



## Quit Because U Can – Behavioural and Pharmacological Interventions for Tobacco Cessation – A Review

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Received 06 August, 2021; Revised: 18 August, 2021; Accepted 20 August, 2021 © The author(s) 2021. Published with open access at [www.questjournals.org](http://www.questjournals.org)

### I. INTRODUCTION

Tobacco is a global health emergency<sup>1</sup>. Tobacco use and second-hand smoke kill 8 million people each year and leave many more in poor health. There are almost 267 million tobacco users in India, out of which 28.6% are adults<sup>2</sup>. Each year tobacco use kills about one million Indians, accounting for 9.5% of all deaths<sup>3</sup>. According to report by Indian council of medical Research, tobacco accounts for about 30% of all cancers in men and women. Oral cancer is most common and accounts for 42% and 18.3% of all male and female deaths respectively followed by lung cancer.<sup>4,5</sup>

Tobacco contains more than 4000 chemicals out of which 69 are known to cause cancer. Smoking tobacco releases carbon monoxide which binds with haemoglobin in the blood more easily than oxygen does, thus reducing the amount of oxygen circulating in the body.

Many tobacco users want to quit but do not have access to cessation services. Some of cessation services include advice at primary care facilities, behavioural tobacco cessation interventions, treatment with cost covered tobacco cessation medications. About 40% of current smokers attempt to quit each year and 4-6% are successful<sup>4</sup>.

Tobacco eradication may be eminently possible through various measures such as education and awareness, stopping the cultivation of tobacco, providing alternative livelihood to the workers involved in the tobacco industry, stringent tobacco control legislations, banning tobacco advertisements and active intervention for tobacco cessation, compared to other tobacco control measures, tobacco cessation can bring immediate results in terms of reducing the mortality and morbidity related to tobacco use and maximise the advantage for a habitué who quits the habit.

The ministry of Health and Family welfare, Government of India, has started Tobacco cessation clinics on a pilot basis in 13 centers and in 2002 WHO supported the setting up of 12 tobacco cessation clinics (TCCs) in diverse settings and later expanded to 18 centers to help people stop tobacco use<sup>6</sup>. Health care providers play an important role in tobacco cessation and abstinence<sup>7</sup>. The Dental health care providers role in tobacco cessation in India is neither extensively documented nor fully utilized on a larger platform. The Dental Health Care provider not only assist in early diagnosis with the help of basic clinical skills and academic knowledge but also make referrals, generate awareness, offer indispensable care, necessary surgical and behavioural support. Dental health care provider can collaborate with an interdisciplinary team to assist the individual to quit the habit<sup>8</sup>. Establishing a Tobacco Cessation Centre in a Dental institute is prepared with an intention to encourage and create interdisciplinary clinics in dental institute across the country that contribute in tobacco control and protecting patients from this public health problem. Studies have shown that health care providers and their staff can be trained to successfully deliver tobacco cessation interventions and these interventions significantly improve cessation rates<sup>9,10</sup>. Hence, the aim of this review is to provide information on various tobacco cessation interventions available, their benefits and harms in tobacco cessation.

## **II. HEALTH CONSEQUENCES OF TOBACCO**

The adverse effects of tobacco on oral health includes both common and rare conditions. Some of the harmless and life-threatening conditions include (staining and discoloration of teeth and dental restorations, halitosis, effect on taste and smell acuity, wound healing, oral mucosal disease including smoker's melanosis, potentially malignant lesions, oral cancer and candidiasis). The risk of destructive periodontal disease is 5-20-fold higher for a smoker compared with a never smoker, there is a dose dependent relation between periodontitis and exposure, treatment outcome for smokers is inferior to that of non-smokers<sup>11</sup>.

The overall odds ratio for the relation of grey hair and smoking was calculated, for both men and women, allowing for the relation between grey hair colour and age, giving a value of 4.40 (3.24 to 5.96). This indicates a significant relation between grey hair and smoking ( $P < 0.0001$ )<sup>12</sup>. If young people can be persuaded that smoking will lead to premature grey hair, and in men to baldness, this may offer a promising line of approach in health education against smoking.

