not approved by the Minister for use in New

# Zealand and is currently being considered for registration as a smoking cessation therapy.

#### Quality of evidence: I

#### Nicobrevin

- This product is composed primarily of menthyl valerate (plus quinine, camphor and oil of eucalyptus) and sold as a smoking cessation aid in New Zealand. Only one RCT was identified in a Medline search and in discussions with the New Zealand distributor.<sup>25</sup> This study indicated substantial benefit that was statistically significant.<sup>61</sup> However, the study size was small (N = 43 in intervention group).<sup>62</sup> Nicobrevin is not mentioned in any international guidelines as an aid to smoking cessation.
- **Summary**: given the small sample size and possible methodological problems with blinding in the only RCT identified, it is not possible to comment on the effectiveness of Nicobrevin.

#### Quality of evidence: insufficient.

#### 6.2.2 Lobeline

• This substance is a partial nicotinic agonist that has been used for smoking cessation. The FDA banned it in the US in 1993 due to lack of acceptable clinical efficacy data. While one short-term RCT has been undertaken and another is planned, no trials with long-term follow up were identified in a recent Cochrane review.<sup>63</sup> These reviewers concluded that 'there is **no evidence** available from long term trials that lobeline can aid smoking cessation.'

**Summary**: a systematic review has concluded there is no evidence to support the effectiveness of Lobeline.

#### Quality of evidence: insufficient.

#### 6.2.3 Anxiolytics

• A Cochrane review of six RCTs of anxiolytics (including meprobamate, diazepam, oxprenolol, metoprolol, buspirone) found **no evidence** for effectiveness.<sup>59</sup>

Summary: good evidence that anxiolytics are not effective aids to smoking cessation.

#### **Quality of evidence**: I

#### 6.2.4 Clonidine

- The USPSTF considers there is **insufficient evidence** for or against clonidine as an effective adjunct to tobacco cessation counselling.<sup>26</sup> However, a more recent Cochrane review of five RCTs found clonidine to be effective in promoting smoking cessation (OR = 1.87, 95 percent CI = 1.27 to 2.77).<sup>64</sup>
- The high incidence of **adverse side-effects** means clonidine is not a first-line treatment for smokers (e.g. it should probably follow a trial of NRT and be used in smokers expected to experience high levels of agitation and anxiety when they stop smoking).<sup>25</sup>

**Summary**: although clonidine is effective in promoting smoking cessation, the high incidence of side-effects precludes its use as first-line therapy.

**Quality of evidence** : I

#### 6.3 Choice of pharmacotherapy for smoking cessation

- As stated above, **nicotine replacement therapy** (NRT) remains the first-line pharmacotherapy for smoking cessation and the most detailed smoking cessation guideline, produced by the US Department of Health and Human Services in 1996,<sup>10</sup> did not favour any other pharmacotherapy.
- Treatment with antidepressants could be appropriate for smokers who do not wish to use NRT or whose treatment with NRT failed.<sup>57</sup>
- Choosing between NRT and antidepressant therapies must take into account factors such as ease of administration, cost, compliance and particular **vulnerabilities to side-effects**. Nicotine gum, for example, may be a problem for patients with dentures; nicotine patches may present a problem for patients with chronic skin diseases; nicotine nasal spray should not be used by those with rhinitis or sinusitis. Bupropion should not be used for patients with seizure disorders, patients concurrently receiving monoamine oxidase inhibitors or those with current or prior diagnoses of bulimia or anorexia nervosa.<sup>65</sup> Nortriptyline, like all tricyclic antidepressants, can have serious anticholinergic side-effects and overdose is potentially lethal.
- Bupropion and nortriptyline are thought to pose little **risk of dependence**. People can become dependent on NRT, an effect probably related to the body's rate of nicotine absorption. Thus, risk of dependence is expected to be greatest with nicotine nasal spray, less with nicotine gum and minimal with patches.<sup>66</sup> Risk of dependence is still low overall and must be compared to the harm of continuing to smoke.
- As with all clinical decisions, **choice of medication** must weigh up evidence for benefit against potential risks, and also take into account individual patient preferences. The goal of therapy is to treat withdrawal and concurrently develop anti-smoking skills. Most meta-analyses and trials indicate that, unlike other dependencies, formal psychosocial treatment is not essential to obtain benefit from the pharmacological therapies, but increased quit rates are observed when these are combined with brief advice plus follow-up.<sup>67</sup>