The leucoplakia is found to be associated with smoking and chewing habits. The highest percentage of leucoplakia (8.7%) is found among the reverse smokers in Andhra Pradesh. Next in association with leucoplakia are the smoking habits in Gujarat and Kerala<sup>13</sup>.

The impact of smoking on cancer is substantial. Smoking accounts for at least 30% of all cancer deaths and 80% of lung cancer deaths<sup>14</sup>. It not only raises the risk of cancer but also worsens cancer outcomes. Cancer patients who were smokers are most likely to have decreased therapeutic responses, increased cancer recurrences, and increased cancer treatment complications (including problems with wound healing, infections, cardiovascular complications and the development of secondary malignancy)<sup>15</sup>.

Reverse smoking has detrimental effects on the palatal mucosa, which is clinically characterized by the presence of palatal keratosis, excrescence, patches, red areas, ulceration and pigmentation. The incidence rates of palatal changes observed among 10,000 individuals of Srikakulam, Andhra Pradesh were 24.9 per 1000 men and 39.6 per 1000 women per year, almost all the lesions occurred among smokers<sup>16</sup>.

Srivastava et al reported that Oral submucous fibrosis (OSMF) is emerging as a new epidemic, especially among the youth with a prevalence rate of 2.8%. This dramatic increase in OSMF among young people in India has been attributed to chewing gutka and pan masala<sup>17</sup>.

### **Tobacco Cessation: Scope and Needs**

There are currently about 267 million tobacco users causing about 7,00,000 deaths per year . It has been projected that by 2050, if the focus is only on prevention and not on cessation, the result will be an additional 160 million deaths. The majority of tobacco-related deaths that can be prevented over the next 40 years are current smokers who can be persuaded to quit, according to a WHO projection. Tobacco cessation interventions are clinically effective and cost-effective, relative to other commonly used disease prevention interventions and medical treatments. It is also established that a majority of smokers (as many as 70%) desire to quit, but only 30% actually try each year, and only 3%-5% actually succeed in quitting<sup>18</sup>.

### **Intervention Methodology:**

Tobacco is used in various forms in India; however, the intervention modalities are same for chewing, smoking and snuff which includes behavioural, pharmacological and nicotine replacement therapies. Quitting tobacco use is well described by a 'stages of change' model (Prochaska and DiClemente 1983)<sup>19</sup>, according to this model, smokers move along a continuum of behaviour, from pre-contemplation (not thinking of quitting), to contemplation (preparing to quit), action (cessation), and finally maintenance. Many factors may influence movement along this continuum. Information will move some smokers from pre-contemplation to contemplation of quitting. Advertising and promotion ban, higher taxes may reduce the environmental cues and may encourage some smokers to try quitting. The availability of effective cessation therapy might also help move smokers from pre-contemplation and contemplation stages to action and maintenance.

The intervention programmes can be classified and conducted at the following four settings such as clinic, community, worksite and (educational) institutions.

### **Community based Intervention:**

Being the developing country, resource allocation for every issue is not typically possible. Therefore, the professionals and non-professionals who are working at the community for various social issues in the Government and NGO can be trained and utilized for tobacco cessation. Moreover, the local community people who have good rapport with the local people such as anganwadi workers, self-help group leaders, social workers, community nurses and health workers can be trained on tobacco cessation in order to have the sustainable programmes at the community. They will sensitize the people at the community and will prepare the individuals to move from pre-contemplation to preparation stage. The chances of quitting increases at the clinic-

based intervention when the individual is already in the preparatory stage and the chance of dropping out from the programme also decreases.

**Worksite Intervention:**

The intervention at the worksite for the employees by the health care professional or HR professionals at the corporate sector will encourage the workers to quit the tobacco use. The chances of drop-out are less at the worksite intervention since they are the regular employees. Incorporating tobacco cessation programmes into the regular employee's welfare programmes will yield good results. Corporate or worksite intervention will make the cessation accessible for the users who want to quit. Therefore, it is imperative to train the health professional at the worksite on tobacco cessation.

**Clinic/Hospital based Intervention:**

The cessation centres at the hospital or other health care delivery systems should act as the referral centres and can be the tertiary level management centres for the tobacco users. The clients who have failed to quit at the community or institution or corporate intervention can be referred to the exclusive tobacco cessation centres.

**Support groups:**

Support groups such as nicotine anonymous and tobacco free association provides the venue to share the challenges in quitting and to get the support to quit the habit. Joining the support groups helps the client to prevent the relapse and to maintain the long-term abstinence.

**Cessation incorporated into primary care:**

Integrating tobacco cessation into primary health care and other routine medical visits provides the health-care system with opportunities to remind users that tobacco harms their health and that of others around them. Repeated advice at every medical visit reinforces the need to stop using tobacco and can also greatly increase abstinence rates. This intervention is relatively inexpensive because it is part of an existing service that most people use at least occasionally. It can be particularly effective because it is provided by a well-respected health professional with whom tobacco users may have a good relationship. Beyond basic training for healthcare workers on cessation counselling and development of informational materials for tobacco users, there is no major investment required. This treatment approach can also mobilize healthcare workers and patients to support other tobacco control efforts.

**Quit lines**

Well-staffed quit lines should be accessible to a country's entire population through toll free phone numbers and waivers of access charges for mobile phone users. Quit lines are inexpensive to operate, easily accessible, confidential and can be staffed for long hours, many tobacco users may be unable or unwilling to call during business hours. Additionally, quit lines can reach individuals in remote places and can be tailored to specific population groups<sup>20</sup>.

### **III. INTERVENTIONS**

#### **COGNITIVE BEHAVIOUR THERAPY FOR TOBACCO CESSATION**

Cognitive behaviour therapy (CBT) is a psychotherapeutic treatment that helps patients to understand their thoughts and feelings that influence behaviours. CBT is commonly used to treat a wide range of psychological disorders, including nicotine addiction. The underlying concept behind CBT is that our thoughts and feelings play a fundamental role in our behaviour. Two of earliest forms of CBT were rational emotive behaviour therapy and cognitive therapy. Cognitive therapy helps people to develop alternative ways of thinking and behaving, which aims to reduce their psychological distress, Whereas CBT aims to help people become aware of when they make negative interpretations, and of behavioural patterns which reinforce the distorted thinking.

CBT includes cessation of the habit, risk perceptions (e.g., for recurrence), quitting self-efficacy, fatalistic beliefs, pros and cons of quitting, and emotional distress<sup>21</sup>. This provides encouragement, support, education and coping skills training for quitting the deleterious habits of the individuals, also providing the basic health education (BHE) improves the knowledge of individuals on the danger of cigarette smoking and encourages quitting of tobacco use<sup>22</sup>. In a study conducted by **Raja M et al** in Lucknow it was concluded though CBT performed better than BHE, mean score reduction was found to be more in CBT than in BHE<sup>23</sup>.

### **MOTIVATIONAL INTERVIEWING (MI)**

In MI, counsellors help patients explore and resolve their ambivalence about quitting smoking and enhance their motivation to make healthy changes. MI is patient focused and non-confrontational, and providers point out discrepancies between patients' goals or values and their current behaviours. They adjust to patient's resistance to change and support self-efficacy and optimism. Studies of MI suggest that this intervention results in higher quit rates than brief advice to stop smoking or usual care.

### **TEXT MESSAGING, WEB-BASED SERVICES AND SOCIAL MEDIA SUPPORT**

Technology including mobile phones, internet and social media platforms can be used to provide smoking cessation interventions. These technologies have the power to increase access to care by extending the work of counsellors and overcoming the geographical barriers that may deter people from entering treatment.

### **NICOTINE REPLACEMENT THERAPY**

It is observed that although the majority of smokers express a desire to quit, the average smoker makes several quit attempts before succeeding. Difficulty quitting is best predicted by how much one smokes on a daily basis and smoking within 30 minutes of waking up each day, both of which are measures of nicotine dependence.

It has now been established that tobacco smoking often involves a dependence to nicotine. This is usually seen as a problem, but often as an opportunity. The cigarette is the most contaminated drug-delivery device. If nicotine is largely what the smoker needs, the use of nicotine from alternative sources to sustain smoking reduction could be exploited for long-term harm reduction to the smoker unable to quit. The first study to test this idea was in heavy smokers with COPD, where a substantial reduction in smoking was found, resulting in reduced bronchial inflammation when nicotine gum was substituted for cigarettes<sup>24</sup>.