# 7. Professionally delivered smoking cessation interventions

#### 7.1 Acupuncture

• A Cochrane review identified 16 controlled trials that have compared acupuncture with sham acupuncture.<sup>68</sup> A meta-analysis of these trials found **no significant benefit** from acupuncture at any particular point (early, six months or 12 months). Despite these results, the reviewers noted significant evidence that acupuncture may reduce symptoms associated with acute substance withdrawal.

Summary: good evidence that acupuncture acts only as a placebo in smoking cessation.

Quality of evidence: I

#### 7.2 Homeopathy and herbal products

• No randomised controlled **trials** of homeopathic or herbal products were identified in the Medline-indexed literature.<sup>25</sup>

Summary: no trials of homeopathic and herbal products appear in the medical literature.

Quality of evidence: insufficient

#### 7.3 Smoking cessation in pregnancy

- Smoking in pregnancy carries risks for both the woman and the fetus. Smoking remains one of the few potentially preventable factors associated with low birth weight, very preterm birth and perinatal death. It is this that makes it an important public health issue in pregnancy, as well as a significant personal health issue.<sup>69</sup>
- Up to a quarter of women who smoke before pregnancy stop before their first antenatal visit. Spontaneous quitters usually: smoke less; are more likely to have stopped smoking before or to have a non-smoking partner; are more likely to have support and encouragement at home for quitting; or are more likely to have stronger beliefs about the dangers of smoking.<sup>69</sup>
- There are marked social differences between women who smoke in pregnancy and those who do not. Continued smoking and high daily consumption show a strong association with social disadvantage, high parity, being without a partner, and low income.<sup>69</sup>
- The US smoking cessation guidelines recommend that pregnant women be strongly encouraged to quit throughout pregnancy.<sup>10</sup> Quitting smoking prior to conception or in early pregnancy is most beneficial but health benefits result from cessation at any time.

#### 7.4 Counselling pregnant women smokers

- Counselling pregnant women has been found to be effective in reducing smoking. A **meta-analysis** of nine trials by Law and Tang found personal advice and encouragement to pregnant women in a routine consultation achieved an eight percent quit rate at one year.<sup>32</sup>
- The efficacy of **self-help manuals** in pregnancy was nine percent (seven trials), much higher than that found in 11 trials in non-pregnant subjects for such manuals.<sup>32</sup>
- The most recent Cochrane review of smoking cessation programs implemented during pregnancy examined 40 trials and pooled data from 30. A **significant reduction** in the odds of continued smoking in late pregnancy was noted for women receiving a formal smoking cessation programme (OR = 0.51, 95% CI = 0.45 to 0.58).<sup>69</sup> The absolute difference in the proportion continuing to smoke was 6.6 percent. Similar results were obtained when only biochemically validated trials were examined, and a better result (9.2 percent absolute difference, NNT=11) was evident with a high intensity intervention.<sup>69</sup>
- A RCT in New York identified a decrease in cigarettes consumed among pregnant women smokers visited regularly by **nurses**, compared to those not visited.<sup>70</sup> It might be relatively cost-effective to include brief counselling for smoking cessation in home visiting programmes especially for pregnant women.

**Summary**: there is good evidence for counselling interventions for pregnant women who smoke. Self-help manuals, particularly material specifically directed to pregnancy, are more effective in this population than in other groups.

#### Quality of evidence: I

#### 7.5 NRT for pregnant women

- No specific efficacy studies have been identified in this area. Although nicotine blood levels with patches and gum are lower than with smoking itself, there have been **theoretical concerns** about potential harm to the fetus from this intervention.<sup>25</sup>
- Some authorities recommend pregnant smokers should first attempt cessation without pharmacological help before NRT is tried.<sup>10</sup> The US smoking cessation guidelines suggest "NRT should be used during pregnancy only if the increased likelihood of smoking cessation, with its potential benefits, outweighs the risk of nicotine replacement and concomitant smoking."<sup>10</sup>

**Summary**: NRT should be considered for use in pregnant women who smoke more than 15 cigarettes/day, who are motivated to quit and who have attempted unsuccessfully to quit without NRT. NRT should only be used in conjunction with regular follow-up and other supportive measures and close monitoring for symptoms of over or under-dose.