The Public Health Service guidelines for treating tobacco use and dependence, (updated in 2008) endorse the use of several proven pharmacotherapies for cessation including nicotine replacement (e.g., patch, lozenge, gum/resin, inhaler, and nasal spray), bupropion (Wellbutrin/Zyban) and varenicline (Chantix), as well as the combination of counselling support and pharmacotherapy<sup>25</sup>.

The most widely used cessation aid introduced in 1984 is nicotine replacement therapy, it has become an important aspect of smoking cessation interventions (due to wide availability and low price) and has shown positive effects particularly among heavy smokers. Quit rates for nicotine replacement therapy (NRT) range between 20-24 %, compared to 30% for bupropion and 44% for varenicline.

### **FORMS OF NRT:**

**TRANSDERMAL PATCH:** The nicotine patch is a transdermal delivery system which is used as an aid to overcome nicotine dependence during attempts to stop smoking. It is supplied as a course of treatment with the intent of "weaning" the user off nicotine dependence by gradually reducing the amount/dose of nicotine delivered through the skin. The length of treatment recommended by various manufacturers varies between eight and 18 weeks, and the total weeks of treatment in controlled clinical trials has ranged from two to 18 weeks.

Nicotine patches are currently designed for 24-hour wear (usually containing 7, 14, or 21mg of nicotine) or for 16-hour wear (5, 10 and 15mg of nicotine). Client applies one patch a day just after getting up and nicotine is continuously released through the skin for either 16 or 24 hours. The whole therapy should last about three months. Within the therapy period, dosages are gradually decreased. The main advantage of patches is very easy application and regular release of nicotine. Allergic skin reaction can occur rarely<sup>26</sup>.

**NICOTINE CHEWING GUMS** are designed in 2mg and 4mg dosage. Clients use 8–12 gums daily and gradually reduce the number of used gums per day. A dosage of 4mg is appropriate for heavy smokers during first weeks of therapy while in moderate smokers (15–20 cigarettes per day) both dosages have shown approximately the same effect. The therapy course also should last about three months. The main advantages of gums are a possibility to individually tailor the usage according to current needs, for example craving, etc., as well as relatively rapid release of nicotine into bloodstream. The main disadvantage of nicotine gums is a need for appropriate technique of chewing to avoid gastrointestinal irritation and nausea<sup>27</sup>.

**NICOTINE MOUTH SPRAY:** Delivering nicotine via mouth spray is one promising approach to a faster and more palatable form of nicotine delivery. Compared with chewing gum, lozenge or sublingual tablet, mouth spray delivers nicotine in solution quickly on a large surface area of the buccal mucosa<sup>28</sup>.

**NICOTINE LOZENGES:** This novel oral formulation, (lozenge containing nicotine bitartrate dihydrate) has been developed to enlarge the offer for efficient smoking cessation drug therapies, assuming that increasing treatment options will bring more smokers to find the support they personally need to stop smokers. Nicotine lozenges were found to be safe with mainly mild and reversible adverse events<sup>29</sup>.

**SUBLINGUAL NICOTINE TABLETS:** Tablets and lozenges were created for people who cannot or prefer not to use chewing-gum. Sublingual tablets exist in 2- and 4-mg doses. The tablet is held under the tongue until

it dissolves, delivering nicotine similarly to chewing-gum. Food and acidic drinks should be avoided 15 min before and during use. One nicotine sublingual tablet can be used hourly, as needed. The maximum recommended daily dose is 80 mg for 3 months, followed by a gradual reduction in use over the next 3 months for a treatment period of 6 months.

**BUPROPION:** Bupropion was originally approved as an antidepressant. It works by inhibiting the reuptake of the brain chemicals norepinephrine and dopamine as well as stimulating their release. Bupropion has been found to increase quit rates compared with placebo in both short and long-term follow-up studies (**Aubin H J et al**<sup>30</sup>, **Hughes JR et al**<sup>31</sup>, **Douaihy AB et al**<sup>32</sup>) and is indicated for smoking cessation. It is equally effective to NRT.