Quality of evidence: nil specific to pregnant women more evidence on safety is desirable

#### 7.6 Cessation in children and adolescents

• Little research evidence exists regarding either the effectiveness of psychosocial cessation interventions with children and adolescents, or the safety and efficacy of pharmacological interventions with this population. Because there is no evidence that nicotine replacement is harmful for children and adolescents, the USDHHS suggests clinicians consider its use when nicotine dependence is obvious.<sup>10</sup> This is qualified by the need to confirm a genuine nicotine dependence and desire to quit before instituting therapy, along with its use as part of a structured cessation programme.

**Summary:** there is insufficient research in this area.

Quality of evidence: insufficient

# 8. Cessation Related Issues

#### 8.1 Weight gain

- Anxiety about weight gain is an important **impediment** to smoking cessation. The issue should be discussed openly. Research regarding weight gain and smoking cessation has identified a number of key facts.<sup>10</sup>
  - The majority of smokers who quit smoking **gain weight**. Most will gain less than 4.5 kg but there is a broad range of weight gain with up to 10 percent of quitters gaining as much as 13.5 kg.<sup>71</sup>
  - Women tend to gain slightly more weight than men and, for both sexes, people under the age of 55 and heavy smokers (more than 25 cigarettes per day) are at elevated risk of major weight gain.<sup>71,72</sup>
  - For many smokers, particularly women, concerns about weight or fears about weight gain are **motivators** to start or continue smoking.<sup>73,74,75</sup>
  - Weight gain following smoking cessation is a negligible health threat compared with the risks of continued smoking.<sup>71</sup>
  - Some evidence suggests that attempts to prevent weight gain (eg. strict dieting) may **undermine** the attempt to quit smoking.<sup>76,77,78</sup> However, a recent Swedish study found that combining a smoking cessation programme (including use of nicotine gum) with a behavioural weight control programme including a very low energy diet resulted in better 1 year quit rates in the diet group than the control group: 28% quit at one year in the diet group compared to 16% in the control group (smoking cessation programme and nicotine gum without the diet).<sup>79</sup>

- Nicotine replacement in particular, nicotine gum appears to be effective in delaying post-cessation weight gain. There appears to be a dose-response relationship between gum use and weight suppression. However, once nicotine gum use ceases, the quitting smoker gains about the same amount of weight as if s/he had never used gum.<sup>72,80,81</sup>
- Post-cessation weight gain appears to be caused both by increased intake and by metabolic changes. The involvement of **metabolic mechanisms** suggests that even if quitting smokers do not increase their caloric intake, they will still gain some weight.<sup>82,83,84</sup>
- This evidence summary shows weight gain is a **significant impediment** to smoking cessation. Many smokers are concerned about their weight and fear that quitting will result in weight gain. Many also believe they can do little to prevent post-cessation weight gain except return to smoking. These beliefs are especially difficult to address clinically because they have some basis in fact.<sup>10 above</sup>
- Increasing physical activity after quitting smoking, learning healthy eating strategies, and convincing the smoker to tolerate a moderate amount of weight gain over the first three months and work on losing weight later on, can be recommended.<sup>67</sup>

9.

# Appendix 1

#### 9.1 Focus Group Feedback

A focus group with six smokers and one ex-smoker was held to review the Guidelines for Smoking Cessation and comment on implementation. The group was facilitated by two members of the working group, Julia Carr and Wilma Olsen.

Feedback was summarised by Julia Carr and approved by the focus group participants as an accurate reflection of their input.

#### Asking about smoking at every visit:

It depends totally on the attitudes and communication skills of the doctor whether this is viewed as a positive aspect or a factor which makes people dread going to the doctor.

There is a big 'turn off' factor when judgmental attitudes are conveyed and the response results in a 'lecture'.

"They just ask you how much you smoke then treat you like a leper. They make you feel guilty so you don't even want to talk about it...We all know smoking is not good for you."

Most commented that their experience was being asked if they smoked, then asked "how many?", then no comment was made. "*What is the point?*"

Many people are already afraid of doctors or are not going to doctors when they should, so there is a need to be sensitive about the way smoking issues are brought up and handled. Respectful attitudes are important rather than 'telling people off'. This is especially important if the patient is older than the doctor.

Ex-smokers get sick of being asked when, in their view, it should already be documented that they no longer smoke.

#### Advise

Some who smoke and have asthma appreciated the suggestion to cut down if they could not stop at this time.

Information about the positives of giving up is useful.

"Everyone is sick of the graphic ads on TV and the 'death' stuff. It just turns you off. We need something people can relate to, less of a guilt trip...information about the positives of giving up and things like the fact that it may take time to stop [smoking]."

"There should be more information...like about smoking affecting whether you can get pregnant and about the problems of passive smoking in the car...I didn't know that".

Generally there is a need for health professionals to understand that people need to be treated sensitively when it comes to smoking. There are cultural differences in how you approach a serious subject and for many people a more subtle approach, with some humour (to get their attention and make it a safe topic) works better.

#### Assist

It would be helpful if the doctor or nurse could give you something with two or three options for smoking cessation support e.g. the QUITLINE, plus one or two others. Maybe a paragraph on each option stating what it offers, something about NRT choices, etc. Not too much written material but simple and with options.

There was a suggestion that primary care people should talk with some of the smokers attending their service to help educate themselves about smokers' perspectives and design locally appropriate and useful information material. Health professionals were asked to spend **less time** *talking at* **and more time** *talking with* **smokers**.

#### **Nicotine Replacement Therapy**

Most people can't afford NRT. What you'd spend on cigarettes may be similar but you spend it in smaller amounts over time. The initial outlay for some forms of NRT and high overall cost is a major barrier.

Having NRT available more widely (e.g. supermarkets) is a good idea.

If NRT was free and more widely available, there is more chance of being prompted to try it (and cessation generally).

Pressure is a big "turn-off".

"Everyone has their reasons for smoking and it is up to them to decide if and when they want to stop."

10.

# Glossary

#### Absolute risk reduction (ARR)

The absolute benefit from an intervention compared with no intervention in the population of interest.

e.g. If 20% of smokers have quit smoking at 12 months after intervention compared to 10% of smokers in the no intervention group, the absolute risk reduction from the intervention is 10% (20% minus10%).

#### **Confidence interval (CI)**

A method of expressing statistical significance, traditionally used at 95% significance level. The CI is significant if the number one is not included in the range given. The further from one the range is (either greater or less than), the higher the significance.

#### **Meta-analysis**

A statistical technique that summarises the results of several studies in a single estimate, in which more weight is given to results from larger studies.

#### Number needed to treat (NNT)

The number of patients with a specified condition who must follow the specified regimen for a prescribed period in order to prevent the adverse outcome. This number is the reciprocal of the absolute risk reduction.

e.g. The absolute risk reduction in smoking at one year from brief advice is 2.7% (or 0.027). The number needed to treat is 1/0.027 (=37). This means that for every 37 people given brief advice, this intervention could be expected to result in one smoker remaining quit at one year.

#### Odds ratio (OR)

One measure of treatment effectiveness. It is the probability of an event happening rather than not happening. If the OR is equal to one, then the effects of the treatment are no different from those of the control treatment. If the OR is greater (or less) than one, then the effects of the treatment are more (or less) than those of the control treatment.

The odds ratio of being quit (e.g. at one year) having been exposed to an intervention compared with smokers not exposed to the intervention is calculated in the following way:

	Exposed to intervention	No intervention
Smoking at 1 year	a	b
Quit at one year	С	d

Odds ratio = ad/bc

#### Randomised controlled trial (RCT)

A trial in which participants are randomly allocated into groups, usually called study and control groups, to receive or not to receive an experimental preventative or therapeutic intervention. The results are assessed by comparing the outcome of interest (e.g. having quit smoking) in the study and control groups.

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