**VARENICLINE:** Varenicline helps reduce nicotine cravings by stimulating the alpha-4 beta-2 nicotinic receptor and increases the likelihood of quitting compared with placebo, some studies find that it is more effective than single forms of NRT and bupropion. In a primary care setting, 44% of patients on varenicline either alone or combined with counselling, were abstinent at the 2-year follow-up. Patients who participated in group therapy and adhered to the medication were more likely to remain abstinent. Research also suggests that this medication may be more effective than bupropion<sup>33</sup>.

#### IV. RELATIVE SAFETY OF NRT:

The acute lethal dose of nicotine in humans is believed to be in the range of 40–60 mg (< 1 mg/kg). The nicotine in NRT is delivered in low doses (e.g., nicotine gum is supplied in 2-mg and 4-mg units), with mean circulating nicotine concentrations in subjects receiving NRT in the range of 10 to 15 ng/ml<sup>34</sup>. Therefore, the risk of fatality from direct nicotine poisoning must be considered remote. However, nicotine overdose can occur through inappropriate use of NRT, such as higher-than recommended dosing, continuation of smoking while receiving NRT or use of more than one form of NRT. Nausea, salivation, abdominal pain, sweating, headache, diarrhoea, dizziness and weakness are among the symptoms of nicotine overdose.

**Mills et al**<sup>35</sup> conducted a systematic review and meta-analysis to determine the magnitude of reported adverse effects with NRT which included 92 RCTs involving 32,185 participants and 28 observational studies involving 145, 205 participants. Pooled RCT evidence of varying NRT formulations found an increased risk of heart palpitations, chest pains, nausea and vomiting, gastrointestinal complaints, and insomnia. Pooled evidence specific to the NRT patch found an increase in skin irritations. Orally administered NRT was associated with throat soreness, mouth ulcers hiccoughs and coughing. There was no statistically significant increase in anxiety or depressive symptoms associated with NRT use. Non-comparative observational studies demonstrated the prevalence of these events in a broad population which concluded that the use of NRT is associated with a variety of side effects. In addition to counselling and medical monitoring, clinicians should inform patients of potential side effects which are associated with the use of NRT for the treatment of tobacco dependence.

#### V. DISCUSSION

Tobacco use is a risk factor for many diseases, especially those affecting the heart, liver and lungs as well as many cancers. In 2008, the WHO named tobacco use as the worlds single greatest preventable cause of death. Tobacco cessation counseling has been shown to improve the likelihood of achieving success. Counseling programs help tobacco users by providing information and resources to develop a quit plan, address specific barriers to quitting, provides support for their efforts and manage withdrawal symptoms and stress to prevent relapse. The most effective counseling is tailored to meet individual needs and preferences. CBT helps to deal with overwhelming problems in a more positive way by breaking them down into smaller parts and focuses on current problems, rather than focusing on issues from the past.

Behavioural interventions have been found to have maximum benefit in SLT cessation as compared to pharmacotherapy (**Stevens V J et al**<sup>36</sup>, **Cummings S R et al**<sup>37</sup>, **Severson H H et al**<sup>38</sup>, **Mishra G A et al**<sup>39</sup>, **Fisher K J et al**<sup>40</sup>, **Gupta P C et al**<sup>41</sup>, **Danaher B G et al**<sup>42</sup>, **Boyle R G et al**<sup>43</sup>)

A study conducted by **Schnoll RA et al**<sup>22</sup>. revealed no noteworthy distinction in 30-day point-prevalence abstinence between the CBT and BHE at either 1-month (44.9% vs 47.3%, separately) or 3 months (43.2% vs 39.2%, individually) follow-up assessments. In a study demonstrated by **Webb MS et al**<sup>44</sup> the 7-day point-prevalence abstinence (ppa) was fundamentally more noteworthy in the CBT than in the BHE condition toward the end of counselling (51% vs 27%), at 3 months (34% vs 20%), and 6 months (31% vs 14%).

**Killen J D et al**<sup>45</sup> reported that CBT at 20-week follow-up, produced a better treatment response than brief supportive therapy. The superiority of CBT suggests that continued emphasis on the development of cognitive and behavioural relapse prevention strategies during an extended treatment phase may help smokers to maintain abstinence. A systematic review by **Lancaster and Stead**<sup>46</sup> estimated that a brief advice intervention by a physician can increase quitting by a further 1%–3% when unassisted quit rate was assumed to be 2%–3%.

**Selvamary et al**<sup>47</sup> stated that CBT plays a vital role in achieving continuous abstinence, overcoming social factors, and reducing lapse among the tobacco users.

Carr and Ebbert<sup>48</sup> in a systematic review stated that behavioral interventions for tobacco cessation conducted by oral health professionals incorporating an oral examination component in the dental office or community setting may increase tobacco abstinence rates among both cigarette smokers and smokeless tobacco (SLT) users.

Some patients have used hypnotherapy as an aid for smoking cessation, especially in attempting to alleviate or lessen the urge to smoke<sup>49</sup>. Abbott N<sup>50</sup> in a meta-analysis of 9 randomized trials of hypnotherapy for smoking cessation compared hypnotherapy with or without counselling, hypnotherapy with or without group therapy, psychological treatments, no therapy and concluded that hypnotherapy did not demonstrate greater rates of cessation at 6 months compared with other interventions or with no therapy.

Two trials in India have been performed successfully utilizing brief advice for tobacco cessation among both smokers and SLT users i.e., an overall quit rate of 67.3 per cent was reported by Kaur et al<sup>51</sup>, and 2.6 per cent by Sarkar et al<sup>52</sup>.

Ebbert JO et al<sup>53</sup> in a systematic review of 10 studies conducted in the USA, reported that telephone support/quitlines, behavioural interventions and pharmacological interventions proved beneficial in SLT cessation.

The effect of Trans theoretical model-based smoking cessation among high school students reported by Erol S et al<sup>54</sup> determined that the program was effective, and 26.5% of the students quit smoking. Smoking cessation was evaluated based on personal statements, and the cessation rates were confirmed by verbal feedbacks from families and teachers.

Hughes<sup>55</sup> concluded that the absolute effects of NRT use will depend on the baseline quit rate, which varies in different clinical settings. Studies of people attempting to quit on their own suggest that success rates after six to 12 months are 3-5%.

Baker TB et al<sup>56</sup> reported that compared with the nicotine patch, both varenicline and C-NRT (nicotine patch + nicotine lozenge) significantly reduced withdrawal and craving symptoms. In addition, C-NRT produced higher initial abstinence rates than did the other 2 pharmacotherapies.

Fiore M C et al<sup>57</sup> in his meta-analysis reported that varenicline, C-NRT, and the nicotine patch yielded model-estimated abstinence rates of 33%, 37%, and 23% at 5 months or longer post-TQD (target quit date), respectively.

The seven-day point prevalence of abstinence was significantly higher in the varenicline group than the placebo group, although by week 26 the difference between the groups was no longer significant in study conducted by Fagerstrom et al<sup>58</sup>.

In a 2009 meta-analysis by Mills E J et al<sup>35</sup> of 101 studies, varenicline was found to be more effective than bupropion (odds ratio 1.40) and NRTs (odds ratio 1.56).

Cahill k et al<sup>59</sup> reported that varenicline was found to be slightly superior to single forms of NRT in two trials, with an RR of 1.13 (95% CI: 0.94-1.35; 2 trials, 778 people) but was not more effective than combination NRT.

A recent study by Wang C et al<sup>60</sup> on effectiveness of varenicline among smokers from Asian populations (China, India, Philippines and Korea) showed that overall, 46.4% of people successfully quit smoking by the end of 12 week.

## VI. CONCLUSION

The introduction of NRT represents a landmark in the treatment of tobacco dependence. It can effectively increase quit rate in cigarette smokers and at the same time its use is exceptionally safe and any adverse effects are infrequent and benign. The systemic nicotine load in individuals undergoing replacement therapy is generally lower than during active smoking. Nicotine is only one of many thousands of constituents of tobacco smoke. Furthermore, nicotine replacement is usually delivered over the short term (a matter of weeks). Therefore, nicotine replacement is recognized as a relatively safe and effective aid to smoking cessation.

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